



SAN FRANCISCO PLANNING DEPARTMENT

Executive Summary Conditional Use

HEARING DATE: NOVEMBER 6, 2014

Date: October 30, 2014
Case No.: **2014.0206C**
Project Address: **1963 Ocean Avenue**
Zoning: Ocean Avenue NCT (Neighborhood Commercial Transit)
45-X Height and Bulk District
Block/Lot: 6915/020
Project Sponsor: Cong Phuong T Nguyen/Yong (Blake) He [agent]
948 Moscow Street
San Francisco, CA 94112
Staff Contact: Marcelle Boudreaux – (415) 575-9140
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Recommendation: **Approval with Conditions**

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PROJECT DESCRIPTION

The project sponsor proposes to open a Tobacco Paraphernalia Establishment retail use in a vacant retail space to be known as “Happy Vape”, which will include e-cigarette sales at the ground floor and a steam stone hookah lounge at the basement level. The existing tenant space measures approximately 1,334 square feet at ground floor and 1,054 square feet at basement level. The project also includes minor interior tenant improvements and new signage, but otherwise no storefront alterations are proposed.

The project sponsor proposes a business that will sell devices (e-cigarettes/vaporizers), vaping liquids/e-juices and batteries both in-store, with some accessory sales on-line. In the basement level, the project sponsor proposes establishing a steam stone hookah lounge with maximum occupancy of 21 people. Together, these activities have been determined as Tobacco Paraphernalia Establishment uses and account for more than 10% of the square footage of occupied floor area. The proposed hours of operation are from 11 a.m. to 12 a.m. daily. No ABC license is being sought in conjunction with this Conditional Use authorization. Per the business plan for Happy Vape, no one under the age of eighteen will be allowed; this will be made clear through a sign on the entrance door and checking of identification.

E-cigarette smoking, or “vaping”, is not allowed inside commercial establishments within San Francisco, or within 15 feet of entrances to commercial establishments.

SITE DESCRIPTION AND PRESENT USE

The project is located on the south side of Ocean Avenue, between Ashton Street and Victoria Avenue, on an approximately 4,500 square foot parcel. The subject property is located within the Ocean Avenue NCT (Neighborhood Commercial Transit) District and the 45-X Height and Bulk District. The property is developed with a one-story-over-partial-basement commercial building, with tenants including a travel

agent and a massage/acupuncture establishment. The tenant space at 1963 Ocean Avenue, occupying the ground floor and the basement level, is currently vacant but was previously occupied by a retail aquarium store known as "Aquatic Central". The proposed Tobacco Paraphernalia Establishment occupies 20 feet of street frontage.

SURROUNDING PROPERTIES AND NEIGHBORHOOD

The length of the Ocean Avenue NCT District is approximately ¾ mile and the City College of San Francisco anchors the southern end of the district, with approximately 35,000 students enrolled annually. The area surrounding the project site on Ocean Avenue is mixed-use in character. A variety of commercial establishments are located within ground floor storefronts in the Ocean Avenue NCT, including restaurants, cafes, professional services, convenience stores, liquor stores, auto service stations, and other types of retailers.

Buildings along Ocean Avenue typically range from one to five stories in height. Upper floors of buildings are generally occupied by residential units. The surrounding properties are located within the RH-1(D) (Residential House, One-Family Detached), RH-1 (Residential House, One-Family) and RH-2 (Residential House, Two-Family) Districts, with some NC-2 and NC-1 zoned districts interspersed. The area is transit-oriented with the MUNI K-Ingleside line on Ocean Avenue, several bus lines on or connecting to Ocean Avenue and the regionally-serving Balboa Park BART station at Geneva and San Jose Avenues approximately ¾ mile to the south. The Ocean Avenue NCT District is intended to provide convenience goods and services to the surrounding neighborhoods as well as limited comparison shopping goods for a wider market. The range of comparison goods and services offered is varied and often includes specialty retail stores, restaurants, and neighborhood-serving offices.

ENVIRONMENTAL REVIEW

The Project is exempt from the California Environmental Quality Act ("CEQA") as a Class 1 categorical exemption.

HEARING NOTIFICATION

TYPE	REQUIRED PERIOD	REQUIRED NOTICE DATE	ACTUAL NOTICE DATE	ACTUAL PERIOD
Classified News Ad	20 days	October 17, 2014	October 15, 2014	22 days
Posted Notice	20 days	October 17, 2014	October 16, 2014	21 days
Mailed Notice	20 days	October 17, 2014	October 16, 2014	21 days

The proposal requires a Section 312-neighborhood notification, which was conducted in conjunction with the conditional use authorization process.

PUBLIC COMMENT

- To date, the Department has received emails and letters in opposition to the proposal from 22 individuals, and 2 letters of opposition from neighborhood groups, including the Westwood Park Association and from the Ingleside Terraces Homes Association. These individuals and groups expressed concerns regarding the safety of e-cigarettes, the safety and welfare of children in

relation to e-cigarettes, possibility of odor, crime in the area, and problems with the outdoor area (which the project sponsor has since removed from the project).

- The Department has also received a letter of support from the Ocean Avenue Association. The project sponsor has obtained 21 signed letters of support from neighboring business owners, including a petition with two signatures.

ISSUES AND OTHER CONSIDERATIONS

- On October 21, 2008, the Board of Supervisors (BOS) passed Ordinance No. 244-08, which created a new use category in the Planning Code for Tobacco Paraphernalia Establishments, defined as a retail use where more than 15% of the gross square footage of the establishment is dedicated to such sales. This use required Conditional Use Authorization in all Commercial and Industrial districts throughout San Francisco. Effective February 16, 2010 the BOS adopted Ordinance No. 03-10 that amended the definition of a Tobacco Paraphernalia Establishment where more than 10% of the square footage of occupied floor area or 10 linear feet of display area is dedicated to such sales. No restrictions were placed on the proximity of Tobacco Paraphernalia Establishments to each other or to other uses. Per the Ordinance, Tobacco Paraphernalia Establishments were defined as separate and distinct from Medical Cannabis Dispensaries.
- The Department of Public Health is the City's regulatory agency for tobacco permits. Ordinance No. 030-14 amended the Health Code with restrictions on the sale and use of electronic cigarettes through Board of Supervisor action, effective March 25, 2014. The ordinance generally amended Article 19(N): to prohibit the use of e-cigarettes where smoking is otherwise prohibited; require a tobacco permit for the sale of e-cigarettes; and prohibit the sale of e-cigarettes where the sale of tobacco products is otherwise prohibited.
- On August 5, 2014, the Director of SF Department of Public Health sent a letter to the Federal Drug Administration urging regulation of new noncombustible products, including e-cigarettes. The focus of the recommendations was that the FDA require: regulation of e-cigarettes (and other noncombustibles) in the same manner as existing tobacco products, including to be properly labeled and tested; regulation of marketing/advertising; and restriction of flavorings; and to require child-resistant packaging.
- There are no other retail shops completely dedicated to e-cigarette sales in the Ocean Avenue NCT, nor are there other Tobacco Paraphernalia Establishments that have been through the conditional use process. The approximate concentration of establishments that sell e-cigarettes – as peripheral goods and the proposed business - within the Ocean Avenue NCT is 6% of commercial frontage. This represents seven stores, including the subject proposal, out of 144 storefronts in the Ocean Avenue NCT. The two other nearest retail stores dedicated to e-cigarette sales appear to be located approximately 1.5 miles away from the subject site. However, the Planning Code does not outline restrictions on concentration percentage or proximity to other Tobacco Paraphernalia Establishments.

- Although not required for purposes of this Conditional Use Authorization process, the Planning Department requested that the project sponsor host a Pre-Application meeting according to Department standards. Adjacent property owners and occupants to the subject property, and neighborhood organizations from the Ocean View and West of Twin Peaks areas were invited. Nine people attended two Pre-Application meetings, hosted by Blake He (agent and co-owner) on May 5 and May 21, 2014, at the subject site. In addition, the project sponsor has presented at an Ocean Avenue Association monthly board meeting, presented at an Ocean Avenue Street Life Committee meeting, and attended an Ingleside Terraces Homes Association board meeting to field questions.
- The Invest in Neighborhoods (IIN) program of the Mayor's Office of Economic and Workforce Development prepared a neighborhood snapshot of Ocean Avenue corridor from Phelan Avenue to Manor Drive in February 2013. Out of 144 storefronts, the report's analysis determined an 11% vacancy rate -- a "relatively low commercial vacancy rate". However, according to a map produced of vacancy locations, the concentration of vacancies appear located at the northern end of the commercial district between Ashton Avenue and Manor Drive which were considered "dead blocks" through a survey conducted for this IIN report.
- The project sponsor had initially proposed an outdoor activity area for sampling e-cigarettes that required conditional use authorization; this request has been removed from the project.

REQUIRED COMMISSION ACTION

In order for the project to proceed, the Commission must grant conditional use authorization to allow the establishment of a Tobacco Paraphernalia Establishment, pursuant to Planning Code Sections 737.69.

BASIS FOR RECOMMENDATION

- The project promotes a locally-owned business and contributes to the commercial diversity of Ocean Avenue NCT.
- The project fills a vacant retail storefront and would not displace a retail tenant providing convenience goods and services to the neighborhood.
- The project meets all applicable requirements of the Planning Code.
- The project is desirable for, and compatible with the surrounding commercial neighborhood.
- The business is not a Formula Retail use and would serve the immediate and surrounding neighborhood.
- This type of retail sales must meet obtain other agency permits prior to occupancy and opening.

RECOMMENDATION:	Approval with Conditions
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Attachments:

Block Book Map
Sanborn Map
Aerial Photographs
Public Correspondence (see also Project Sponsor Submittal)
Reduced Plans

Project Sponsor Submittal, including:

- Letter to Commissioners
- Letters of Support
- Business Plan
- Information and research about e-cigarettes
- Photographs

Attachment Checklist

- | | |
|--|--|
| <input checked="" type="checkbox"/> Executive Summary | <input checked="" type="checkbox"/> Project sponsor submittal |
| <input checked="" type="checkbox"/> Draft Motion | Drawings: <u>Existing Conditions</u> |
| <input type="checkbox"/> Environmental Determination | <input checked="" type="checkbox"/> Check for legibility |
| <input checked="" type="checkbox"/> Zoning District Map | Drawings: <u>Proposed Project</u> |
| <input checked="" type="checkbox"/> Height & Bulk Map | <input checked="" type="checkbox"/> Check for legibility |
| <input checked="" type="checkbox"/> Parcel Map | 3-D Renderings (new construction or significant addition) |
| <input checked="" type="checkbox"/> Sanborn Map | <input type="checkbox"/> Check for legibility |
| <input checked="" type="checkbox"/> Aerial Photo | <input type="checkbox"/> Wireless Telecommunications Materials |
| <input checked="" type="checkbox"/> Context (Rear Yard) Photos | <input type="checkbox"/> Health Dept. review of RF levels |
| <input checked="" type="checkbox"/> Site Photos | <input type="checkbox"/> RF Report |
| | <input type="checkbox"/> Community Meeting Notice |
| | <input type="checkbox"/> Housing Documents |
| | <input type="checkbox"/> Inclusionary Affordable Housing Program: Affidavit for Compliance |

Exhibits above marked with an "X" are included in this packet

MWB
Planner's Initials



SAN FRANCISCO PLANNING DEPARTMENT

Subject to: (Select only if applicable)

- | | |
|--|--|
| <input type="checkbox"/> Affordable Housing (Sec. 415) | <input type="checkbox"/> First Source Hiring (Admin. Code) |
| <input type="checkbox"/> Jobs Housing Linkage Program (Sec. 413) | <input type="checkbox"/> Child Care Requirement (Sec. 414) |
| <input type="checkbox"/> Downtown Park Fee (Sec. 412) | <input type="checkbox"/> Other |

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Planning Commission Draft Motion

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Recommendation: **Approval with Conditions**

ADOPTING FINDINGS RELATING TO THE APPROVAL OF CONDITIONAL USE AUTHORIZATION PURSUANT TO SECTIONS 303 AND 737.69 OF THE PLANNING CODE TO ALLOW ESTABLISHMENT OF A TOBACCO PARAPHERNALIA ESTABLISHMENT (D.B.A. HAPPY VAPE) WITHIN THE OCEAN AVENUE NCT (NEIGHBORHOOD COMMERCIAL TRANSIT) DISTRICT AND A 45-X HEIGHT AND BULK DISTRICT.

PREAMBLE

On February 7, 2014 Cong Phuong Nguyen (hereinafter “Project Sponsor”) filed an application with the Planning Department (hereinafter “Department”) for Conditional Use Authorization under Planning Code Section(s) 737.69 to allow establishment of a Tobacco Paraphernalia Establishment retail use (d.b.a. Happy Vape) within the Ocean Avenue NCT (Neighborhood Commercial Transit) District and a 45-X Height and Bulk District.

On November 6, 2014, the San Francisco Planning Commission (hereinafter “Commission”) conducted a duly noticed public hearing at a regularly scheduled meeting on Conditional Use Application No. 2014.0206C.

The Project is exempt from the California Environmental Quality Act (“CEQA”) as a Class 1 categorical exemption.

The Commission has heard and considered the testimony presented to it at the public hearing and has further considered written materials and oral testimony presented on behalf of the applicant, Department staff, and other interested parties.

MOVED, that the Commission hereby authorizes the Conditional Use requested in Application No. 2014.0206C, subject to the conditions contained in "EXHIBIT A" of this motion, based on the following findings:

FINDINGS

Having reviewed the materials identified in the preamble above, and having heard all testimony and arguments, this Commission finds, concludes, and determines as follows:

1. The above recitals are accurate and constitute findings of this Commission.
2. **Site Description and Present Use.** The project is located on the southern side of Ocean Avenue, between, Block 6915, Lot 020. The property is located within the Ocean Avenue NCT (Neighborhood Commercial Transit) District with 45-X height and bulk district. The property is developed with a one-story-over-partial-basement commercial building, with tenants including a travel agent, a massage/acupuncture establishment and the vacant retail space at 1963 Ocean Avenue. The street frontage of the proposed tenant space is 20 feet. The parcel is approximately 4,500 square feet.
3. **Surrounding Properties and Neighborhood.** The length of the Ocean Avenue NCT District is approximately $\frac{3}{4}$ mile and the City College of San Francisco anchors the southern end of the district, with approximately 35,000 students. The area surrounding the project site on Ocean Avenue is mixed-use in character. A variety of commercial establishments are located within ground floor storefronts in the Ocean Avenue NCT, including restaurants, cafes, professional services, convenience stores, liquor stores, auto service stations, and other types of retailers.

Buildings along Ocean Avenue typically range from one to five stories in height. Upper floors of buildings are generally occupied by residential units. The surrounding properties are located within the RH-1(D) (Residential House, One-Family Detached), RH-1 (Residential House, One-Family) and RH-2 (Residential House, Two-Family) Districts, with some NC-2 and NC-1 zoned districts interspersed. The area is transit-oriented with the MUNI K-Ingleside line on Ocean Avenue and several bus lines on and connecting to Ocean Avenue. The Ocean Avenue NCT District is intended to provide convenience goods and services to the surrounding neighborhoods as well as limited comparison shopping goods for a wider market. The range of comparison goods and services offered is varied and often includes specialty retail stores, restaurants, and neighborhood-serving offices.

4. **Project Description.** The project sponsor proposes to establish a Tobacco Paraphernalia Establishment retail use in a vacant retail space to be known as "Happy Vape", which will include e-cigarette sales at the ground floor and a steam stone hookah lounge at the basement

level. The existing tenant space measures approximately 1,334 square feet at ground floor and 1,054 square feet at basement level. The project also includes minor interior tenant improvements, new signage but otherwise proposed no storefront alterations.

The project sponsor proposes a business that will sell devices (e-cigarettes/vaporizers), vaping liquids/e-juices and batteries both in-store and some accessory sales on-line. In the basement level, the project sponsor proposes establishing a steam stone hookah lounge. Together, these activities have been determined as Tobacco Paraphernalia Establishment uses and account for more than 10% of the square footage of occupied floor area. The proposed hours of operation are from 11 a.m. to 12 a.m. daily. No ABC license is being sought in conjunction with this Conditional Use authorization.

E-cigarette smoking, or “vaping”, is not allowed inside commercial establishments within San Francisco.

The proposed use is an independent use and locally owned, which has been encouraged throughout San Francisco. The proposed use is not a Formula Retail use. The proposal requires a Section 312-neighborhood notification, which was conducted in conjunction with the Conditional Use Authorization process.

The proposed operation will employ between 2-4 employees. The subject site is well served by public transit so that potential customers should not adversely affect the traffic flow.

5. **Public Comment.** To date, the Department has received emails and letters in opposition to the proposal from 22 individuals, and 2 letters of opposition from neighborhood groups, including the Westwood Park Association and from the Ingleside Terraces Homes Association. These individuals and groups expressed concerns regarding the safety of e-cigarettes, the safety and welfare of children in relation to e-cigarettes, possibility of odor, crime in the area, and problems with the outdoor area (which the project sponsor has since removed from the project). The Department has also received a letter of support from the Ocean Avenue Association. The project sponsor has obtained 21 signed letters of support from neighboring business owners, including a petition with two signatures.
6. **Planning Code Compliance:** The Commission finds that the Project is consistent with the relevant provisions of the Planning Code in the following manner:
 - A. **Use Size.** Planning Code Section 737.21 permits use sizes up to 3,999 square feet, with a Conditional Use Authorization required for use sizes of 4,000 square feet and above, as defined by Planning Code Section 790.130.

The proposed use size of the ground floor and basement level is approximately 2,423 square feet.

- B. **Outdoor Activity.** Planning Code Section 737.24 states that a Conditional Use Authorization is required for an Outdoor Activity Area, as defined by Planning Code Section 790.70.

The Project Sponsor does not intend to establish an outdoor activity area.

- C. **Hours of Operation.** Planning Code Section 737.27 permits operation by-right from 6 a.m. to 2 a.m. Operation between the hours of 2 a.m. to 6 a.m is allowed through conditional use authorization only.

The Sponsor does not seek to operate beyond the permitted hours of operation for the Zoning District. The proposed hours of operation for Happy Vape are 11 a.m. to 12 a.m. daily in the ground and basement levels.

- D. **Rear Yard Requirement in the Ocean Avenue NCT District.** Planning Code Section 737.12 and 134 states that the minimum rear yard depth shall be equal to 25 percent of the total depth of a lot in which it is situated, but in no case less than 15 feet.

The proposal does not include any structural expansion. The rear yard meets the Planning Code requirements.

- E. **Parking.** Planning Section 151 of the Planning Code requires off-street parking for every 200 square-feet of occupied floor area, where the occupied floor area exceeds 5,000 square-feet.

The Subject Property contains approximately 2,423 square-feet of occupied floor area and thus does not require any off-street parking.

- F. **Street Frontage in Neighborhood Commercial Districts.** Section 145.1 of the Planning Code requires that within NC Districts space for active uses shall be provided within the first 25 feet of building depth on the ground floor. Frontages with active uses must be fenestrated with transparent windows and doorways for no less than 60 percent of the street frontage at the ground level and allow visibility to the inside of the building.

The subject commercial space has approximately 20-feet of frontage on Ocean Avenue with approximately 20 feet devoted to either the retail entrance or window space. The windows are proposed as clear and unobstructed. There are no changes proposed to the commercial frontage.

- G. **Signage.** Any proposed signage will be subject to the review and approval of the Planning Department per Article 6 of the Planning Code.

7. **Planning Code Section 303** establishes criteria for the Planning Commission to consider when reviewing applications for Conditional Use approval. On balance, the project does comply with said criteria in that:

- A. The proposed new uses and building, at the size and intensity contemplated and at the proposed location, will provide a development that is necessary or desirable, and compatible with, the neighborhood or the community.

The size of the proposed use is in keeping with other storefronts on the block face. The proposed Tobacco Paraphernalia Establishment will not impact traffic or parking in the District, as the use is not changing from retail. This will compliment the mix of goods and services currently available in the district by providing diverse commercial offerings and contribute to the economic vitality of the neighborhood by removing a vacant storefront.

- B. The proposed project will not be detrimental to the health, safety, convenience or general welfare of persons residing or working in the vicinity. There are no features of the project that could be detrimental to the health, safety or convenience of those residing or working the area, in that:

- i. Nature of proposed site, including its size and shape, and the proposed size, shape and arrangement of structures;

The height and bulk of the existing building will remain the same and will not alter the existing appearance or character of the project vicinity. The proposed work will not affect the building envelope.

- ii. The accessibility and traffic patterns for persons and vehicles, the type and volume of such traffic, and the adequacy of proposed off-street parking and loading;

The Planning Code does not require parking or loading for a 2,423 occupied square-foot retail use. The proposed use is designed to meet the needs of the immediate neighborhood as well as limited comparison shopping goods for a wider market. The site is easily accessible by transit for surrounding neighborhoods, and should not generate significant amounts of vehicular trips from the immediate neighborhood or citywide.

- iii. The safeguards afforded to prevent noxious or offensive emissions such as noise, glare, dust and odor;

The proposed use is subject to conditions of approval outlined in Exhibit A. Conditions 3 and 6 specifically obligates the project sponsor to mitigate odor generated by the Tobacco Paraphernalia Use.

- iv. Treatment given, as appropriate, to such aspects as landscaping, screening, open spaces, parking and loading areas, service areas, lighting and signs;

The proposed use does not require additional exterior improvements, nor does the project require parking or loading. The Department shall review all signs proposed for the new business in accordance with Article 6 of the Planning Code.

- C. That the use as proposed will comply with the applicable provisions of the Planning Code and will not adversely affect the General Plan.

The Project complies with all relevant requirements and standards of the Planning Code and is consistent with objectives and policies of the General Plan as detailed below.

- D. That the use as proposed would provide development that is in conformity with the purpose of the applicable Neighborhood Commercial District.

The proposed project is consistent with the stated purposes of the Ocean Avenue NCT District in that the intended use is located at the ground floor and below, will provide convenience goods and services to the surrounding neighborhoods as well as limited comparison shopping goods for a wider market. The proposal enhances the range of comparison goods and services offered by adding another specialty retail store to the District. The project seeks to retain an existing storefront, which will preserve the fine grain character of the district. Further, a survey conducted by the Mayor's Office of Economic and Workforce Development Invest in Neighborhoods program (February 2013) determined that more diverse commercial offerings were desired by the neighborhood.

- E. With respect to a Tobacco Paraphernalia Establishment, as defined in Section 227(v) of the Planning Code, the Commission shall make the following findings:

- i. The concentration of such establishments in the particular zoning district for which they are proposed does not appear to contribute directly to peace, health, safety, and general welfare problems, including drug use, drug sales, drug trafficking, other crimes associated with drug use, loitering, and littering, as well as traffic circulation, parking, and noise problems on the district's public streets and lots;

The proposal is a new establishment, which proposes to utilize a vacant retail space for an electronic cigarette retail store and steam stone hookah lounge. There are no other Tobacco Paraphernalia Establishments within the Ocean Avenue NCT that have received Conditional Use authorization. The approximate concentration of establishments that sell e-cigarettes – including as peripheral goods and the proposed business - within the Ocean Avenue NCT is 6% of commercial frontage. The project sponsor will maintain current contact information for a Community Liaison per Condition 6 in Exhibit A, will endeavor to create a safe business environment, discourage loitering and e-cigarette smoking outside the storefront, and maintain the public space in front of the storefront free from litter per Condition 4 in Exhibit A. Street parking exists along Ocean Avenue and the area is well-served by MUNI K-Ingleside light rail line and several bus lines on and connecting to Ocean Avenue.

- ii. The concentration of such establishments in the particular zoning district for which they are proposed does not appear to adversely impact the health, safety, and welfare of residents of nearby areas, including fear for the safety of children, elderly and disabled residents, and visitors to San Francisco;

The proposal is a new establishment, which proposes to utilize a vacant retail space for an electronic cigarette retail store and steam stone hookah lounge. There are no other Tobacco Paraphernalia Establishments within the Ocean Avenue NCT that have received Conditional Use authorization. The approximate concentration of establishments that sell e-cigarettes –

including as peripheral goods and the proposed business - within the Ocean Avenue NCT is 6% of commercial frontage. The project sponsor will maintain current contact information for a Community Liaison per Condition 6 in Exhibit A, will endeavor to create a safe business environment, discourage loitering and e-cigarette smoking outside the storefront, and maintain the public space in front of the storefront free from litter per Condition 4 in Exhibit A.

- iii. The proposed establishment is compatible with the existing character of the particular district for which it is proposed.

The proposal is a new commercial establishment, which proposes to utilize a vacant retail space for an electronic cigarette retail store and steam stone hookah lounge. The use will remain as retail establishment, and no changes are proposed to the fine-grained, pedestrian-oriented storefront. The establishment is compatible with the existing character of particular district for which it is proposed.

- 8. **General Plan Compliance.** The Project is, on balance, consistent with the following Objectives and Policies of the General Plan:

NEIGHBORHOOD COMMERCE

Objectives and Policies

OBJECTIVE 1:

MANAGE ECONOMIC GROWTH AND CHANGE TO ENSURE ENHANCEMENT OF THE TOTAL CITY LIVING AND WORKING ENVIRONMENT.

Policy 1.1:

Encourage development which provides substantial net benefits and minimizes undesirable consequences. Discourage development that has substantial undesirable consequences that cannot be mitigated.

Policy 1.2:

Assure that all commercial and industrial uses meet minimum, reasonable performance standards.

Policy 1.3:

Locate commercial and industrial activities according to a generalized commercial and industrial land use plan.

The proposed development will provide specialty goods and services to the neighborhood and will provide employment opportunities to those in the community. Further, the Project Site is located within a Neighborhood Commercial District and is thus consistent with activities in the commercial land use plan.

OBJECTIVE 2:

MAINTAIN AND ENHANCE A SOUND AND DIVERSE ECONOMIC BASE AND FISCAL STRUCTURE FOR THE CITY.

Policy 2.1:

Seek to retain existing commercial and industrial activity and to attract new such activity to the City.

The Project will introduce a new commercial retail use and will enhance the diverse economic base of the City.

OBJECTIVE 6:

MAINTAIN AND STRENGTHEN VIABLE NEIGHBORHOOD COMMERCIAL AREAS EASILY ACCESSIBLE TO CITY RESIDENTS.

Policy 6.1:

Ensure and encourage the retention and provision of neighborhood-serving goods and services in the city's neighborhood commercial districts, while recognizing and encouraging diversity among the districts.

No commercial tenant would be displaced and the project would not prevent the district from achieving optimal diversity in the types of goods and services available in the neighborhood. The proposed business seeks to occupy a vacant retail storefront with a diverse commercial use.

Policy 6.2:

Promote economically vital neighborhood commercial districts which foster small business enterprises and entrepreneurship and which are responsive to the economic and technological innovation in the marketplace and society.

An independent entrepreneur is sponsoring the proposal. This is not a Formula Retail use.

9. **Planning Code Section 101.1(b)** establishes eight priority-planning policies and requires review of permits for consistency with said policies. On balance, the project does comply with said policies in that:

- A. That existing neighborhood-serving retail uses be preserved and enhanced and future opportunities for resident employment in and ownership of such businesses be enhanced.

The proposal would enhance the district by filling a vacant storefront and preserve a retail use. The business would be locally owned and it creates 2-4 employment opportunities for the community. The proposed alterations are within the existing building footprint.

- B. That existing housing and neighborhood character be conserved and protected in order to preserve the cultural and economic diversity of our neighborhoods.

The existing units in the surrounding neighborhood would not be adversely affected. The proposal includes the use of the outside activity area but restricts the hours of this space to between 11 a.m. and 8 p.m. daily.

- C. That the City's supply of affordable housing be preserved and enhanced,

No housing is removed for this Project.

- D. That commuter traffic not impede MUNI transit service or overburden our streets or neighborhood parking.

The site is on Ocean Avenue and is well served by transit. Street parking lines both sides of Ocean Avenue. Ocean Avenue has one MUNI light-rail (K-Ingleside) and several bus lines on and connecting to Ocean Avenue.

- E. That a diverse economic base be maintained by protecting our industrial and service sectors from displacement due to commercial office development, and that future opportunities for resident employment and ownership in these sectors be enhanced.

The Project will not displace any service or industry establishment. The project will not affect industrial or service sector uses or related employment opportunities. Ownership of industrial or service sector businesses will not be affected by this project.

- F. That the City achieve the greatest possible preparedness to protect against injury and loss of life in an earthquake.

This proposal will not impact the property's ability to withstand an earthquake.

- G. That landmarks and historic buildings be preserved.

A landmark or historic building does not occupy the Project site.

- H. That our parks and open space and their access to sunlight and vistas be protected from development.

The project will have no negative impact on existing parks and open spaces. The Project does not have an impact on open spaces.

10. The Project is consistent with and would promote the general and specific purposes of the Code provided under Section 101.1(b) in that, as designed, the Project would contribute to the character and stability of the neighborhood and would constitute a beneficial development.
11. The Commission hereby finds that approval of the Conditional Use authorization would promote the health, safety and welfare of the City.

DECISION

That based upon the Record, the submissions by the Applicant, the staff of the Department and other interested parties, the oral testimony presented to this Commission at the public hearings, and all other written materials submitted by all parties, the Commission hereby **APPROVES Conditional Use Application No. 2014.0206C** subject to the following conditions attached hereto as "EXHIBIT A" in general conformance with plans on file, dated October 30, 2014, and stamped "EXHIBIT B", which is incorporated herein by reference as though fully set forth.

APPEAL AND EFFECTIVE DATE OF MOTION: Any aggrieved person may appeal this Conditional Use Authorization to the Board of Supervisors within thirty (30) days after the date of this Motion No. XXXXX. The effective date of this Motion shall be the date of this Motion if not appealed (After the 30-day period has expired) OR the date of the decision of the Board of Supervisors if appealed to the Board of Supervisors. For further information, please contact the Board of Supervisors at (415) 554-5184, City Hall, Room 244, 1 Dr. Carlton B. Goodlett Place, San Francisco, CA 94102.

Protest of Fee or Exaction: You may protest any fee or exaction subject to Government Code Section 66000 that is imposed as a condition of approval by following the procedures set forth in Government Code Section 66020. The protest must satisfy the requirements of Government Code Section 66020(a) and must be filed within 90 days of the date of the first approval or conditional approval of the development referencing the challenged fee or exaction. For purposes of Government Code Section 66020, the date of imposition of the fee shall be the date of the earliest discretionary approval by the City of the subject development.

If the City has not previously given Notice of an earlier discretionary approval of the project, the Planning Commission's adoption of this Motion, Resolution, Discretionary Review Action or the Zoning Administrator's Variance Decision Letter constitutes the approval or conditional approval of the development and the City hereby gives **NOTICE** that the 90-day protest period under Government Code Section 66020 has begun. If the City has already given Notice that the 90-day approval period has begun for the subject development, then this document does not re-commence the 90-day approval period.

I hereby certify that the Planning Commission **ADOPTED** the foregoing Motion on November 6, 2014.

Jonas P. Ionin
Commission Secretary

AYES:

NAYS:

ABSENT:

ADOPTED: November 6, 2014

EXHIBIT A

AUTHORIZATION

This authorization is for a conditional use to allow a Tobacco Paraphernalia Establishment (d.b.a. **Happy Vape**) located at 1963 Ocean Avenue, Block 6915, Lot 020, pursuant to Planning Code Section(s) **303, 737.69, and 737.24** within the **Ocean Avenue NCT** District and a **45-X** Height and Bulk District; in general conformance with plans, dated **October 30, 2014**, and stamped "EXHIBIT B" included in the docket for Case No. **2014.0206C** and subject to conditions of approval reviewed and approved by the Commission on **November 6, 2014** under Motion No **XXXXXX**. This authorization and the conditions contained herein run with the property and not with a particular Project Sponsor, business, or operator.

RECORDATION OF CONDITIONS OF APPROVAL

Prior to the issuance of the building permit or commencement of use for the Project the Zoning Administrator shall approve and order the recordation of a Notice in the Official Records of the Recorder of the City and County of San Francisco for the subject property. This Notice shall state that the project is subject to the conditions of approval contained herein and reviewed and approved by the Planning Commission on **November 6, 2014** under Motion No **XXXXXX**.

PRINTING OF CONDITIONS OF APPROVAL ON PLANS

The conditions of approval under the 'Exhibit A' of this Planning Commission Motion No. **XXXXXX** shall be reproduced on the Index Sheet of construction plans submitted with the site or building permit application for the Project. The Index Sheet of the construction plans shall reference to the Conditional Use authorization and any subsequent amendments or modifications.

SEVERABILITY

The Project shall comply with all applicable City codes and requirements. If any clause, sentence, section or any part of these conditions of approval is for any reason held to be invalid, such invalidity shall not affect or impair other remaining clauses, sentences, or sections of these conditions. This decision conveys no right to construct, or to receive a building permit. "Project Sponsor" shall include any subsequent responsible party.

CHANGES AND MODIFICATIONS

Changes to the approved plans may be approved administratively by the Zoning Administrator. Significant changes and modifications of conditions shall require Planning Commission approval of a new Conditional Use authorization.

PERFORMANCE

Validity. The authorization and right vested by virtue of this action is valid for three (3) years from the effective date of the Motion. The Department of Building Inspection shall have issued a Building Permit or Site Permit to construct the project and/or commence the approved use within this three-year period.

For information about compliance, contact Code Enforcement, Planning Department at 415-575-6863, www.sf-planning.org

Expiration and Renewal. Should a Building or Site Permit be sought after the three (3) year period has lapsed, the project sponsor must seek a renewal of this Authorization by filing an application for an amendment to the original Authorization or a new application for Authorization. Should the project sponsor decline to so file, and decline to withdraw the permit application, the Commission shall conduct a public hearing in order to consider the revocation of the Authorization. Should the Commission not revoke the Authorization following the closure of the public hearing, the Commission shall determine the extension of time for the continued validity of the Authorization.

For information about compliance, contact Code Enforcement, Planning Department at 415-575-6863, www.sf-planning.org

Diligent pursuit. Once a site or Building Permit has been issued, construction must commence within the timeframe required by the Department of Building Inspection and be continued diligently to completion. Failure to do so shall be grounds for the Commission to consider revoking the approval if more than three (3) years have passed since this Authorization was approved.

For information about compliance, contact Code Enforcement, Planning Department at 415-575-6863, www.sf-planning.org

Extension. All time limits in the preceding three paragraphs may be extended at the discretion of the Zoning Administrator where implementation of the project is delayed by a public agency, an appeal or a legal challenge and only by the length of time for which such public agency, appeal or challenge has caused delay.

For information about compliance, contact Code Enforcement, Planning Department at 415-575-6863, www.sf-planning.org

Conformity with Current Law. No application for Building Permit, Site Permit, or other entitlement shall be approved unless it complies with all applicable provisions of City Codes in effect at the time of such approval.

For information about compliance, contact Code Enforcement, Planning Department at 415-575-6863, www.sf-planning.org

Conditions of Approval, Compliance, Monitoring, and Reporting

1. **Enforcement.** Violation of any of the Planning Department conditions of approval contained in this Motion or of any other provisions of Planning Code applicable to this Project shall be subject to the enforcement procedures and administrative penalties set forth under Planning Code

Section 176 or Section 176.1. The Planning Department may also refer the violation complaints to other city departments and agencies for appropriate enforcement action under their jurisdiction.

For information about compliance, contact Code Enforcement, Planning Department at 415-575-6863, www.sf-planning.org

- 2. Revocation due to Violation of Conditions.** Should implementation of this Project result in complaints from interested property owners, residents, or commercial lessees which are not resolved by the Project Sponsor and found to be in violation of the Planning Code and/or the specific conditions of approval for the Project as set forth in Exhibit A of this Motion, the Zoning Administrator shall refer such complaints to the Commission, after which it may hold a public hearing on the matter to consider revocation of this authorization.

For information about compliance, contact Code Enforcement, Planning Department at 415-575-6863, www.sf-planning.org

DESIGN – COMPLIANCE AT PLAN STAGE

- 3. Odor Control Unit.** In order to ensure any significant noxious or offensive odors are prevented from escaping the premises once the project is operational, the building permit application to implement the project shall include air cleaning or odor control equipment details and manufacturer specifications on the plans. Odor control ducting shall not be applied to the primary façade of the building.

For information about compliance, contact the Case Planner, Planning Department at 415-558-6378, www.sf-planning.org

OPERATION

- 4. Garbage, Recycling, and Composting Receptacles.** Garbage, recycling, and compost containers shall be kept within the premises and hidden from public view, and placed outside only when being serviced by the disposal company. Trash shall be contained and disposed of pursuant to garbage and recycling receptacles guidelines set forth by the Department of Public Works.

For information about compliance, contact Bureau of Street Use and Mapping, Department of Public Works at 415-554-5810, <http://sfdpw.org>

- 5. Sidewalk Maintenance.** The Project Sponsor shall maintain the main entrance to the building and all sidewalks abutting the subject property in a clean and sanitary condition in compliance with the Department of Public Works Streets and Sidewalk Maintenance Standards.

For information about compliance, contact Bureau of Street Use and Mapping, Department of Public Works, 415-695-2017, <http://sfdpw.org>

- 6. Odor Control.** While it is inevitable that some low level of odor may be detectable to nearby residents and passersby, appropriate odor control equipment shall be installed in conformance with the approved plans and maintained to prevent any significant noxious or offensive odors from escaping the premises.

For information about compliance with odor or other chemical air pollutants standards, contact the Bay Area Air Quality Management District, (BAAQMD), 1-800-334-ODOR (6367), www.baaqmd.gov and Code Enforcement, Planning Department at 415-575-6863, www.sf-planning.org

7. **Community Liaison.** Prior to issuance of a building permit to construct the project and implement the approved use, the Project Sponsor shall appoint a community liaison officer to deal with the issues of concern to owners and occupants of nearby properties. The Community Liaison is Yong (Blake) He, at a business address of 1963 Ocean Avenue, San Francisco, CA 94127, and phone number 415-513-2620. Should the contact information change, the Zoning Administrator shall be made aware of such change. The community liaison shall report to the Zoning Administrator what issues, if any, are of concern to the community and what issues have not been resolved by the Project Sponsor.

For information about compliance, contact Code Enforcement, Planning Department at 415-575-6863, www.sf-planning.org

8. **Hours of Operation.** The subject establishment is limited to the following hours of operation: 11 a.m. – 12 a.m. daily.

For information about compliance, contact Code Enforcement, Planning Department at 415-575-6863, www.sf-planning.org

Parcel Map

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6915
INGLESIDE TER. BLK. 12

REVISED '59
" '87

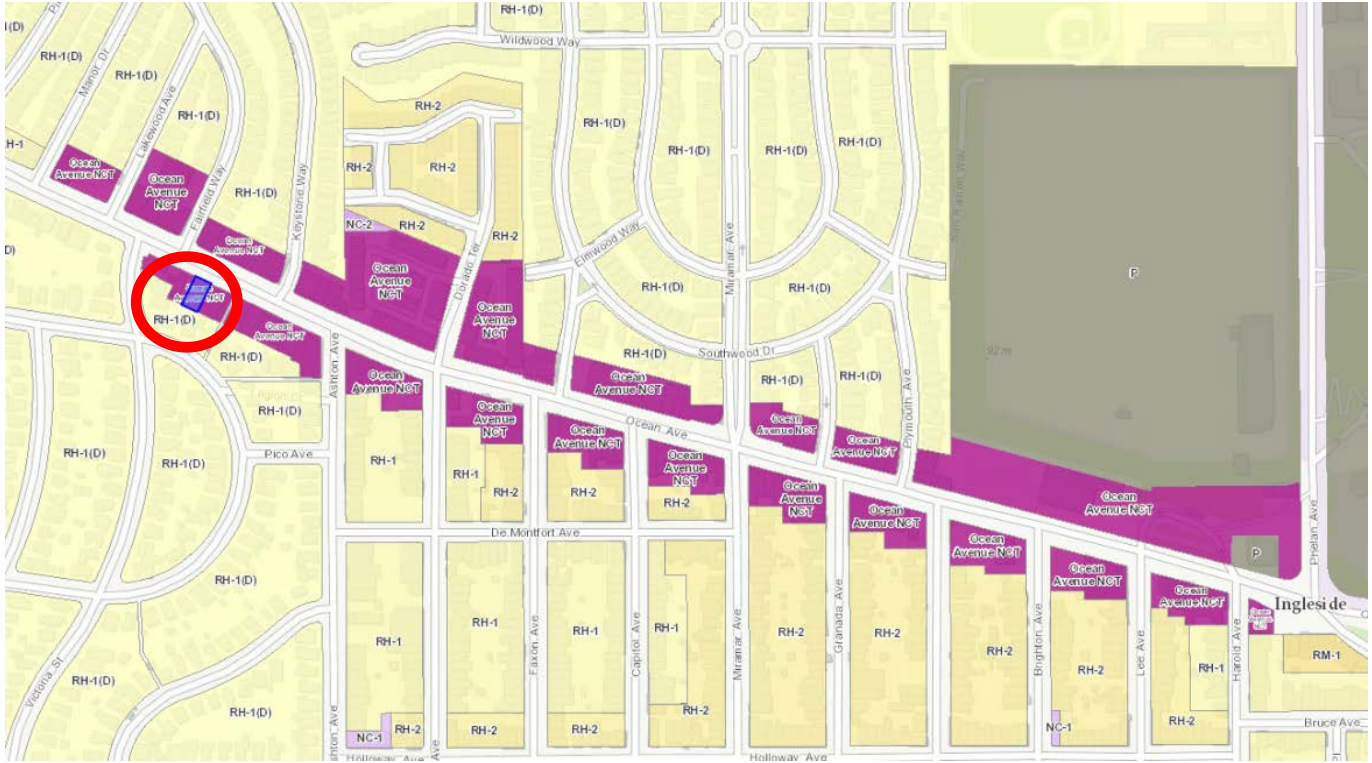


LOTS	MERGED	LOTS
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Conditional Use Authorization Hearing
Case Number 2014.0206C
1963 Ocean Avenue



Zoning Map



Conditional Use Authorization Hearing
Case Number 2014.0206C
1963 Ocean Avenue

Aerial Photo



SUBJECT PROPERTY



Conditional Use Authorization Hearing
Case Number 2014.0206C
1963 Ocean Avenue

Site Photo



SUBJECT PROPERTY

Conditional Use Authorization Hearing
Case Number 2014.0206C
1963 Ocean Avenue



Ocean Avenue Association
1728 Ocean Ave PMB 154
San Francisco, CA 94112

October 20, 2014

Marcelle Boudreaux
San Francisco Department of City Planning
marcelle.boudreaux@sfgov.org
415..575.9140

Dear Marcelle,

The Ocean Avenue Association supports Mr. Blake He's proposal to open the Happy Vape on Ocean Avenue.

The OAA's decision to support the Happy Vape conditional use application should not be construed as an endorsement of the applicant's chosen business nor its compatibility with the surrounding neighborhood. The Board has no position on the matters of public policy raised by members of the community with regard to the nature of the applicant's business. We do not doubt the sincerity of those views. The OAA's purview, however, does not extend to making choices among lawful business that otherwise comply with the City's licensing and regulatory process.

OAA's support is based on the board's view that Happy Vape's operations are consistent with the objectives of the OAA to promote vibrant business along the Ocean Avenue commercial corridor. The management team has shown a commitment to supporting the Ocean Avenue retail district and improving the cleanliness and safety of the commercial area. The OAA board also believes that Mr. He is receptive to the concerns and input of neighbors.

Please contact me if your have questions about this recommendation.

Daniel Weaver
Executive Director

From: [deltabear](#)
To: [Boudreaux, Marcelle \(CPC\)](#)
Subject: 1963 Ocean Ave - Conditional Use Permit Application -- Tobacco Paraphernalia
Date: Monday, October 20, 2014 10:21:06 AM

Thank you for the notice of public hearing for this project.

I reside at 50 Urbano Dr. I am opposed to this project. There are already plenty of shops on Ocean Ave offering tobacco, e-cigarettes, hookah, and medical marijuana. It is creating an atmosphere on Ocean Ave that is not conducive to pedestrian traffic or business. The smells make me cross the street. My children are uncomfortable walking along these blocks of Ocean Avenue.

Adrienne Go

From: SMGraz2001@aol.com
To: [Boudreaux, Marcelle \(CPC\)](#); [Yee, Norman \(BOS\)](#); [Secretary, Commissions \(CPC\)](#)
Cc: smgraz2001@aol.com; calbearsph@gmail.com; rckaris@gmail.com; board@balboaterrace.org
Subject: 1963 Ocean Ave. Proposed Vape Shop
Date: Wednesday, October 22, 2014 12:45:54 PM

Hello SF Planning Commission, Mr. Norman Yee and Ms. Marcelle Boudreaux,

I would like to state my OPPOSITION to the proposed new Vape Shop at 1963 Ocean Ave. I realize that the Vape Shop is applying for a conditional use. At this point, I do not think that this type of business is necessary or desirable on Ocean Ave. corridor. E-Cigarettes can be purchased on Taraval and 19th Ave, which is quite close. On the health issue, E-Cigarettes contain nicotine and the vaporized byproducts include unhealthy chemicals, heavy metals and nanoparticles that accumulate in the lungs. Nicotine is addictive and habit forming. Ingestion of the non-vaporized concentrated ingredients in the cartridges can be poisonous.

There is a garden area in the back that the business wants to use for smokers. Homes are directly located on the other side of the fence. Is this fair to the neighbors?

Lastly, this proposed location is across from a school with children. So, I would appreciate your consideration in not approving this Vape Shop.

Sincerely, Susan Grazioli
Balboa Terrace Director

From: [Maria S Flaherty](#)
To: [Boudreaux, Marcelle \(CPC\); Secretary, Commissions \(CPC\)](#)
Cc: Terraces@gogglegroups.com
Subject: 1963 Ocean avenue Happy Vape
Date: Monday, October 27, 2014 7:22:54 PM

I am an adjacent neighbor to the project and member of ITHA residential group. I strongly OPPOSE the Conditional Use authorization to sell tobacco paraphernalia, e-cigarette sales, and oppose to a Stream Stone Hookah Lounge at basement level. Additionally I strongly OPPOSE to any OUTDOOR ACTIVITY for sampling e-cigarettes PERIOD!

In addition, I oppose to any outdoor activity or sampling. This is a nuisance to adjacent neighbors. The vapors are toxic and a health hazard to the public. The lights, noise, sampling are absolutely not welcome in the backyard of neighbors nor our neighborhood! This would set a negative precedence.

Please include my e-mail and document in the planning dept. packet for review by the Planning Commission.

John and Maria Flaherty
Ingleside Terraces
ITHA member

Sent from my iPad

From: [John Stacey](#)
To: [Boudreaux, Marcelle \(CPC\)](#); [Yee, Norman \(BOS\)](#); [Secretary, Commissions \(CPC\)](#)
Subject: 1963 Ocean Avenue Vape Shop
Date: Monday, October 20, 2014 8:47:39 AM

I am writing to let you know of my opposition to the proposed Vape Shop, requesting to be located at 1963 Ocean Ave in San Francisco.

My reasons are fairly straight-forward:

- Ocean Avenue merchants appear to be moving in without much interest from the city on what the street is *becoming*. There are two relatively new tattoo parlors, about six nail shops, at least three massage parlors, two marijuana distributors, a bong shop, and (wait for it...) soon to be a VAPE shop!
- The neighbors deserve better. The (few) upstanding merchants on the street deserve better. Our community deserves better than having our main street turn into San Francisco's location for cheap sex, legal drugs, and various inhaled stimulants
- I realize I probably sound like a staunchy old republican, but I'm not: I am a 47 year old democrat - and own a home just off of Ocean. We have two teen-aged children that walk and drive through the "circus" daily. My wife and I call Ocean "Bangkok."
- In the 15 years that we've lived in our house, we've seen crime rise (including a shooting about 100 yards from this proposed shop). We've seen fast food litter pile up. We've seen drunken and disorderly behavior. We hear the subwoofers. We listen to the sounds of inebriates fighting on the sidewalks.
- It should stop. The city of San Francisco owes it to the local residents to do it's job... and have a commercial zoning plan for Ocean that is more calculated than "we'll rent to anyone the law allows."
- We pay substantial property taxes, and we vote.
- Please carefully consider my plea, as well as those from the neighbors in the community.

I live at 25 Cerritos, and I oppose the permitting of the Vape Shop.

Thank you for your time.

John Stacey
mobile 415-218-3431

From: [Robert Karis](#)
To: [Boudreaux, Marcelle \(CPC\); Secretary, Commissions \(CPC\)](#)
Cc: [Yee, Norman \(BOS\); Low, Jen \(BOS\)](#)
Subject: 1963 Ocean Avenue, Case No.: 2014.0206C
Date: Monday, September 22, 2014 10:43:56 AM

Dear Ms. Boudreaux,

The proposed Happy Vape store at 1963 is a Conditional Use, which means it has to demonstrate that it is necessary or desirable. This business is neither necessary or desirable.

I am opposed to the vape store for several reasons:

1) They are part of an effort by tobacco companies and others to addict young people, 20 somethings, to nicotine, which is a harmful substance http://www.cdc.gov/media/releases/2014/p0825-e-cigarettes.html?s_cid=cdc_homepage_whatsnew_002 E-cigarette ads are targeted towards young people, as is easily demonstrated by googling images of e-cigarette ads.

2) The vapors from e-cigarettes can be harmful, even when they don't contain nicotine http://www.nytimes.com/2014/05/04/business/some-e-cigarettes-deliver-a-puff-of-carcinogens.html?_r=1

E-liquids use propylene glycol as a solvent. In ordinary usage, propylene glycol is safe. But when it is heated, as it is in e-cigarettes, propylene glycol is oxidized and gives rise to a variety of toxic substances, particularly formaldehyde in unsafe amounts. Some earlier studies reported only low doses of formaldehyde, but they may not have used a high enough voltage, 4.8 volts in this study. 4.8 volts is easily and frequently obtained with the devices sold in vape shops, as the higher voltage also results in more nicotine and more effect from the e-cigarette. It is not surprising that heating propylene glycol (P.G.) $C_3H_8O_2$ yields formaldehyde CH_2O , or, to show the chain structure of P.G.,: $CH_2OH-CHOH-CH_3 + 2O_2 > 2CH_2O + 2H_2O + CO_2$. In addition, e-cigarettes contain toxic metals and nanoparticles which result in disease causing inflammation.

3) E-cigarettes may be useful in a few cases as part of a comprehensive stop smoking program <http://www.cdc.gov/tobacco/campaign/tips/quit-smoking/> but the purpose of a stand alone vape shop is to to increase, not decrease, nicotine usage.

As the Planning Department and Commission have a duty to benefit our neighborhoods, I trust they will agree that a vape shop on Ocean Avenue is not necessary or desirable.

Yours truly,
Robert Karis
Ingleside Terraces

From: [Mary Swope](#)
To: [Boudreaux, Marcelle \(CPC\)](#)
Cc: [Yee, Norman \(BOS\)](#)
Subject: anti Happy Vape
Date: Wednesday, October 29, 2014 3:42:59 PM

Dear Mr. Yee and Marcelle Boudreaux, and Planning Commission,
As a resident of the Ingleside, I am strongly opposed to the issuance of a Conditional Use authorization to 'Happy Vape' to sell e-cigarettes. I also oppose any outdoor area dedicated to sampling the product. There are other businesses in the vicinity where e-cigarettes are available. Merchants have been and are continuing to improve the neighborhood. 'Happy Vape' would be a negative to this effort.
Sincerely,
Mary Swope alphogal@sonic.net

From: [Carolyn Karis](#)
To: [Boudreaux, Marcelle \(CPC\)](#)
Cc: [Secretary, Commissions \(CPC\)](#); [Yee, Norman \(BOS\)](#)
Subject: vape store at 1963 Ocean Ave., Letter of Opposition
Date: Tuesday, October 28, 2014 5:44:09 PM
Attachments: [SFBOS e-cigarettes.pdf](#)

Dear Ms. Boudreaux:

I am attaching a copy of San Francisco Ordinance No. 030-14, Restrictions on Sale and Use of Electronic Cigarettes. Harmful chemicals that may be found in the fumes from e-cigarettes are listed on Page 2. Page 3 states that "electronic cigarettes can increase nicotine addiction among young people, may lead youth to try conventional tobacco products" and the fumes released into the air present a danger to others who breathe them. This ordinance was passed unanimously, 11 to 0, by the Board of Supervisors and signed by Mayor Ed Lee on 3/27/14.

E-cigarettes are not a proven method to stop smoking. Although e-cigarettes may replace cigarettes in a few cases, they may not be any healthier. Happy Vape states that they are interested in harm reduction; however, they are a vape shop, not a stop smoking clinic. If they are allowed to open their doors, they will sell e-cigarettes and e-liquids, with and without nicotine, to anyone over the age of 18.

The San Francisco Department of Public Health has asked the FDA to limit advertising for e-cigarettes. The San Francisco Board of Supervisors unanimously passed restrictions on the sale and use of electronic cigarettes. The vape store is a Conditional Use. Because of the harmful effects, listed above and in many other documents, the proposed use is not necessary or desirable to the neighborhood and may have a negative impact on the surrounding neighborhood. I ask that the San Francisco Planning Commission vote against allowing this business to open on Ocean Avenue.

Yours truly,
Carolyn Karis
Ingleside Terraces

1 [Health Code - Restrictions on Sale and Use of Electronic Cigarettes]

2
3 **Ordinance amending the Health Code to prohibit the use of electronic cigarettes where**
4 **smoking is otherwise prohibited; require a tobacco permit for the sale of electronic**
5 **cigarettes; prohibit the sale of electronic cigarettes where the sale of tobacco products**
6 **is otherwise prohibited; and making environmental findings.**

7
8 NOTE: Additions are *single-underline italics Times New Roman*;
9 deletions are ~~*strike-through italics Times New Roman*~~.
10 Board amendment additions are double-underlined;
11 Board amendment deletions are ~~striketrough normal~~.

12
13 Be it ordained by the People of the City and County of San Francisco:

14 Section 1. The Planning Department has determined that the actions contemplated in
15 this ordinance comply with the California Environmental Quality Act (California Public
16 Resources Code Section 21000 et seq.). Said determination is on file with the Clerk of the
17 Board of Supervisors in File No. 131208 and is incorporated herein by reference.

18 Section 2. The San Francisco Health Code is hereby amended by adding Article 19N,
19 Sections 19N.1 – 19N.9, to read as follows:

20 **SEC. 19N.1 FINDINGS AND STATEMENT OF PURPOSE.**

21 (a) Electronic smoking devices, commonly referred to as electronic cigarettes or e-cigarettes,
22 are battery-operated devices that may resemble cigarettes, although they do not contain tobacco leaf.
23 People who use electronic smoking devices inhale vaporized liquid nicotine extracted from tobacco, or
24 inhale other vaporized liquids, created by heat through an electronic ignition system, and exhale the
25 vapor in a way that mimics smoking.

1 ***(b) Electronic cigarettes are presently available for purchase and use in San Francisco.***

2 ***(c) The FDA's Center for Drug Evaluation and Research, Office of Compliance purchased two***
3 ***samples of electronic cigarettes and components from two leading brands. These samples included 18***
4 ***of the various flavored, nicotine, and no-nicotine cartridges offered for use with these products. These***
5 ***cartridges were obtained to test some of the ingredients contained in them and inhaled by users of***
6 ***electronic cigarettes. The FDA's Center for Drug Evaluation and Research, Division of***
7 ***Pharmaceutical Analysis (DPA) analyzed the cartridges from these electronic cigarettes for nicotine***
8 ***content and for the presence of other tobacco constituents, some of which are known to be harmful to***
9 ***humans, including those that are potentially carcinogenic or mutagenic. The DPA's analysis of the***
10 ***electronic cigarette samples showed:***

11 ***(1) The products contained detectable levels of known carcinogens and toxic chemicals to***
12 ***which users could be exposed.***

13 ***(2) Quality control processes used to manufacture these products are inconsistent or non-***
14 ***existent.***

15 ***(3) Tobacco-specific impurities suspected of being harmful to humans—anabasine, myosmine,***
16 ***and β -nicotyrine—were detected in a majority of the samples tested.***

17 ***(4) Three different electronic cigarette cartridges with the same label were tested and each***
18 ***cartridge emitted a markedly different amount of nicotine with each puff. The nicotine levels per puff***
19 ***ranged from 26.8 to 43.2 mcg nicotine/100 mL puff.***

20 ***(d) The Surgeon General has found that the chemical nicotine is a powerful pharmacologic***
21 ***agent that acts in the brain and throughout the body and is highly addictive. The United States***
22 ***Department of Health and Human Services has concluded that nicotine is as addictive as cocaine or***
23 ***heroin and is a highly toxic substance. Use of nicotine in any form may cause or contribute to***
24 ***cardiovascular disease, complications of hypertension, reproductive disorders, cancers of many types,***
25 ***and gastrointestinal disorders, including peptic ulcer disease and gastro esophageal reflux.***

1 (e) The FDA has raised concerns that electronic cigarettes, including but not limited to
2 flavored electronic cigarettes, can increase nicotine addiction among young people and may lead youth
3 to try conventional tobacco products. A CDC study showed that in 2011 4.7% of all high schoolers had
4 tried e-cigarettes and that in 2012 that number increased to 10.0% of all high schoolers. Electronic
5 cigarettes may not be legally sold to minors in California. Electronic smoking devices and other
6 unapproved nicotine delivery products have a high appeal to youth due to their high tech design and
7 availability in child-friendly flavors like cotton candy, bubble gum, chocolate chip cookie dough and
8 cookies and cream milkshake.

9 (f) Health authorities have also expressed concerns that the vapors released into the air
10 through the use of an electronic cigarette present a danger to others who breathe them.

11 (g) The use of an electronic cigarette in public is often indistinguishable from the use of
12 traditional tobacco products, prompting confusion among members of the public wherever smoking is
13 prohibited. Consequently, persons who smoke traditional tobacco products may be induced to do so in
14 areas where smoking is illegal under the mistaken belief that smoking is legal in such areas, or that the
15 ban on smoking in such areas is not being enforced.

16 (h) Owners of establishments such as office buildings and restaurants encounter similar
17 obstacles seeking to comply with the laws prohibiting smoking in certain locations. An owner may
18 request that a patron stop smoking cigarettes in a restaurant only to have the patron demonstrate that it
19 is an electronic cigarette. The Owner may also be placed in the position of having to confront and
20 examine the cigarettes of any number of customers absent a prohibition on the use of electronic
21 cigarettes where traditional cigarettes are banned.

22 (i) The agencies charged with enforcing compliance in enclosed and unenclosed spaces will
23 similarly have to devote considerable time and resources determining the individuals smoking
24 electronic cigarettes versus traditional cigarettes.

1 (i) Some agencies in San Francisco have already adopted restrictions on e-cigarette usage
2 including San Francisco General Hospital, Laguna Honda Hospital, AT&T Ballpark, University of
3 California-San Francisco, San Francisco Department of Public Health and the San Francisco
4 International Airport.

5 **SEC. 19N.2 DEFINITIONS.**

6 (a) "Director" means the Director of Public Health or his or her designee.

7 (b) "Electronic Cigarette" or "E-cigarette" means any device with a heating element, a
8 battery, or an electronic circuit that provides nicotine or other vaporized liquids to the user in a
9 manner that simulates smoking tobacco.

10 (c) "Establishment" means any store, stand, booth, concession or other enterprise that engages
11 in the retail sales of tobacco products and/or electronic cigarettes.

12 **SEC. 19N.3 TOBACCO SALES PERMIT REQUIRED.**

13 (a) An establishment must have a valid tobacco sales permit obtained pursuant to Health Code
14 Section 1009.52 to sell electronic cigarettes.

15 (b) The Director may enforce this section pursuant to Articles 19 et seq. of the Health Code
16 including but not limited to Article 19H.

17 **SEC. 19N.4 PROHIBITING THE USE OF ELECTRONIC CIGARETTES WHEREVER**
18 **SMOKING OF TOBACCO PRODUCTS IS BANNED .**

19 (a) The use of electronic cigarettes is prohibited wherever smoking of tobacco products is
20 prohibited by law including Articles 19 et seq. of the Health Code.

21 (b) The Director may enforce this section pursuant to Articles 19 et seq. of the Health Code
22 including but not limited to the Articles prohibiting smoking in certain spaces or areas.

23 **SEC. 19N.5 PROHIBITING THE SALE OF ELECTRONIC CIGARETTES WHEREVER**
24 **THE SALE OF TOBACCO PRODUCTS IS PROHIBITED.**

1 a) The sale of electronic cigarettes is prohibited wherever the sale of tobacco products is
2 prohibited by law, including as prohibited in Articles 19 et seq. of the Health Code.

3 b) The Director may enforce this section pursuant to Articles 19 et seq. of the Health Code
4 including but not limited to Article 19J.

5 **SEC. 19N.6 CITY UNDERTAKING LIMITED TO PROMOTION OF GENERAL**
6 **WELFARE.**

7 In enacting and implementing this ordinance, the City is assuming an undertaking only to
8 promote the general welfare. It is not assuming, nor is it imposing on its officers and employees, an
9 obligation for breach of which it is liable in money damages to any person who claims that such breach
10 proximately caused injury.

11 **SEC. 19N.7 RULES AND REGULATIONS.**

12 The Director, after a noticed public hearing, may adopt rules and regulations to carry out the
13 provisions of this Article. Such rules and regulations shall take effect 15 days after the public hearing.
14 Violation of any such rule or regulation may be grounds for administrative or civil action against the
15 permittee pursuant to this Article.

16 **SEC. 19N.8 PREEMPTION.**

17 (a) Nothing in this Article shall be interpreted or applied so as to create any power, duty or
18 obligation in conflict with, or preempted by, any Federal or State law. Even if not preempted by
19 Federal or State law, the provisions of this Article shall not apply if the Federal or State law is more
20 restrictive.

21 //

22 //

23 //

24 //

1 **(b) This Article shall not apply to any FDA-approved product marketed for therapeutic**
2 **purposes.**

3 **(c) This Article shall not affect any laws or regulations regarding medical cannabis.**

4 **SEC. 19N.9 SEVERABILITY.**

5 **If any section, subsection, subdivision, paragraph, sentence, clause, or phrase in this Article or**
6 **any part thereof is for any reason held to be unconstitutional or invalid or ineffective by any court of**
7 **competent jurisdiction, such decision shall not affect the validity or effectiveness of the remaining**
8 **portions of this Article or any part thereof. The Board of Supervisors hereby declares that it would**
9 **have passed each section, subsection, subdivision, paragraph, sentence, clause, or phrase thereof**
10 **irrespective of the fact that any one or more subsections, subdivisions, paragraphs, sentences, clauses,**
11 **or phrases be declared unconstitutional, or invalid, or ineffective.**

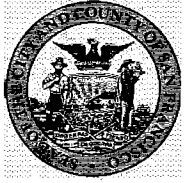
12
13 Section 3. Effective Date. This ordinance shall become effective 30 days after
14 enactment. Enactment occurs when the Mayor signs the ordinance, the Mayor returns the
15 ordinance unsigned or does not sign the ordinance within ten days of receiving it, or the Board
16 of Supervisors overrides the Mayor's veto of the ordinance.

17
18 APPROVED AS TO FORM:
19 DENNIS J. HERRERA, City Attorney

20 By:


21 Aleeta M. Van Runkle
22 Deputy City Attorney

23
24
25 SUPERVISOR MAR
BOARD OF SUPERVISORS



City and County of San Francisco

Tails

Ordinance

City Hall
1 Dr. Carlton B. Goodlett Place
San Francisco, CA 94102-4689

File Number: 131208

Date Passed: March 25, 2014

Ordinance amending the Health Code to prohibit the use of electronic cigarettes where smoking is otherwise prohibited; require a tobacco permit for the sale of electronic cigarettes; prohibit the sale of electronic cigarettes where the sale of tobacco products is otherwise prohibited; and making environmental findings.

March 06, 2014 Rules Committee - RECOMMENDED

March 18, 2014 Board of Supervisors - PASSED, ON FIRST READING

Ayes: 11 - Avalos, Breed, Campos, Chiu, Cohen, Farrell, Kim, Mar, Tang, Wiener and Yee

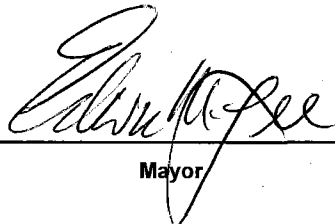
March 25, 2014 Board of Supervisors - FINALLY PASSED

Ayes: 11 - Avalos, Breed, Campos, Chiu, Cohen, Farrell, Kim, Mar, Tang, Wiener and Yee

File No. 131208

I hereby certify that the foregoing Ordinance was FINALLY PASSED on 3/25/2014 by the Board of Supervisors of the City and County of San Francisco.


Angela Calvillo
Clerk of the Board


Mayor

3/27/14
Date Approved

From: [Wendy Portnuff](#)
To: [Boudreaux, Marcelle \(CPC\)](#)
Subject: Conditional Use Permit for Tobacco Paraphernalia at 1963 Ocean Avenue
Date: Saturday, May 10, 2014 3:44:33 PM

Dear Ms. Boudreaux,

I live in Ingleside Terraces, which is adjacent to the location above on Ocean Avenue. Furthermore, I walk past the location almost daily. I object strongly to the introduction of Tobacco Products to this part of our neighborhood. These electronic cigarettes are highly suspect for health reasons. They contain known carcinogens. I do not wish to be exposed to them, and I do not want them to be readily available to neighborhood youth in this part of the city. It's bad enough that there are marijuana stores and tattoo parlors here. Please do not approve yet another storefront that challenges our ability to remain healthy and to be role models for our children.

Wendy Portnuff
The Professional Woman's Guide to Healthy Travel
www.wendypornuff.com
415-269-4398

From: [Dan Hambali](#)
To: [Boudreaux, Marcelle \(CPC\); Secretary, Commissions \(CPC\)](#)
Cc: [Yee, Norman \(BOS\)](#)
Subject: Happy Vape Shop on Ocean Avenue (Planning Commission 2014.0206 C)
Date: Sunday, October 26, 2014 8:59:19 AM
Attachments: [1963_Ocean_Avenue.pdf](#)
[ATT00001.htm](#)
[SmokingEnforcementAlert.pdf](#)
[ATT00002.htm](#)

Dear Sir:

I have received a Notice of Public Hearing regarding the planned operation of a Tobacco Paraphernalia and Cigar Bar in my neighborhood, Ingleside Terraces. The site is located at 1963 Ocean Avenue.

I would like to protest the opening of such an establishment for the following reasons.

1. There are already several vendors of such E-Cigarettes on Ocean Avenue. Through a simple Google search one can find this product sold in these establishments. There are likely more.

- * MMM Smoke Shop - 1936 Ocean Avenue (literally across the street)
- * 1944 Ocean Collective - 1944 Ocean Avenue (literally across the street)
- * Waterfall Wellness Health Center - 1545 Ocean Ave

2. I'm well acquainted with the former site of operations as it used to be an aquarium store that I frequented. The proposed business would have a hookah lounge in the basement and allow its customers to use the back yard area. The back yard is visible from Urbano drive. In no documents that I have seen has the proposed business declared their hours of operation. I've attached a document from SFDPH that states that tobacco products may not be consumed within any enclosed areas without DPH approval. This makes me believe that the business will move its consumption into the back yard—possibly at late hours. As a resident of Ingleside Terraces, I concerns me greatly that we will have late night activity in our neighborhood which would become a nuisance.

3. The nearby businesses and in particular the medicinal marijuana shop, 1944 Ocean Collective, create a parking burden from 1 Urbano (@Ashton to 90 Urbano (@Victoria) where customers of shops on Ocean Avenue avoid the parking meters by parking on Urbano. I regularly see and smell who I presume to be the customers of the medicinal marijuana shop smoke their medicine in their vehicles, and then drive off. Aside from being DUI, it's also creates a traffic burden to a residential neighborhood with young families. It concerns me that this new shop will attract similar customers at late hours as it is being treated as a "cigar bar" (see attached Letter of Determination).

Thank you for your time on this matter,

Daniel Hambali
715 Victoria St.
San Francisco, CA 94127

Attachments: 2



SAN FRANCISCO PLANNING DEPARTMENT

Letter of Determination

September 26, 2014

Marsha Garland
Garland Public & Community Relations
535 Green Street
San Francisco, CA 94133

Site Address:	1963 Ocean Avenue
Assessor's Block/Lot:	6915/020
Zoning District:	Ocean Avenue Neighborhood Commercial Transit
Staff Contact:	Marcelle Boudreaux, (415) 575-9140 or marcelle.boudreaux@sfgov.org

1650 Mission St.
Suite 400
San Francisco,
CA 94103-2479

Reception:
415.558.6378

Fax:
415.558.6409

Planning
Information:
415.558.6377

Dear Ms. Garland:

This letter is in response to your request for a Letter of Determination regarding the property at 1963 Ocean Avenue, a vacant retail use with proposal to establish a retail use selling e-cigarettes and related materials and steam stone hookah lounge with outdoor activity area (dba "Happy Vape"). This parcel is located in the Ocean Avenue Neighborhood Commercial Transit (NCT) Zoning District and 45-X Height and Bulk District.

CURRENT PROPOSAL

Per Planning Code Section 790.123, Tobacco Paraphernalia Establishment is defined as an establishment with greater than 10 linear feet or 10% of sales area devoted to display and sales of tobacco paraphernalia and (per Section 737.69) requires Conditional Use Authorization. Additionally, per Section 737.24, an outdoor activity area also requires a Conditional Use Authorization.

On February 7, 2014, the Project Sponsor submitted a Conditional Use Authorization application (Case No. 2014.0206C) for the subject property to establish a Tobacco Paraphernalia Establishment on the ground floor, a steam stone hookah lounge on the basement level and an outdoor activity area at the rear to allow sampling of e-cigarettes.

LETTER OF DETERMINATION REQUEST

The request seeks answers to the following: are steam stone hookahs allowed for indoor and outdoor use; is vaping allowed for indoor and outdoor use; are sales of packaged snacks and soft drinks allowed on the premises; and, would the use be considered a "cigar bar."

RESPONSE

In regards to allowed areas for steam stone hookahs, note that while the Planning Department would consider the hookah use as part of the overall Tobacco Paraphernalia Establishment use, the Department of Public Health (DPH) is responsible for regulating hookah establishments.

Marsha Garland
Garland Public & Community Relations
535 Green Street
San Francisco, CA 94133

September 26, 2014
Letter of Determination
1963 Ocean Avenue

In regards to allowed areas for vaping, it is the Planning Department's understanding of recent legislation enacted by DPH that vaping/e-cigarette smoking is now regulated in a similar manner to tobacco smoking. Please review Public Health Code Sections 19(N) and 19(F) and note that DPH is responsible for regulating such activity.

In regards to packaged drinks and snacks (food handling) being sold on the same premises as the Tobacco Paraphernalia Establishment and hookah use, please note that DPH is responsible for regulating such activity.

In regards to whether the proposed hookah use would be considered a "cigar bar"; this use would be considered as part of the Tobacco Paraphernalia Establishment use.

APPEAL: If you believe this determination represents an error in interpretation of the Planning Code or abuse in discretion by the Zoning Administrator, an appeal may be filed with the Board of Appeals within 15 days of the date of this letter. For information regarding the appeals process, please contact the Board of Appeals located at 1650 Mission Street, Room 304, San Francisco, or call (415) 575-6880.

Sincerely,



Scott F. Sanchez
Zoning Administrator

cc: Marcelle Boudreaux, Planner
Business Contacts: *Owner* - Cong Phuong Nguyen (948 Moscow St, San Francisco, CA 94112);
Manager - Blake He (blakehe@gmail.com)
Property Owner: Timoleon and Corinne Zaracotas
Neighborhood Groups

Garland Public & Community Relations
535 Green Street
San Francisco, CA 94133
marshagarland@att.net 415/531/2911
stefanocassolato@att.net 415/875/0818

June 24, 2014

Mr. Scott Sanchez, Zoning Administrator
San Francisco Planning Department
1650 Mission Street, 4th Floor
San Francisco, CA 94103

ID # 12004 (SW)
D. WASHINGTON
CR # 5003 \$ 625.-

Re: 1963 Ocean Avenue, Happy Vape 6915/020

Dear Mr. Sanchez:

This letter is to request a Letter of Determination for an innovative concept called Happy Vape at 1963 Ocean Avenue. The business plan for Happy Vape includes selling e-cigarettes, e-cigarette liquids with and without nicotine, packaged snacks, soft drinks and other peripherals associated with e-cigarettes as well as steam stone hookahs. Happy Vape would like to dedicate some of its leased area to lounge space in which customers can vape and socialize.

Happy Vape will occupy a 2,000 square foot commercial space with 1,000 feet on ground level and 1,000 feet below ground. There is also an adjacent outdoor area. Drawings and an aerial photograph are enclosed.

According to the Internet, "Hookah Steam Stones are a new concept in the hookah world. Instead of smoking Steam Stones allow you to inhale vapor. Hookah Steam Stones are available in a variety of flavors. Steam stones are know to produce huge clouds and are a great way to smoke without the nicotine".

On May 5 and May 21, 2014 the project sponsor held pre-application meetings at 1963 Ocean Avenue for the community. In total eight people attended. Attached are copies of their questions and our responses.

The project sponsor has been in touch with Marcelle Boudreaux of the Planning Department and was scheduled for a conditional use permit hearing on July 24. That date has now been continued.

We understand that there is pending legislation regarding e-cigarettes but this is a new concept that has helped many smokers reduce their nicotine intake, if not quit smoking altogether, improve their health risks, and live in a cleaner environment.

Additionally Happy Vape will fill a vacancy on Ocean Avenue, create two or three new jobs, and, with the on site vaping component, will allow patrons the opportunity to taste and sample various flavors in order to make an informed product purchase. The new social activity of sharing a common experience will bring people together and create an opportunity for people to connect and interact.

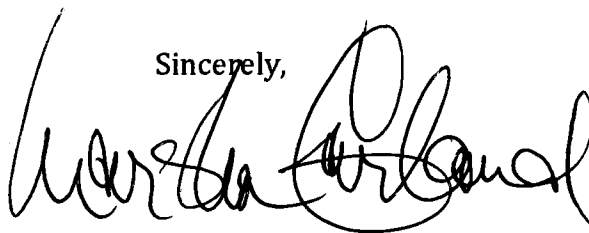
We need to know if steam stone hookahs are legal for indoor use and outdoor use, are packaged snacks and soft drinks allowed on the premises, is vaping allowed inside the premises, and is vaping allowed in the outdoor patio area?

As far as the question of tobacco goes (and tobacco is not in all of the products) would Happy Vape be deemed akin to cigar bars? The project sponsor has been in touch with the Department of Public Health but no one seems to be able to fit them into a suitable category, which is why they are wondering about the comparison to cigar bars.

It is, therefore, the reason they have decided to request a Letter of Determination. Please advise exactly what it is they do need in order for this new business concept to be in compliance with the city's zoning laws.

A check for \$625 made payable to SF Planning is enclosed. We look forward to your response.

Sincerely,

A handwritten signature in black ink, appearing to read "Marsha Garland". The signature is fluid and cursive, with a large initial "M" and "G".

Marsha Garland

1963 Ocean Avenue, San Francisco, CA
1963 Ocean Ave
Explore this area

+Blake Share





Smoking Prohibition Enforcement Alert

Attention All Restaurants, Bars, Night Clubs, Lounges, and Hookah Business Operators

On September 27, 1996, the State of California passed a law that prohibited smoking in all enclosed places of employment including restaurants and bars (California Labor Code § 6404.5).

The City and County of San Francisco also passed a similar law, Article 19F San Francisco Health Code (SFHC 19F), in 1994 and amended this law on March 25, 2010 to prohibit smoking of any tobacco products, plants, or other weeds in all restaurants, bars, lounges, and outdoor dining areas even when food is no longer served in the dining areas (SFHC 19F §§ 1009.21(s); 1009.22(a)).

Except as follows:

- For Businesses that operate only as a bar or tavern at all times and have a side or rear outdoor patio, smoking is allowed in the side or rear outdoor patio portion of the bar except within 10 feet of doors, windows, or vents of the bar. (SFHC 19F §§ 1009.21(m), 1009.22(a) (14)).

Outdoor dining areas of restaurants, including sidewalk dining tables, are not considered outdoor patios even if food is no longer being served or if a bar is located outside. Smoking is not permitted in all outdoor dining areas (SFHC 19F § 1009.21(m)).

- For Bar or Tavern Operators that have received approved DPH exemptions (SFHC 19F §§ 1009.21(a) (14); 1009.23(c) or (d)). Exemption applications for DPH approval expired July 31, 2010. DPH does not have authority to issue exemption approvals for applications submitted after July 31, 2010. For Businesses without an exemption approval from DPH, smoking is not allowed in any enclosed areas of the business.

There are no other exemptions in SFHC 19F.

If your business is affected as described above, you are to immediately cease and desist all smoking activities that violate SFHC 19F. Failure to comply may result in enforcement action against the Business Operator and/or Property Owner including, but not limited to, penalties, cost recovery, suspension or revocation of Environmental Health permit(s), or referral to City Attorney's Office.

For more information about SFHC 19F, please contact Senior Inspector Janine Young, Secondhand Smoke Ordinance Compliance and Enforcement Program Coordinator, at (415) 252-3903.

For complaints about businesses violating SFHC 19F, please call 311 (within San Francisco) or (415) 701-2311 (outside San Francisco).



Oct. 20, 2014

To: Marcelle Boudreau,


I am writing in regard to the proposed Tobacco Paraphernalia Establishment on 1963 Ocean Avenue at the cross streets of Ashton and Victoria. This business intends to include e-cigarette sales, a hookah lounge - and even an area for cigarette sampling in the rear yard. Everyone in our neighborhood is furious about this. What can they be thinking! Surely you won't approve this.

Nationally, for the sake of everyone's health, we, as a country, are attempting to stamp out smoking. Now this group is trying to encourage it - especially among young people, for this location is almost adjacent to a church-run school and is only a few blocks from Aptos Junior High School. It is indefensible!

There are already four other locations on Ocean Avenue that sell e-cigarettes - and homes can be harmful - to anyone, even passersby.

Please realize that this Establishment is an affront to the neighborhood - and our young people, as this atmosphere can lead to substance abuse and addiction. Surely San Francisco - and City Planners should work to protect its citizens.

Sincerely,





October 28, 2014

Marcelle Boudreaux, AICP
Planner, Southwest Quadrant
San Francisco Planning Department
1650 Mission Street, Suite 400
San Francisco, CA 94103

By E-mail Only: marcelle.boudreaux@sfgov.org

RE: 1963 Ocean Avenue; 2014.0206C - Hearing Date: November 6, 2014

Dear Ms. Boudreaux:

On behalf of the Ingleside Terraces Homes Association (“ITHA”), I am writing to express concern about “Happy Vape,” the proposed business at 1963 Ocean Avenue, San Francisco, in particular the business owners’ plan to use the rear yard for daily sampling of its retail products. The store hours are proposed for 11 a.m. to 12 a.m., with the outdoor activity conducted voluntarily limited from 11 a.m. to 8 p.m. There are serious noise and environmental issues for our neighborhood in this proposal.

As described in the Conditional Use application, “Happy Vape” is an electronic vaporizer retailer and steam stone hookah lounge. In the retail store, customers can purchase electronic vaporizers and e-liquids, both nicotine and non-nicotine. The business owners want to use the site’s rear yard as the e-liquid sampling area where customers sample products before purchase. The use of the rear yard is requested because indoor “vaping,” the recently-regulated equivalent of indoor smoking, is prohibited by the San Francisco Health Code.

A primary purpose of ITHA, as a non-profit homeowner’s association, is to promote the “collective and individual property and civic interests and rights” of the homeowners and residents of Ingleside Terraces. The Happy Vape proposal to use the store’s rear yard for vaping will create noise daily from mid-day to evening. And e-cigarettes, whether nicotine-filled or not, pose still-unknown potential health risks to those who breathe the vapors. This business proposal jeopardizes our residents’ property and health rights, particularly those residents who live at 70 Urbano Drive, 90 Urbano Drive, and 816 Victoria Street, homes adjacent to or abutting the rear yard of 1963 Ocean Avenue.

The “Happy Vape” proposal does not comply with the Planning Code criteria for Conditional Use approval as set forth in Planning Code section 303. Specifically, the proposed use of the rear yard for vaping (1) is not necessary or desirable for or compatible with the neighborhood, and (2) is detrimental to the health, safety, and general welfare of persons residing in the vicinity of the site, particularly the residents of Ingleside Terraces whose

residences about the proposed site. For this reason, on October 16, 2014, the Board of Directors of ITHA passed the following resolution:

“ITHA opposes the outdoor use, during any business hours, of electronic cigarettes or apparatus unless the business owners and operators of Happy Vape are able to contain or filter the vapors and noise so as to control their effect on adjacent property owners. Outdoor hours should be limited to 8 p.m. as a conditional use condition.”

1. The Project As Proposed Is Not Necessary or Desirable or Compatible With the Neighborhood.

If the requested Conditional Use is approved, there will be sampling and vaping of e-cigarettes in the rear yard of the site every evening until at least 8 p.m. This means 3 - 9 people (a number provided by the Happy Vape business manager at our meeting), at any given time, socializing, talking, laughing, and trying the various products that Happy Vape intends to sell. The noise of so many people in the rear yard each afternoon and evening is the equivalent of a daily party interfering with the peace and quiet of the homes along Victoria Street and Urbano Drive adjacent to and near the rear yard of 1963 Ocean Avenue. The re-purposing of the rear yard by Happy Vape, to transact commerce outside the store because the San Francisco Health Code prohibits such transaction inside the store, should not transcend the right of the Ingleside Terraces neighbors to the peaceful and quiet enjoyment of their homes and yards.

2. The Proposed Use Is Detrimental to the Health and Welfare of the Neighbors In Ingleside Terraces.

Article 19N of the San Francisco Health Code prohibits the use of electronic cigarettes where smoking is otherwise prohibited and the sale of electronic cigarettes where the sale of tobacco products is otherwise prohibited. As support for the Health Code restrictions on the sale and use of electronic cigarettes, the San Francisco Board of Supervisors, when legislating Article 19N, included the following in their Findings and Statement of Purpose:

“(c) The FDA’s center for Drug Evaluation and Research, Division of Pharmaceutical Analysis (DPA) analyzed the cartridges from . . . electronic cigarettes for nicotine and for the presence of other tobacco constituents. . . The DPA’s analysis of the electronic cigarette samples showed:

(1) The products contained detectable levels of known carcinogens and toxic chemicals to which users could be exposed.

(2) Quality control processes used to manufacture these products are inconsistent or non-existent.

* * * * *

(f) Health authorities have also expressed concerns that the vapors released into the air through the use of an electronic cigarette present a danger to others who breathe them in.” (emphasis added)

The San Francisco Health Commission, in its Resolution 7-11 passed June 21, 2011, declared “[t]here is no evidence that the vapors released into the air through the use of an electronic cigarette do not present a danger to others who breathe them.” Recent scientific studies include findings of a total of 22 elements in vapors produced by electronic smoking devices, and three of these elements (lead, nickel, and chromium) appear on the FDA’s “Harmful and Potentially Harmful Chemicals List.”¹ No one should be exposed to the potentially harmful chemicals that the e-cigarette emits without his or her consent. If the rear yard at 1963 Ocean Avenue is used for vaping and sampling, our residents are involuntary exposed to this environmental risk. Cities throughout California, including our own, recognize this health risk in larger venues - Concord, California has declared a 17-block downtown business district to be 100% smoke-free (including use of e-cigarettes), the City of Los Angeles prohibits electronic smoking devices at the beaches, and electronic smoking devices are prohibited AT&T Park. A San Francisco resident should also be free of these risks in his/her own backyard. The harm done by e-cigarettes may be significant, both to direct users and to those exposed to the smoke and vapors secondhand. The residents of Ingleside Terraces should not be put at risk to potential or actual health risks of the developing, and mostly unregulated, e-cigarette market.

ITHA requests that its residents not be exposed to this potential, or actual health hazard at Happy Vape, 1963 Ocean Avenue, and that the Planning Commission withhold conditional use approval of the proposed rear yard vapor area unless noise is minimal and regulated filter and air quality controls are installed.

Sincerely,

INGLESIDE TERRACES HOMES ASSOCIATION



Mark V. Scardina, President

copy: Project Applicant, blakehe@gmail.com
Ocean Avenue Association, info.oacbd@gmail.com

¹Rachel Grana, Neal Benowitz, Stanton A. Glantz. “E-Cigarettes: A Scientific Review.” Circulation. 2014; 129: 1972-1986; <http://circ.ahajournals.org/content/129/19/1972.full>



Show ▾

From: [Robert Karis](#)
To: [Boudreaux, Marcelle \(CPC\)](#)
Cc: [Yee, Norman \(BOS\)](#); [Secretary, Commissions \(CPC\)](#)
Subject: 1963 Ocean Avenue, Case No.: 2014.0206C, letter of opposition
Date: Thursday, October 23, 2014 12:18:55 PM
Attachments: [FDA-Deeming-Comments-San Francisco DPH.pdf](#)

Dear Ms. Boudreaux:

The attached document demonstrates why the San Francisco Planning Commission should deny the Conditional Use application for a vape shop at 1963 Ocean Avenue.

The document by Barbara A. Garcia, MPA, Director of Health, San Francisco Department of Public Health, is dated August 5, 2014. This letter was written on behalf of the SFDPH in response to regulations proposed by the United States Food and Drug Administration. Please include the document "FDA-Deeming-Comments-San Francisco-DPH.pdf" and my email in the case report for project 2014.0206C. Comments in the document pertaining to e-cigarettes, which I have highlighted, include the following:

Section 3, p.2:

FDA and other independent scientists have found numerous potentially dangerous chemicals and carcinogens as well as varying levels of nicotine that are inconsistent with the amount indicated on the labels of e-cigarette solutions....there is a lack of credible information on the full range of chemicals being produced by the large number of different e-cigarettes currently on the market.

Section 3, p.3:

CDC reported that e-cigarette use more than doubled among U.S. middle and high school students between 2011-2012. There is evidence that e-cigarettes help youth to initiate smoking habits – only 20% of middle school e-cigarette users reported never having smoked conventional cigarettes. Youth are also impressionable and can succumb to marketing ploys such as the numerous fruity and candy flavored e-cigarettes and to youth-oriented company advertising.

We recognized that these products pose a threat to the public health and are clearly serving as starter products for young people in our community....Surveys of local youth and adults show that the industry has created a great deal of confusion about these products and the general public repeats back the unsubstantiated claims made by e-cigarette marketers- eerily similar to claims made by the tobacco industry a generation earlier.

Current e-cigarette advertisements target youth with marketing strategies such as celebrity endorsements, and messaging that promote freedom, rebelliousness, and glamour with e-cigarette use.

Section 5, p.3:

Currently, e-cigarette liquid refill containers are not required to be sold in child-resistant packaging and that may encourage children to ingest the product's

poisonous content. Some e-cigarette refill product packaging features cartoons, colorful labeling, or illustrates edible ingredients representing particular flavors, such as cherry, chocolate, or bubble gum. The contents themselves can have the aroma of the edible ingredient pictured on the label. Any of these factors can prompt a child to investigate and the contents can be extremely dangerous, if not lethal.

CDC analyzed calls to U.S. Poison Centers from 2010 to 2014 related to e-cigarette exposures. The results showed that e-cigarettes accounted for an increasing proportion of the calls, 0.3% in September 2010 to 41.7% in February 2014. Half of the calls made regarding exposure were for incidents involving children ages 0-5. The prevalence of poisonings and the potential danger to children promoted the American Association of Poison Control Centers and its member centers to issue a statement warning e-cigarette users to keep the devices and liquids away from children. One teaspoon (5 ml) of a 1.8% nicotine solution can be lethal for a person weighing 200 pounds. Most nicotine solutions range between 1.8% and 2.4%, and the refill bottles contain 10-30 ml of solution.

It is obvious from reading this document why a vape store, whose purpose is to increase the use of e-cigarettes, vaporizing devices, and e-liquids, and to addict our relatives and neighbors to nicotine and to expose them and people near them to the harmful chemicals contained in the e-cigarette vapors (actually fumes), is not desirable in our neighborhood. The letter from the SFDPH focuses on youth, but college students and older residents of our neighborhood are also adversely affected by the advertising, availability, and unhealthy effects of these products. E-cigarettes result in previous non-smokers using e-cigarettes and possibly cigarettes.

E-cigarettes are reported to be about as effective as nicotine patches for smoking cessation. However, e-cigarettes contain a coil heated to 600 degrees Fahrenheit (which, of course, is not true of nicotine gum or patches), resulting in the emission of harmful fumes that have been found to contain formaldehyde, heavy metal nanoparticles, and other breakdown products which are deposited in the lungs. Vape shops sell devices with larger batteries than e-cigarettes. This allows higher voltages than found in e-cigarettes, which results in higher temperatures, more nicotine delivered to the user, more production of harmful breakdown products from the propylene glycol solvent, and very likely more metallic nanoparticles from the coil.

Due to insightful legislation passed by the San Francisco Board of Supervisors in recent years, with input from the DPH, tobacco paraphernalia establishments, including e-cigarettes and e-liquids, require Conditional Use Authorization. This allows neighborhoods in San Francisco to limit the number of these stores. Ocean Avenue has four stores nearby that sell e-cigarettes; the three liquor stores and the 7-Eleven. There are two vape stores within a 1.5 mile radius of 1963 Ocean Ave.

I ask that the Planning Commission agree that the health of our neighbors is infinitely more important than the interests of a new business, and vote to deny this Conditional Use Application. A vape shop on Ocean Avenue is not necessary or desirable.

Yours truly,
Robert Karis
Ingleside Terraces

Addendum:

The four stores on Ocean Avenue that sell e-cigarettes are:

No Limit Liquor & Food Mart, 1015 Ocean Ave.

A & N Liquors, 1521 Ocean Ave.

Homrun Liquors, 1551 Ocean Ave.

7-Eleven, 2000 Ocean Ave.

The two vape shops within a 1.5 mile radius of 1963 Ocean Ave. are:

Juicebox Vapor, 907 Taraval St. at 19th Ave.

Dream Cloud Vapors, 4971 Mission St., near Geneva Ave.



City and County of San Francisco
Edwin M. Lee
Mayor

San Francisco Department of Public Health

Barbara A. Garcia, MPA
Director of Health

August 5, 2014

The Honorable Margaret Hamburg, Commissioner
United States Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act
Docket No. FDA-2014-N-0189, RIN 0970-AG38

Dear Commissioner Hamburg,

On behalf of the San Francisco Department of Public Health I am writing to provide comments on the proposed rule "Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act." The City and County of San Francisco has long recognized the need to tackle tobacco addiction head-on, leading the country in some of the earliest and strongest regulations of the use, sale, and marketing of tobacco products in our community. Even with our investment in our proven community-engagement policy development model and ongoing innovative educational and quitting programs, we continue to see the substantial impact of the tobacco industry negatively affecting the health of San Franciscans.

San Francisco Department of Public Health applauds the Food and Drug Administration (FDA) for proposing this rule to identify additional products to be deemed as tobacco and subject to the requirements of the Family Smoking Prevention and Tobacco Control Act. Many cities and counties across the country such as San Francisco have passed our own legislation regulating these products in order to protect their communities. Federal regulation is absolutely needed to unite efforts already begun at the local level, provide a uniform set of standards and take action where local jurisdictions are prohibited from doing so. We can only take the regulation so far at the local level, and there are considerable gaps in our system that only FDA action is empowered to resolve.

In response to the proposed rule, San Francisco Department of Public Health offers the following comments and recommendations.

1. Cigar regulation option

San Francisco Department of Public Health recommends use of Option 1 regarding cigar deeming, to include all types of cigars. Our agency does not recommend Option 2, which excludes premium cigars from the proposed rule, defeating the intention of regulating various cigar products equally under the law. This is important, as producers have skirted the intention of various laws by claiming their youth-marketed products are technically cigars. We need a consistent application of the law around cigars. Both premium and non-premium cigars contain cancer causing chemicals that increase the smoker and non-smoker risk for lung disease, chronic bronchitis, and oral cavity, larynx, esophagus, pancreas, bladder, and lung cancers.^{1,2} Both types of cigars

negatively affect the public's health. The differences between these cigar types speak to the ingredients and price, but not to their effects on health. Thus, if the FDA's intent for this proposed rule is to take action to address the public health risk associated with the use of tobacco products, premium cigars should not receive an exemption. Exempting premium cigars may set back the FDA's work to reduce tobacco use and disease risk in the United States.

Cigar use is popular among youth. The Centers for Disease Control and Prevention (CDC) reported that cigarette and cigar use in high school students was nearly identical in 2012. This similarity is also seen in middle schools students who smoked cigarettes and cigars.³ When youth are faced with premium cigars and cigarettes of the same price, premium cigars may be the product of choice because premium cigars are not subject to accessibility restrictions as promulgated for cigarettes. For example, cigars can be sold in self-service displays and sold individually.

2. Flavored products

San Francisco Department of Public Health urges the FDA to apply the same flavor restrictions promulgated by the Tobacco Control Act on cigarettes to newly-deemed tobacco products. As flavors such as cherry, vanilla, and apple contribute to the increasing popularity of e-cigarettes, hookah, and cigars among youth, regulation is critical for the same reasons the FDA restricted flavor options for cigarettes. The FDA's *Parental Advisory on Flavored Tobacco Products* states that flavored tobacco products:⁴

- Appeal to kids.
- Disguise the bad taste of tobacco, easing adoption by youth.
- Are just as addictive as regular tobacco products.
- Have the same harmful health effects as regular tobacco products.

Local and state health departments have already taken the initiative to regulate the sale of non-regulated flavored tobacco products in their jurisdictions. Maine banned the sale and distribution of flavored cigarettes and cigars in the state in 2009.⁵ In 2011, New York City banned the sale of flavored tobacco products.⁶ Providence (RI) banned sale of flavored tobacco products and redemption of tobacco industry coupons and discounts in 2013.⁷ In 2014, Chicago banned the sale of all flavored tobacco products, including e-cigarettes (regulated as tobacco products), within a 500-foot radius of any elementary, middle, or secondary school.⁸ Our community continues to examine options for addressing how the harsh flavors of cigarettes can be masked by candy and sweet flavorings. Prior generations became addicted to cigarettes in large numbers despite the harsh taste and difficulty initiating the smoking habit. With cherry and cotton candy and vanilla starter products now, the current generation of youth face fewer barriers to initiation of nicotine addiction and are more targeted by the industry than ever before.

3. Regulation of the new noncombustible products

San Francisco Department of Public Health urges FDA to regulate the newly-deemed tobacco products, including e-cigarettes, dissolvables, hookah, and cigars, in the same manner as existing tobacco products. Federal regulation offers an opportunity to more fully assess the public health risks of these products, which have grown in popularity since the passage of the Tobacco Control Act. There are currently no federal consumer protections in place to ensure that e-cigarettes are properly labeled and tested. FDA and other independent scientists have found numerous potentially dangerous chemicals and carcinogens as well as varying levels of nicotine that are inconsistent with the amount indicated on the labels of e-cigarette solutions. For example, a recent study of e-cigarette refill fluids found that the majority (65%) of nicotine fluids tested deviated by more than ten percent from the nicotine concentrations on the label.⁹ Furthermore, because e-cigarettes are unregulated, there is a lack of credible information on the full range of chemicals being produced by the large number of different e-cigarettes currently on the market. The same flavoring, marketing, and self-service access rules should apply to newly-deemed products because they also pose risk to the public and can spur initiation or joint use of multiple tobacco products.

CDC reported that e-cigarette use more than doubled among U.S. middle and high school students between 2011-2012. There is evidence that e-cigarettes help youth to initiate smoking habits – only 20% of middle school e-cigarette users reported never having smoked conventional cigarettes.¹⁰ Youth are also impressionable and can succumb to marketing ploys such as the numerous fruity and candy flavored e-cigarettes and to youth-oriented company advertising.

It is these startling facts about youth use of e-cigarettes and alternative products that caused San Francisco to join Los Angeles, Chicago, Philadelphia, and New York early this year in regulating e-cigarettes locally. We recognized that these products pose a threat to the public health and are clearly serving as starter products for young people in our community. Without regulation of advertising, content of the product, claims made by the industry, and flavors available, the proliferation of this product will likely continue exponentially. Surveys of local youth and adults show that the industry has created a great deal of confusion about these products and the general public repeats back the unsubstantiated claims made by e-cigarette marketers- eerily similar to claims made by the tobacco industry a generation earlier.

San Francisco Department of Public Health calls on the FDA to restrict the flavor offerings as in cigarettes for the same reasons that the agency restricted cigarette flavor offerings. Current e-cigarette advertisements target youth with marketing strategies such as celebrity endorsements, and messaging that promote freedom, rebelliousness, and glamour with e-cigarette use. The FDA should also restrict new product advertising in the same way that cigarette and smokeless tobacco advertising is restricted.

4. New product warnings

Product warning labels are incredibly useful tools in FDA's effort to protect public health. However, the proposed warning labels for newly covered tobacco products can be strengthened to be more effective.

Since the first warning labels appeared on cigarette packages in 1965, warning labels have been an important source of information for tobacco users.¹¹ While there is evidence that warning labels can become stale,¹² and the need for large graphic warning labels is clear,^{13,14,15} the newly covered products will be marketed with minimal warning. This may contribute to confusion about the health effects of the newly covered products. The proposed textual warnings for cigars are fairly strong, but the single warning for the remaining products is weak and does not convey the potential extent of health risk associated with use of the products. The FDA should require large graphic warnings for all tobacco products, similar to those required for combustible cigarettes. There is significant evidence of the specific health harms of the new products and those caused by nicotine that support stronger, more specific warnings in the "2014 U.S. Surgeon General's Report: The Health Consequences of Smoking—50 Years of Progress." The City of San Francisco cannot introduce a mandate for packaging with striking graphic images that tells consumers the truth about the health impacts of tobacco (similar to those required in nearly every country in the world), but we very much support the move by FDA to require those warnings.

5. Additional opportunities

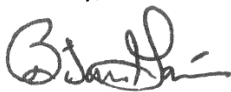
The proposed rule presents an opportunity to require child-resistant packaging for e-cigarette liquids to prevent child poisonings. Currently, e-cigarette liquid refill containers are not required to be sold in child-resistant packaging and that may encourage children to ingest the product's poisonous content.¹⁶ Some e-cigarette refill product packaging features cartoons, colorful labeling, or illustrates edible ingredients representing particular flavors, such as cherry, chocolate, or bubble gum. The contents themselves can have the aroma of the edible ingredient pictured on the label.¹⁷ Any of these factors can prompt a child to investigate and the contents can be extremely dangerous, if not lethal.

CDC analyzed calls to U.S. Poison Centers from 2010 to 2014 related to e-cigarette exposures. The results showed that e-cigarettes accounted for an increasing proportion of the calls, 0.3% in September 2010 to 41.7% in February 2014.¹⁸ Half of the calls made regarding exposure were for incidents involving children ages 0-5.¹⁸ The prevalence of poisonings and the potential danger to children promoted the American Association of Poison Control Centers and its member centers to issue a statement warning e-cigarette users to keep the devices and

liquids away from children.¹⁹ One teaspoon (5 ml) of a 1.8% nicotine solution can be lethal for a person weighing 200 pounds.¹⁶ Most nicotine solutions range between 1.8% and 2.4%, and the refill bottles contain 10-30 ml of solution.²⁰ Due to the dramatic increase in calls to poison control centers, some states have taken precautions through new regulations. Minnesota and Vermont created statutes that require child protective packaging on all liquid nicotine refill bottles, and some retailers have voluntarily begun selling their refills with child-resistant caps.²⁰ While those who oppose such requirements note there have been no confirmed poisoning deaths in the United States due to the ingestion of liquid nicotine, the FDA must not wait for tragic consequences before acting.

San Francisco Department of Public Health is pleased to support the deeming of additional products as tobacco as proposed in the rule and urges FDA to do the following: include premium cigars in cigar regulations; apply the same requirements of the Family Smoking Prevention and Tobacco Control Act for combustible cigarettes to all of the newly deemed products regarding flavors, marketing, and self-service access; strengthen the content and requirements for the warning labels on newly deemed products; and create a requirement for child-resistant packaging for e-cigarette liquids. Thank you for your attention to these recommendations.

Sincerely,



Barbara A. Garcia, MPA
Director of Health
San Francisco Department of Public Health

¹ National Cancer Institute. (2010). Fact sheet: Cigar smoking and cancer. Retrieved Jul. 16, 2014, from <http://www.cancer.gov/cancertopics/factsheet/Tobacco/cigars>.

² American Cancer Society. (2014). Cigar smoking: Tobacco and cancer. Retrieved Jul. 16, 2014, from <http://www.cancer.org/cancer/cancercauses/tobaccocancer/cigarsmoking/cigar-smoking-cancer-and-health>.

³ Centers for Disease Control and Prevention. Youth and tobacco use webpage. Retrieved Jul. 22, 2014, from http://www.cdc.gov/tobacco/data_statistics/fact_sheets/youth_data/tobacco_use/index.htm.

⁴ U.S. Food and Drug Administration. (2013). FDA parental advisory on flavored tobacco products - what you need to know. Retrieved Jul. 22, 2014, from <http://www.fda.gov/TobaccoProducts/ProtectingKidsfromTobacco/FlavoredTobacco/ucm183196.htm>.

⁵ State of Maine. (2007, September 25). News: Governor celebrates ban on flavored cigarettes. Retrieved Jul. 16, 2014, from <http://www.maine.gov/tools/whatsnew/index.php?topic=Portal+News&id=42524&v=article-2006>.

⁶ New York City Department of Health and Mental Hygiene. Smoking legislation webpage. Retrieved Jul. 22, 2014, from <http://www.nyc.gov/html/doh/html/environmental/smoke-law.shtml>.

⁷ City of Providence, Rhode Island. (2013). Providence tobacco laws go into effect January 3. Retrieved Jul. 16, 2014, from <http://www.providenceri.com/healthy-communities/providence-tobacco-laws-go-into-effect-january-3>.

⁸ City of Chicago. Tobacco regulations webpage. Retrieved Jul. 16, 2014, from http://www.cityofchicago.org/city/en/depts/bacp/supp_info/tobaccoregulations.html.

⁹ Davis, B., Dang, M., Kim, J., Talbot, P. (2014, May 26). Nicotine concentrations in electronic cigarette refill and do-it-yourself fluids. *Nicotine & Tobacco Research* (published online). doi: 10.1093/ntr/ntu080.

¹⁰ Centers for Disease Control and Prevention. (2013, September 6). Notes from the field: Electronic cigarette use among middle and high school students – United States, 2011-2012. *MMWR*, 62(35), 729-730. Retrieved on Jul. 7, 2014, from <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6235a6.htm>.

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- ¹¹ U.S. Department of Health and Human Services. (2000). *Reducing tobacco use: A report of the Surgeon General*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health.
- ¹² Institute of Medicine (U.S.). Committee on Reducing Tobacco Use: Strategies, Barriers, and Consequences. (2007). *Ending the tobacco problem: A blueprint for the nation*. R. J. Bonnie, K. Stratton, R. B. Wallace (Eds.) Washington, DC: National Academies Press.
- ¹³ Azagba, S., & Sharaf M.F. (2013). The effect of graphic cigarette warning labels on smoking behavior: Evidence from the Canadian experience. *Nicotine & Tobacco Research*, *15*(3), 708-17. doi: 10.1093/ntr/nts194.
- ¹⁴ Cantrell, J., Vallone, D. F., Thrasher, J. F., Nagler, R. H., Feirman, S. P., Muenz, L. R., et al. (2013). Impact of tobacco-related health warning labels across socioeconomic, race and ethnic groups: Results from a randomized web-based experiment. *PLoS One*, *8*(1), e52206. doi: 10.1371/journal.pone.0052206.
- ¹⁵ Strasser, A. A., Tang, K. Z., Romer, D., Jepsen, C., & Cappella, J. N. (2012). Graphic warning labels in cigarette advertisements: Recall and viewing patterns. *American Journal of Preventive Medicine*, *43*(1), 41-7. doi: 10.106/j.ameprev.2012.02.026.
- ¹⁶ Bassett, R. A., Osterhoudt, K., & Brabazon, T. (2014). Nicotine poisoning in an infant. *New England Journal of Medicine*, *370*(23), 2249–50. doi: 10.1056/NEJMc1403843.
- ¹⁷ Leys, T. (2014, March 25). Iowa Poison Control Center: E-cigarette liquid refill warning. Retrieved Jul. 7, 2014, from <http://www.iowapoinson.org/news-and-recalls/e-cigarette-liquid-refill-warning/>.
- ¹⁸ Chatham-Stephens, K., Law, R., Taylor, E., Melstrom, P., Bunnell, R., Wang, B., et al. (2014, April 4). Notes from the field: Calls to Poison Centers for exposures to electronic cigarettes. *MMWR*, *63*(13), 292–293. Retrieved on Jul. 7, 2014, from <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6313a4.htm>.
- ¹⁹ American Association of Poison Control Centers. (2014, March 25). News Release: AAPCC and Poison Centers issue warning about electronic cigarette devices and liquid nicotine. Retrieved Jul. 7, 2014, from https://aapcc.s3.amazonaws.com/pdfs/releases/E-cigarette_Release.pdf.
- ²⁰ Richtel, R. (2014, March 23). Selling a poison by the barrel: Liquid nicotine for e-cigarettes. *The New York Times*. Retrieved Jul. 4, 2014, from <http://www.nytimes.com/2014/03/24/business/selling-a-poison-by-the-barrel-liquid-nicotine-for-e-cigarettes.html?module=Search&mabReward=relbias%3Aw>.

From: [a infusino](#)
To: [Boudreaux, Marcelle \(CPC\)](#); [Yee, Norman \(BOS\)](#); [Secretary, Commissions \(CPC\)](#)
Subject: Neighbor OPPOSING 1963 Ocean Avenue Vape Shop
Date: Tuesday, October 28, 2014 9:56:17 PM

Dear Planning Commission, Mr. Norman Yee, and Ms. Marcelle Boudreaux:

I am writing to strongly oppose the proposed Conditional Use Authorization for 'Happy Vape' at 1963 Ocean Avenue. As the neighbor who lives directly behind this proposed business, I do not support the retail Tobacco Paraphernalia Establishment, the steam stone hookah lounge at the basement level, or the outdoor activity area for e-cigarette sampling. Please see the following reasons why this business is not a good fit for our neighborhood:

1. There are at least 4 businesses just on Ocean Avenue that already sell e-cigarettes. By walking 10 minutes or less, I can purchase a variety of different e-cigarettes at each of these stores.
2. E-cigarettes are unregulated and under researched and the full risks on human health have yet to be determined.
 1. As the neighbor that lives directly behind this proposed "outdoor activity area for cigarette sampling," my family and I will be adversely affected by the chemicals in these e-cigarettes.
 2. The proposed outdoor activity space in the backyard at 1963 Ocean Avenue, is approximately 20 feet from my property line (measurements taken from the back wall of proposed business to my property line). Depending on where the owners of the business decide to place the "tables, awning or tent," customers will be smoking even closer to my property line. The proposed "Outdoor activity area" is too close to surrounding residents. (Please see attached picture of the back of 1963 Ocean Avenue where the smoking section will be and my property line)
 3. Moreover, as an asthma sufferer and as someone who will be starting a family soon, having people smoke approximately 20 feet from my property will in turn make my backyard an unusable space unless I choose to subject my future child or myself to chemicals that will irritate, harm, or otherwise affect our bodies.
 4. Additionally, there are many children living in the houses surrounding the backyard of this business. Each of these children will be subject to the unregulated and under-researched chemicals emitted from these e-cigarettes.
3. This business will bring nuisance to the neighborhood.
 1. The outdoor space and hookah lounge will add outdoor lights and additional noise from people talking and smoking in the backyard. The hookah lounge is marketed to be a place where people can hang out

and socialize. Given that this part of the business will be open until 12am, this will be an additional noise disturbance to the surrounding neighbors. Overall, it will ruin the peaceful, quiet neighborhood we currently live in.

2. Ocean avenue is a neighborhood where outdoor backyard retail spaces are uncommon. This is because the surrounding neighborhoods are quiet, peaceful, family friendly neighborhoods.
3. This proposed business will decrease the home values of the surrounding neighbors. Who would want to pay the market neighborhood rate and move into a home which is adjacent to an outdoor smoking patio?

4. This business is not favorable for the surrounding family communities and undesirable considering the 8 schools that are less than 1 mile from the proposed business.

1. E-cigarette have a high appeal to youth due to their high tech design and availability in child friendly flavors like cotton candy, bubble gum, chocolate chip cookie dough, and cookie and cream milkshake.
 1. According to the U.S. Centers for Disease Control and Prevention (CDC), 250,000 youths who had never before smoked, tried e-cigs in 2013 — a threefold increase since 2011.
 2. Within a 1 mile radius of the proposed business, there are 8 schools, including 4 high schools, and 3 schools with middle school aged children.
2. According to recent census demographics for Ingleside terrace 40.6% of households in this neighborhood have children. The same census demographics show that in Mount Davison Manor, the neighborhood directly across from this business on Ocean Avenue, 69.7% of households have children. Moreover, a few blocks down from Mount Davison Manor, in Westwood park the census data states that 71.3% of their households have children. How is this a desirable business for this neighborhood?
3. All in all, considering the percentage of households with children in the nearby communities adjacent to Ocean Avenue, in addition to the other businesses that already sell e-cigarettes, this additional business is unneeded and unwelcome.

As a strong supporter to revitalize Ocean Avenue, I wholeheartedly see the changes that are possible. These changes however, will not happen if we continue to promote businesses that do not add to the neighborhood. In the past 2 years that I have lived here, I have seen Champa Gardens, Whole Foods, the new hardware store, The Dailey Method, Yoga Flow, and a few other businesses open their doors. Adding more businesses that will be patronized and supported by people in the surrounding communities is what will make Ocean Avenue a nice place to walk, shop, and stay. Adding another place to buy e-cigarettes is not going to attract other desirable businesses or shoppers.

Please include my e-mail and attached picture in the Planning Dept. packet for review by the Planing Commission.

Respectfully submitted,

Angela Button
70 Urbano Drive
San Francisco, CA 94127

From: [Michelle Schulze](#)
To: [Boudreaux, Marcelle \(CPC\)](#); [Yee, Norman \(BOS\)](#); [Secretary, Commissions \(CPC\)](#)
Subject: Neighboring Residents OPPOSED to 1963 Ocean Ave Happy Vape
Date: Tuesday, October 28, 2014 1:34:56 PM

Dear Planning Commission, Mr. Yee and Ms. Marcelle Boudreaux:

We are adjacent neighbors to the project at 1963 Ocean Ave. (Happy Vape). We are also members of the ITHA residential group. We **strongly OPPOSE** the Conditional Use Authorization to sell tobacco paraphernalia, e-cigarette sales. There are already two other 'vape' shops within a 1.5 mile distance of the proposed site. Tobacco and tobacco products can be found at various stores along the Ocean Avenue Corridor. There is no need for this business in this location. We are also strongly opposed to a Steam Stone Hookah Lounge at basement level and especially **OPPOSED to ANY OUTDOOR ACTIVITY** that samples or promotes e-cigarettes or Hookah or for that matter ANY type of smoking. The latter is planned to be across the street from our home, backing directly adjacent to our neighbor's back yard. **This is a FAMILY NEIGHBORHOOD**. There are many families with small children in this area. We are strongly opposed to any type of outdoor sampling or activity regarding this type of business. The vapors are toxic and a health hazard to the public. The lights, noise, and sampling are **absolutely not welcome** in the backyard of our neighbors nor of our neighborhood! The proposed business of HAPPY VAPE is not consistent with the 'beautifying' of Ocean Avenue, nor is it wanted in **a family neighborhood**. This would set a very negative precedence.

We are aware of the empty store fronts along Ocean Avenue. Simply because it is empty does not mean it needs to be filled with businesses such as Happy Vape. Our neighborhood would love to see more positive, family friendly businesses such as Fog Lifter Café, YogaFlow, Whole Foods and Elevate Fitness-these are the types of businesses that our locals deserve & desire. They would attract similar businesses that our families can walk to and shop at.

Please include my email and document in the Planning Department packet for review by the Planning Commission.

Sincerely,

Derek & Michelle Schulze
Ingleside Terraces

From: [James Spalding Jr.](#)
To: [Boudreaux, Marcelle \(CPC\)](#)
Subject: No Vape shop on Ocean Avenue
Date: Monday, October 27, 2014 2:47:19 PM

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James H. Spalding Jr. CPA/MSTax
180 De Soto Street
San Francisco CA 94127-2183
cpaspalding@gmail.com
415-337-6799, cel 415-517-2539

Word of mouth is the best source of new business for Spalding and Company.
Thanks for your good word referrals.

From: [Donna Howe](#)
To: [Boudreaux, Marcelle \(CPC\)](#)
Subject: Opposition to proposed permit for 1963 Ocean Ave
Date: Thursday, May 15, 2014 2:23:52 AM

To: Marcelle Boudreaux
From: Donna Howe, 85 Entrada Court

Message:

I am a long time resident of the Ingleside Terraces. I am the third generation of our family to have lived at Entrada Court, and my son and his family are the fourth and fifth generations and currently reside nearby on Urbano Drive. That being said, **I wish to voice my strong opposition to the permit application reference the establishment of a business offering tobacco paraphernalia at the vacant retail space at 1963 Ocean Avenue.**

There are several schools (Commodore Sloat Elementary School, St. Francis Preschool, Straford Academy, Voice of Pentecost Academy, Aptos Junior HS, and Lick-Wilmerding) nearby. I have serious concerns about the negative social and health impact a tobacco shop will have on the neighborhood.

There are already several cannabis dispensaries along the Ocean Ave. corridor between Junipero Serra and Howth. So far, the city has not seen fit to honor the wishes of our neighbors by failing to discourage the clustering of dispensaries; **if a tobacco shop were to be permitted to open and operate nearby it would be a clear indication that "the City" Planning Department does not support efforts to draw residents and family-friendly businesses to our historic neighborhood.**

For a number of years I maintained a residence in the east bay city of Fremont. The Smoke Shop there was a constant source of problems in the Nilas District. That was in the days before ecigarettes, so it was full of such products as rolling papers, "dooie clips", scales, drug kits, bonges, and other assorted tobacco paraphernalia.

Establishing a similar business on Ocean Avenue can only bring negative outcomes that will far outweigh the generation of any commercial revenue for this city that I love. It would be naive to think the proposed business would offer only ecigarettes, cigarettes, cigars, snuff, chew and loose tobacco; all of which, I believe, are easily procured at a variety of other locations. There is no need for such a business in our neighborhood. Although I am sure it would be popular with college students from City College of San Francisco and San Francisco State University, it would also be a distraction from their educational pursuits and not likely to be popular with their parents.

I hope my work schedule will permit me to attend any community outreach meetings regarding this proposal, but I do wish to go on record now with the Planning Commission as being **opposed** to permitting the proposed business.

From: [Gail Dent](#)
To: [Boudreaux, Marcelle \(CPC\)](#)
Subject: proposed "Vape"shop on Ocean Ave
Date: Monday, October 20, 2014 1:01:09 PM

This proposal is of concern to my family and me. I understand smoking an e cigarette is not allowed in a public indoor space in San Francisco and that is why an area in the back of the store is to serve as an outdoor smoking area. Everyday I walk my dog around Urbano and pass the home which abuts the proposed smoking area. Many other people pass this way on their way to other places on Ocean Ave. Does anyone know if the second hand vapor is dangerous? Will this shop be allowed to sell to minors? If not, why are there flavors which would attract children? How much research on e cigarettes will the committee do before they make a decision? Will they look at the actions other cities in California have taken?

I hope our planning commissioners will do their due diligence before voting.

From: [Mary Schembri](#)
To: [Boudreaux, Marcelle \(CPC\)](#); [Yee, Norman \(BOS\)](#); [Secretary, Commissions \(CPC\)](#)
Cc: [Bob Karis](#)
Subject: RE: <OPPOSED to 1963 Ocean Ave Happy Vape Conditional Use and business!
Date: Wednesday, October 29, 2014 12:04:48 PM

Dear Planning Commission Members, Supervisor Norman Yee and Ms. Marcelle Boudreaux:

I am a member of the Ingleside Terraces Homeowners Association (ITHA) and have lived in the Terraces all of my life. I strongly OPPOSE the Conditional Use authorization to sell tobacco paraphernalia, e-cigarette sales, and oppose to a Steam Stone Hookah Lounge at any location on Ocean Avenue corridor. Additionally, I strongly OPPOSE to any OUTDOOR ACTIVITY for sampling e-cigarettes.

This type of business is not necessary on Ocean Avenue. E-cigarettes can be purchased at 7-Eleven-2000 Ocean Ave, Homrun Liquors-1551 Ocean, A& N Liquors-1521 Ocean, No Limit Liquor & Food Mart-1015 Ocean. Two Vape shops are within a 1.5 mile distance of 1963 Ocean: Juice box Vapor, 907 Taraval St. Dream Cloud Vapors, 4971 Mission St near Geneva Ave.

This type of business is not desirable in our neighborhood as it concentrates in addicting our neighbors to nicotine, and expose them and people near them to harmful chemicals contained in the e-cigarette vapors.

After many years of vacant store fronts, we finally have some businesses that are making a positive difference, such as Whole Foods, CVS, and coffee shops.

Please support the health of our neighborhood and deny this permit.

Thank you,

Mary Male Schembri
84 De Soto Street
San Francisco, CA 94127
415-420-9448

From: [Linda McGilvray](#)
To: [Boudreaux, Marcelle \(CPC\)](#)
Subject: Re: the Vape Shop at 1963 Ocean. . .
Date: Wednesday, October 22, 2014 5:56:43 PM

Dear Ms. Boudreaux,

The neighbors in Ingleside Terraces are very concerned about this proposed shop. It has been researched and found that these vapors and e cigarettes are not all that harmless to people. The neighbors with adjoining properties are certainly opposed to such activities that would pollute the air right outside the back of their homes. There also are a couple of private schools in the area that might be influenced by the wares. Trying to improve the quality of retail establishments on Ocean Avenue has been the focus, even though a few questionable shops have opened. Please consider the plight of the neighbors in considering licensing this shop.

Thanks for your consideration.

Linda McGilvray
Board member of ITHA
Oct. 22, 2014

From: steve@stevholm.com
To: [Boudreaux, Marcelle \(CPC\)](#); [Yee, Norman \(BOS\)](#); [Secretary, Commissions \(CPC\)](#)
Subject: regarding Conditional Use at 1963 Ocean Avenue - Happy Vape
Date: Monday, October 27, 2014 9:26:36 PM

Hello,
I'm a board member on the Ocean Avenue Association. I'm also a business owner on Ocean Avenue; Yoga Flow SF.

Although our board supported Happy Vape, I did not vote in support. I do believe this store has a demand in this neighborhood, therefore it is necessary and desirable; so, I do support the proposal for Conditional Use authorization to allow establishment of a Tobacco Paraphernalia Establishment retail use (d.b.a. Happy Vape) to include e-cigarette sales at the ground floor.

However, **I do NOT support** The Conditional Use authorization to establish an **outdoor activity area** for e-cigarette sampling within the existing **rear yard**. This yard is adjacent to a detached single family residence, so it does not seem fit for an outdoor smoking area. My business is far enough away, we would not smell this, but the families living adjacent would be negatively affected.

Thank you,
Steven Holm
Yoga Flow SF

From: [Rene Casis](#)
To: [Yee, Norman \(BOS\)](#); [Boudreaux, Marcelle \(CPC\)](#); [Secretary, Commissions \(CPC\)](#)
Subject: Regarding proposed vape shop at 1963 Ocean Ave.
Date: Monday, October 27, 2014 2:53:59 PM

To Supervisor Yee, Mr. Boudreaux, and Planning Commission Secretary,

I am writing in **opposition** to the proposed vapor tobacco shop at 1963 Ocean Avenue.

To put it plainly, this business has no positive impact to the community. Tobacco products (including the vapor variety) are currently available in the already established liquor stores/convenience markets. In addition, the close proximity of schools and hence the high concentration of youth traffic in the area is of great concern to me as a parent. I have no problem with the products as an alternative for cigarette smokers but I also do not believe that vapor products are a 100% healthy alternative. The promotion of vapor products via a store front will undoubtedly have a negative impact on highly impressionable children. Our children face enough peer pressure in the world without having a store front openly promoting the "benefits" and "allure" of tobacco vapor products.

Furthermore, I would like to state that I am extremely disappointed with Supervisor Yee and Planning Department's current business expansion efforts this area. First there is the push for additional medical cannabis distribution centers and now the proposal for a tobacco vapor shop. I do not feel like the community is being appropriately represented. The neighborhoods comprising of the community West of Twin Peaks is one of the few remaining areas where San Franciscans can remain in the City while raising families in a positive and safe environment. Interesting that neighborhoods like Glen Par, West Portal, and Miraloma Park do not have MCDs and vapor shops. For me, this really calls into question Supervisor Yee's ability to represent **all** of District 7.

This is a call for you take action and do what is right for everyone, especially the children, in this neighborhood and that is to see to it that there is no tobacco vapor shop at 1963 Ocean Avenue or anywhere else in this neighborhood.

Sincerely,
Rene Casis

From: [Pat R](#)
To: [Secretary, Commissions \(CPC\); Boudreaux, Marcelle \(CPC\)](#)
Cc: [Yee, Norman \(BOS\)](#)
Subject: Neighboring Residents OPPOSED to 1963 Ocean Ave Happy Vape Conditional Use and business!
Date: Monday, October 27, 2014 1:53:28 PM

 [DPH_FactSheetFeb2013.pdf](#)

Dear Planning Commission, Mr. Norman Yee and Ms. Marcelle Boudreaux:

I am an adjacent neighborhood to the project and a member of ITHA residential group. I strongly OPPOSE the Conditional Use authorization to sell tobacco paraphernalia, e-cigarette sales, and oppose to a steam stone hookah lounge at basement level. Additionally I strongly OPPOSE to any OUTDOOR ACTIVITY for sampling e-cigarettes PERIOD!

I am opposing this type of business to operate on Ocean Ave corridor. This type of business is not necessary in Ocean Ave. E-cigarettes can be purchased at 7-Eleven-2000 Ocean Ave, Homrun Liquors-1551 Ocean, A& N Liquors-1521 Ocean, No Limit Liquor & Food Mart-1015 Ocean. Two Vape shops are within a 1.5 mile distance of 1963 Ocean: Juice box Vapor, 907 Taraval St. Dream Cloud Vapors, 4971 Mission St near Geneva Ave.

This type of business is not desirable in our neighborhood as it concentrates in addicting our neighbors to nicotine, and expose them and people near them to harmful chemicals contained in the e-cigarette vapors.

I have included Mayor Edwin Lee's *E-cigarettes fact sheet by the Dept. of Public Health: "E-cigarette turn nicotine and other chemicals into a vapor that is inhaled by the user." "The FDA conducted a preliminary analysis of 18 various types of cartridges from 2 leading brands of e-cigs, labeled as flavored, nicotine and no-nicotine. Following were findings of the samples tested.":

- Diethylene glycol, an ingredient used in anti-freeze that is toxic to humans, was found in one sample.
- Certain tobacco-specific nitrosamines that are carcinogens for humans were found in half of the samples.
- Tobacco-specific impurities suspected of being harmful to humans were found in most of the samples. These included anabasine, myosine, and B-nicotyrine.
- Cartridges labeled as "no nicotine" had low levels of nicotine, with the exception of one.
- e-cigarettes available in chocolate, strawberry and mint flavors would appeal to children.
- NOT a SMOKING CESSATION DEVICE. These products have not been tested for safety of efficacy in helping people quit smoking.

* E-Cigarette Fact Sheet, Mayor Edwin Lee, Dept. of Public Health, Population Health and Prevention, February 4, 2013.

In Addition, I oppose to any outdoor activity or sampling. This is a nuisance to adjacent neighbors. The vapors are toxic and a health hazard to the public. The lights, noise, sampling are absolutely not welcome in the backyard of neighbors nor

our neighborhood! This would set a negative precedence.

Let's keep the beautification of Ocean Ave Corridor that the City has invested. Let's continue with stores like Whole Foods, CVS Pharmacy, Fog Lifter Cafe, Elevate Fitness, and Yoga Flow that will attract similar businesses that residents can walk and shop to. I, along with other neighbors, attended and spoke at the most recent Ocean Ave Assoc Board and ITHA board meetings. We experience that those Board Presidents were more focused on supporting the landlord's interest in renting the "empty locations" than hearing neighbor's concerns. This is our opportunity for residents and SF citizens for non-smoking rights to be heard!

Please include my e-mail and document in the Planning Dept. packet for review by the Planing Commission.

Sincerely,
Pat H. Ryan
Ingleside Terraces
ITHA member

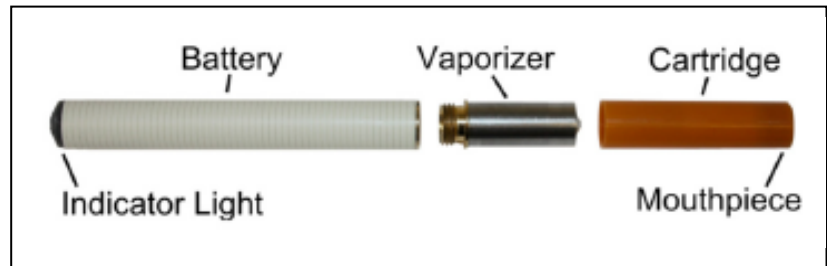


E-Cigarette Fact Sheet

February 4, 2013

What Are E-Cigarettes?

E-cigarettes are electronic cigarettes that are battery-operated devices designed to look like and to be used like conventional cigarettes. The devices contain cartridges filled with nicotine, flavor and other chemicals. E-cigarettes turn nicotine and other chemicals into a vapor that is inhaled by the user. No smoke or combustion is involved. Rather the device emits a vapor. E-cigarettes are marketed as less expensive and safer than tobacco cigarettes, as a more socially acceptable way to smoke in smoke-free environments and as providing relief from the social stigma of being a smoker.



E-cigarettes are marketed as less expensive and safer than tobacco cigarettes, as a more socially acceptable way to smoke in smoke-free environments and as providing relief from the social stigma of being a smoker.

Health Risks Identified by the Food and Drug Administration (FDA)

The FDA and many public health experts are concerned about health risks posed by e-cigarettes. The FDA has conducted a preliminary analysis of 18 of the various types of cartridges from 2 leading brands of e-cigarettes, labeled as flavored, nicotine and no-nicotine. Following were findings of the samples tested:

- Diethylene glycol, an ingredient used in antifreeze that is toxic to humans, was found in one sample.
- Certain tobacco-specific nitrosamines that are carcinogens for humans were found in half of the samples.
- Tobacco-specific impurities suspected of being harmful to humans were found in most of the samples. These included anabasine, myosine, and β -nicotyrine.
- Cartridges labeled as “no nicotine” had low levels of nicotine, with the exception of one.
- The amount of nicotine emitted with each puff varied markedly among 3 cartridges that all had the same label.
- One high-nicotine cartridge delivered twice the amount of nicotine compared to an FDA approved nicotine inhalation product that was developed as a smoking cessation aid.

Additional Health Concerns

- The devices include no health warnings.
- E-cigarettes could increase nicotine addiction among young people and encourage them to try other tobacco products such as conventional cigarettes due to introduction to addictive nicotine.
- E-cigarettes available in chocolate, strawberry and mint flavors would appeal to children.

- Consumers have no information about the safety of these products, the types and concentrations of nicotine and other chemicals inhaled when using them.
- Research conducted at the Lawrence Berkeley National Laboratory found that nicotine in third hand smoke, the residue from tobacco smoke that clings to surfaces long after a cigarette has been extinguished, reacts with a common indoor air pollutant called nitrous acid and produces a hazardous carcinogen. This study demonstrates that nicotine, the addictive ingredient in tobacco smoke, is harmful. Research co-author James Pankow has stated that the results of this study should raise concerns about the safety of electronic cigarettes.
<http://www.sciencedaily.com/releases/2010/02/100208154651.htm>

Not a Smoking Cessation Device

- These products have not been tested for safety or efficacy in helping people quit smoking.
- The American Cancer Society, American Heart Association, and American Lung Association have developed statements expressing concern about the increase of e-cigarette marketing and use.

Undermine Progress in Changing Social Norms around Smoking

- A key benefit to smoke-free laws is to change social norms around smoking and to make smoking less socially acceptable. E-cigarette use, particularly in areas that are covered by the second hand smoke ordinance, would undermine the progress made in social norm change.
- Use of e-cigarettes in non-smoking areas would give the public the impression that smoking is permitted as these products closely resemble traditional cigarettes and one could easily assume that the vapor emitted is smoke. In addition, e-cigarette use in areas where smoking is prohibited misleads people into believing that smoking is permitted in these areas without any consequence.

Complicate Enforcement Efforts

- Allowing use of e-cigarettes would likely complicate efforts by the City as well and business owners to enforce Health Code Article 19F. Since enforcement is complaint driven, there will be no way to distinguish whether a complaint is based on e-cigarettes or smoking of traditional cigarettes. Business owners' attempts to comply with the law would also be complicated if use of e-cigarettes is not banned in the same areas.

E Cigarettes Already Regulated by San Francisco Government Entities

- San Francisco General Hospital (SFGH) adopted a smoke free campus policy in 2008. In 2011, the policy was amended to include a ban on e-cigarettes on campus.
- E-cigarette use at SF Airport: In response to concerns regarding use of e-cigarettes at the airport and impact on compliance with smoke-free legislation, the Executive Committee of the San Francisco Airport Commission approved a proposal on September 20, 2010 to adopt a policy to ban the use of e-cigarettes where conventional cigarette smoking is prohibited.
- Department of Transportation prohibits use of e-cigarettes on airline flights:

On June 17, 2010, at a Senate Committee on Commerce, Science and Transportation hearing, the Assistant Secretary for Aviation and International Affairs of the U.S. Department of Transportation stated that smoking of electronic cigarettes was already banned on U.S. air carrier and foreign air carrier flights in scheduled intrastate, interstate and foreign air transportation (49 USC §41706 and 14 CFR Part 252). Additionally, the Department of Transportation planned to issue a notice of proposed rulemaking that would amend the existing general regulatory language in Part 252 to explicitly ban smoking of electronic cigarette aboard aircraft.

FDA Legal Authority

- The FDA could issue regulations of e-cigarettes as a tobacco product under the 2009 the Family Smoking Prevention and Tobacco Control Act. However the FDA cannot regulate where e-cigarettes are used and it cannot prohibit their use in places where smoking traditional cigarettes is already prohibited. The FDA also provides state and local governments with the authority to regulate the sale or use of tobacco products, including e-cigarettes.
- In September 2008, the FDA moved to establish authority over e-cigarettes as drug delivery devices based on the Food, Drug and Cosmetic Act. Specifically, the FDA banned the import of new e-cigarette product shipments.
- E-cigarette manufacturers sued the FDA, claiming that their products should be regulated as tobacco products, not as drugs.
- In January 2010, a Washington DC district court ruled that the FDA could not regulate e-cigarettes as a drug or drug delivery device (because the nicotine was derived from tobacco) but that the FDA could regulate them as tobacco products.

Authority of State or Local Governments to Regulate E-cigarettes

1. Local smoke free laws can include e-cigarettes in their definition of smoking.
2. Local tobacco licensing laws can include a requirement to obtain a local tobacco permit to sell e-cigarettes. In San Francisco, no tobacco permits are allowed in business establishments with pharmacies or on city and county property.
3. New local legislation can be adopted with findings unique to e-cigarettes that apply local smoking restrictions to e-cigarettes.

Limits on E-cigarettes Adopted by State and Local Governments

As of September 2010, California law banned e-cigarette sales to minors, putting the product in the same category as traditional cigarettes. The table below provides a list of e-cigarette legislation adopted by various government entities, including the rationale cited for the policies.

E-cig Law Enacted	Sale of E-cigarettes	Use of E-cigarettes
Canada, Argentina, Singapore, Brazil, Israel, Hong Kong,	No e-cigarette sales, distribution or importation.	

Jordan, Victoria (Australia), Turkey		
Malta		Bans use in public places where smoking is banned.
California	No sales to minors	
Savannah, Georgia		Bans use in public places and workplaces
Madison County, Kentucky		Bans use in public places and workplaces
New Jersey	No sales to minors	Bans use in enclosed indoor places of public access and workplaces
New Hampshire	No sales to minors or free sampling; Includes liquid nicotine	
Utah		Bans use in public places
Boston, Massachusetts	No sales of unregulated nicotine delivery products to minors	Bans use in workplaces
North Adams, Massachusetts	No sales to or use by minors	Bans use in public places and workplaces
Great Barrington, Massachusetts		Bans use where smoking is prohibited
Saugus, Massachusetts	No sales to minors	Bans use in public places.
Paramus, NJ		Bans use in indoor public places and workplaces
Cattaraugus County, NY	No sales to minors	Bans use in public places and workplaces
Suffolk County, NY	No sales to minors	Bans use in public places and workplaces
Bergen County, NJ		Bans use in county parks where children present, inside county buildings, and county vehicles
King County, WA (includes Seattle)	No sales to minors, or sampling, or coupons	Bans use in places where smoking is prohibited by law (workplaces, public places)
Tacoma- Pierce County, Washington	No sales to minors or free sampling.	Bans use in public places where minors are permitted (exempts places of employment that are not public places)

Ordinance Proposed would:

1. Prohibit use of and sale of e-cigarettes on City and County property.
2. Prohibit use of e-cigarettes in places where smoking is prohibited by law.
3. Require a tobacco permit for the sale or furnishing of e-cigarettes.

Rationale:

1. A ban on the use and sale of e-cigarettes on City and County property would be of particular priority, to be consistent with other policies adopted by the City to protect the public health. These include the bans on: tobacco advertising and tobacco sales on City and County property; smoking in City parks, gardens and squares, smoking within 20 feet of entrances to the airport, as well as the smoke-free campus policy adopted by San Francisco General Hospital in 2008. As an example, SFGH has conducted extensive education and training of staff and outreach to patients and visitors to gain compliance with the smoke-free campus policy. SFGH later amended the policy to ban e-cigarettes. Allowing e-cigarettes in locations where cigarette smoking is not allowed would act as a trigger for smokers and former smokers, and would also send a confusing message regarding the smoking policy.
2. Allowing use of e-cigarettes would likely complicate efforts to enforce Health Code Article 19F by the City as well as business owners. Since enforcement is complaint driven, there will be no way to distinguish whether a complaint is based on e-cigarettes or smoking of traditional cigarettes. A key benefit to smoke-free laws is to change social norms around smoking and to make smoking less socially acceptable. E-cigarette use, particularly in areas that are covered by the second hand smoke ordinance, would undermine the progress made in social norm change.
3. Requiring a tobacco permit for the sale or furnishing of e-cigarettes would provide another mechanism to regulate e-cigarettes. Police youth decoy operations conducted to enforce Penal Code 308, the ban on tobacco sales to minors, could be utilized to assure retailers are complying with the California ban on e-cigarette sales to minors. Permitting would additionally result in a ban on the sale of e-cigarettes in pharmacies, consistent with the fact that the FDA has not approved e-cigarettes as medical smoking cessation devices. The permit requirement would ensure establishments selling e-cigarettes be in a permanent location and would not permit temporary e-cigarette booths at shopping malls as have been seen in Westfield and Stonestown shopping centers.

From: creps4@aol.com
To: [Boudreaux, Marcelle \(CPC\)](#)
Subject: vape shop at 1963 Ocean Avenue
Date: Saturday, October 25, 2014 6:10:15 PM

Please come and look at the 1900 block of Ocean and at the surrounding neighborhoods- lovely detached family homes. The 1900 commercial block does not serve our families-cannabis dispensary, billiard parlor, a "massage parlor" that advertises on "adult" websites and tattoo businesses. Many of us have children who walk from Aptos Middle School down Ocean Avenue. As you know vape shops sell devices in flavors such as "bubble gum" and candy flavors to attract middle and high schoolers. On top of everything else the backyard of this shop would be open every night until 8PM for customers to try the merchandise. Are you aware how close people would be exhaling these vapors to the nearest neighbor's back windows? This business is neither necessary nor desirable to our neighborhood. Come and look for yourself. It is unbelievable. Sincerely, Adrienne Sciutto

From: [George Wu](#)
To: [Boudreaux, Marcelle \(CPC\)](#)
Subject: Vape shops
Date: Saturday, October 18, 2014 7:00:15 PM

These Vape shops requesting conditional use permitting are neither necessary nor desirable. Addictive drugs including nicotine and marijuana have no place in family friendly neighborhoods.

What message are we sending to our children?!!!! Are our supervisors THAT desperate to find tax revenues?!!!!

George Wu, MD

Sent from my iPad

From: [Wendy Portnuff](#)
To: [Boudreaux, Marcelle \(CPC\)](#); [Yee, Norman \(BOS\)](#)
Subject: Vapor Shop Conditional Use Permit
Date: Friday, October 17, 2014 11:32:22 PM

I am writing to indicate one more time that I am opposed to the presence of a Vape shop on Ocean Avenue adjacent to The Terraces. I understand that to obtain a permit, the shop must demonstrate that it is necessary or desirable. I see no way that either of these is fulfilled in the case of a vape shop. Such a shop is only necessary or desirable to the owner. There are other vape shops close enough that people who see sucking in toxic fumes to be advantageous can purchase electronic cigarettes. However, there is enough significant scientific evidence that these electronic cigarettes are dangerous that the City of San Francisco, which has such good anti-smoking laws, should not be duped into supporting the expanded use of electronic cigarettes.

Wendy Portnuff

The Professional Woman's Guide to Healthy Travel

www.wendypornuff.com

415-269-4398

WESTWOOD PARK



July 3, 2014

Marcelle Boudreaux, AICP
Planner, Southwest Quadrant
Planning Department, City and County of San Francisco
1650 Mission Street, Suite 400, San Francisco, CA 94103

RE: Letter of Opposition – Vaporizer Lounge and Store located at 1963 Ocean Avenue

Dear Ms. Boudreaux,

I am writing on behalf of the Westwood Park Association Board in opposition to the proposed vaporizer lounge and store at 1963 Ocean Avenue.

Members of our diverse communities surrounding Ocean Avenue have been working for many years to revitalize Ocean Avenue and to attract much needed neighborhood businesses and services to the Ocean Avenue retail corridor. We recently had a number of community meetings on the Ocean Avenue Corridor where residents were asked about what businesses and services they wanted to see on the Ocean Avenue. I can assure you that a vaporizer lounge and store was *not* on the list. By way of reference, the Planning Department representative on this effort is Lily Langlois.

It is our understanding that e-cigarette smoking devices and cartridges as well as nicotine cartridges will be sold, and, there will be a smoking lounge with vaporizing devices for smoking. Food, music and videos/movies will be shown in the lounge area to attract customers.

Currently, we have 4 locations where e-cigarettes and nicotine products are sold – 7-Eleven, Homrun, A&N Liquors, and No Limit – more than adequate for this area. Although the business owners have indicated that smoking nicotine will not be allowed on the premises, enforcement will be difficult.

We have precious few store fronts for the size of our neighborhoods. A vaporizer lounge and store does not propel our revitalization efforts forward nor does it provide the much needed and requested businesses and services to benefit our community.

I am joined by the Westwood Park Association Board members Kathy Beitiks, Anne Chen, Greg Clinton, Tim Emert, Caryl Ito and Anita Theoharis in opposing the proposed vaporizer lounge and store at 1963 Ocean Avenue.

Sincerely,

A handwritten signature in cursive script, appearing to read "Kate Favetti".

Kate Favetti, President
Westwood Park Association



ARCHITECTURE
+ PLANNING
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(Fax) 391-3649

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Project Title:
HAPPY VAPE

1963 OCEAN AVE.

Consultants:

JOB NO. 2014-14

Date: 7/10/14
Checked By: SK
Drawn By: YK

ISSUANCES & REVISIONS:

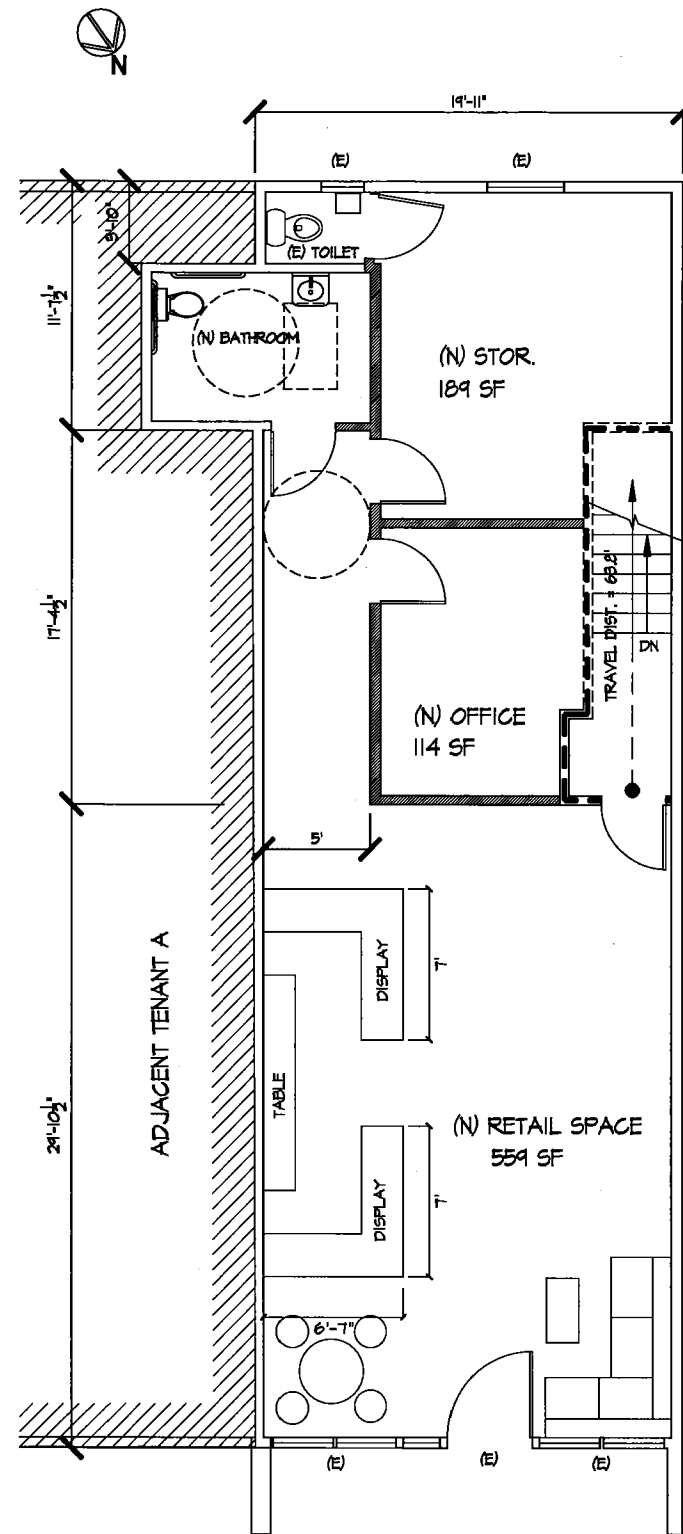
No.	Date	Description
	9/9/14	DESIGN REVISION
	10/22/14	DESIGN REVISION

Stamp:



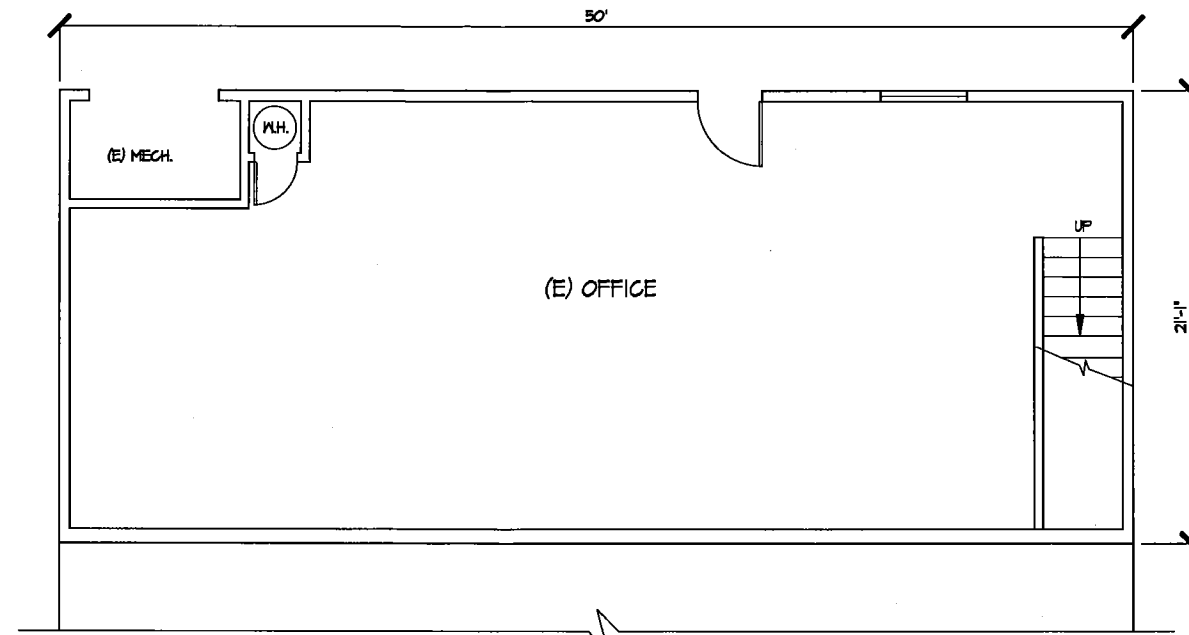
Sheet Title
**PROPOSED 1ST FLOOR PLAN
EXIST. + NEW
BASEMENT PLAN**

Sheet No.
A-2



1 PROPOSED 1ST FLOOR PLAN

SC: 1/4" = 1'-0"

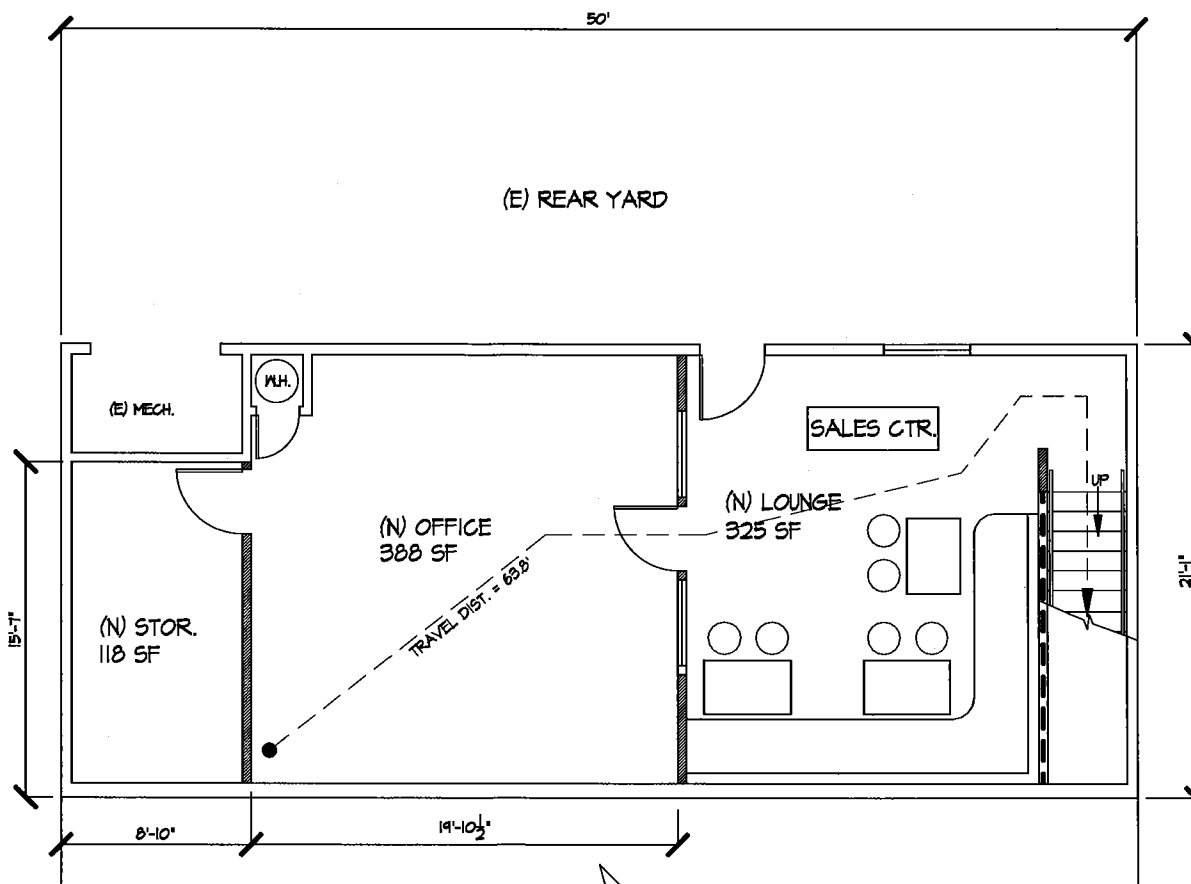


2 EXIST. BASEMENT FLOOR PLAN

SC: 1/4" = 1'-0"

LEGEND

- ACCESS DISTANT OF BASEMENT: '13' < '75'
- ==== (E) WALL
- ==== (N) WALL
- WALL TO BE DEMOLISHED
- ===== ONE HOUR PARTITION



3 PROPOSED. BASEMENT FLOOR PLAN

SC: 1/4" = 1'-0"



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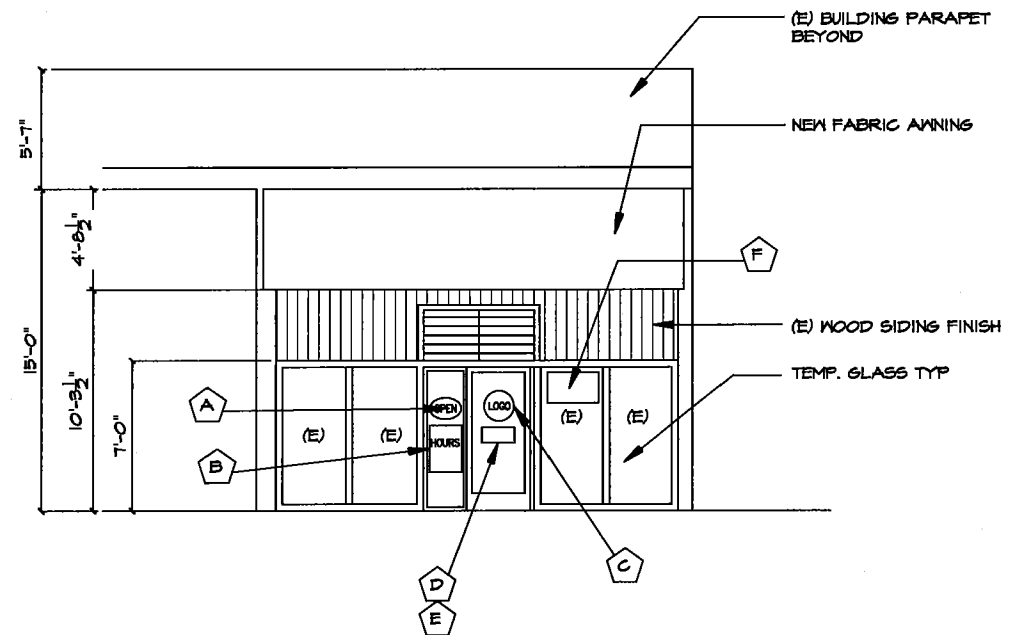
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Project Title:

HAPPY VAPE

1963 OCEAN AVE.

Consultants:



SIGNAGE SCHEDULE	
A	OPEN "LED" SIGN
B	HOURS OF OPERATION
C	LOGO
D	18 AND OVER SIGN
E	WE CHECK ID AND NO VAPING/SMOKING ON PREMISE
F	SF HEALTH CODE ARTICLE 19F SIGN SIGN AT EACH ENTRY NO HIGHER THAN 8' AND LOWER THAN 5', WITHIN 10' OF DOOR TO READ. *SMOKING ONLY 1) AT CURB OR 2) IF NO CURB, AT 15' FROM ENTRANCES, EXITS, OPERABLE WINDOWS, AND VENTS.

1 FRONT ELEVATION
SC: 1/4" = 1'-0"



2 REAR ELEVATION
SC: 1/4" = 1'-0"

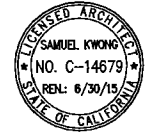
JOB NO. 2014-14

Date: 7/10/14
Checked By: SK
Drawn By: YK

ISSUANCES & REVISIONS:

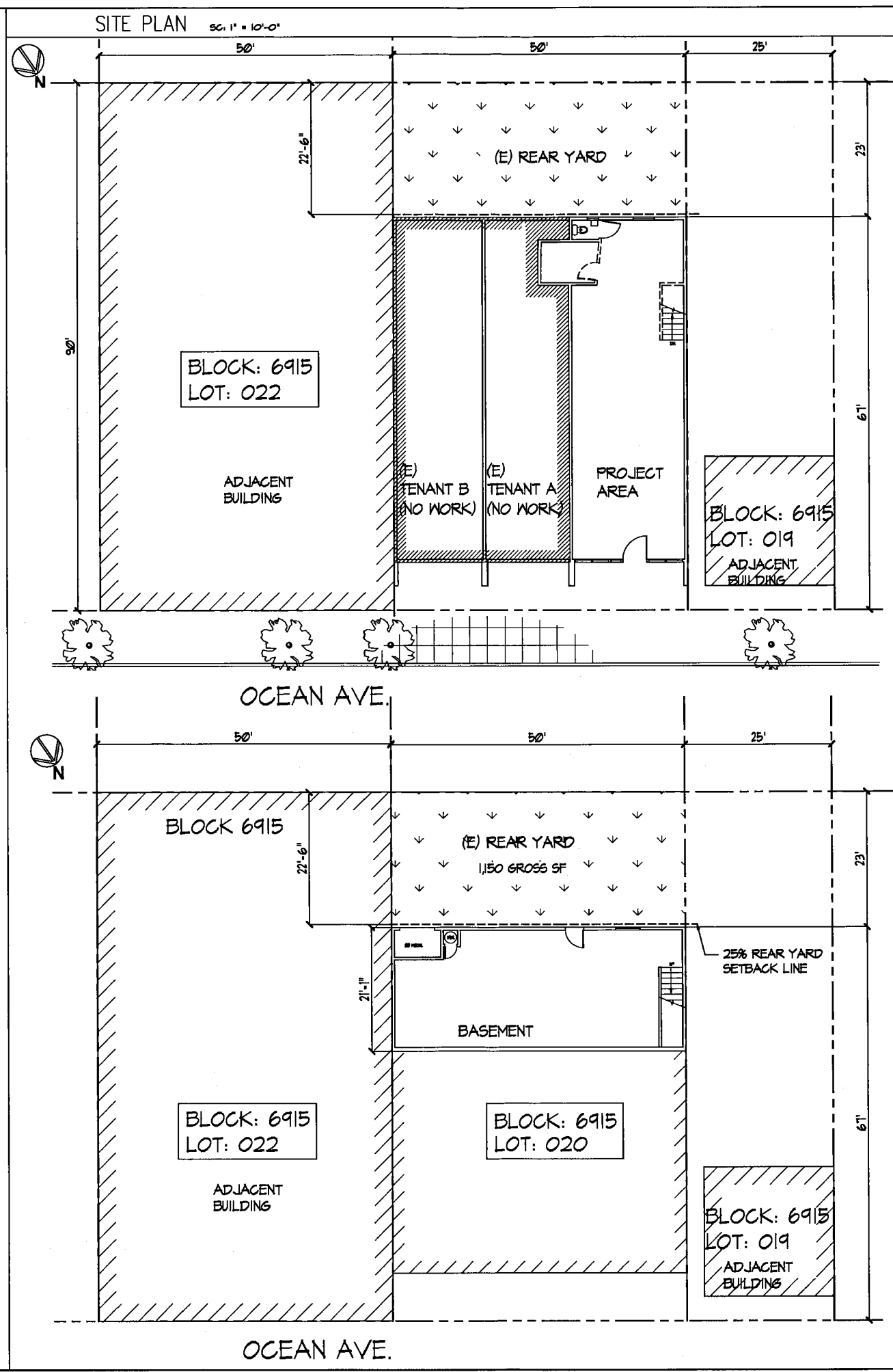
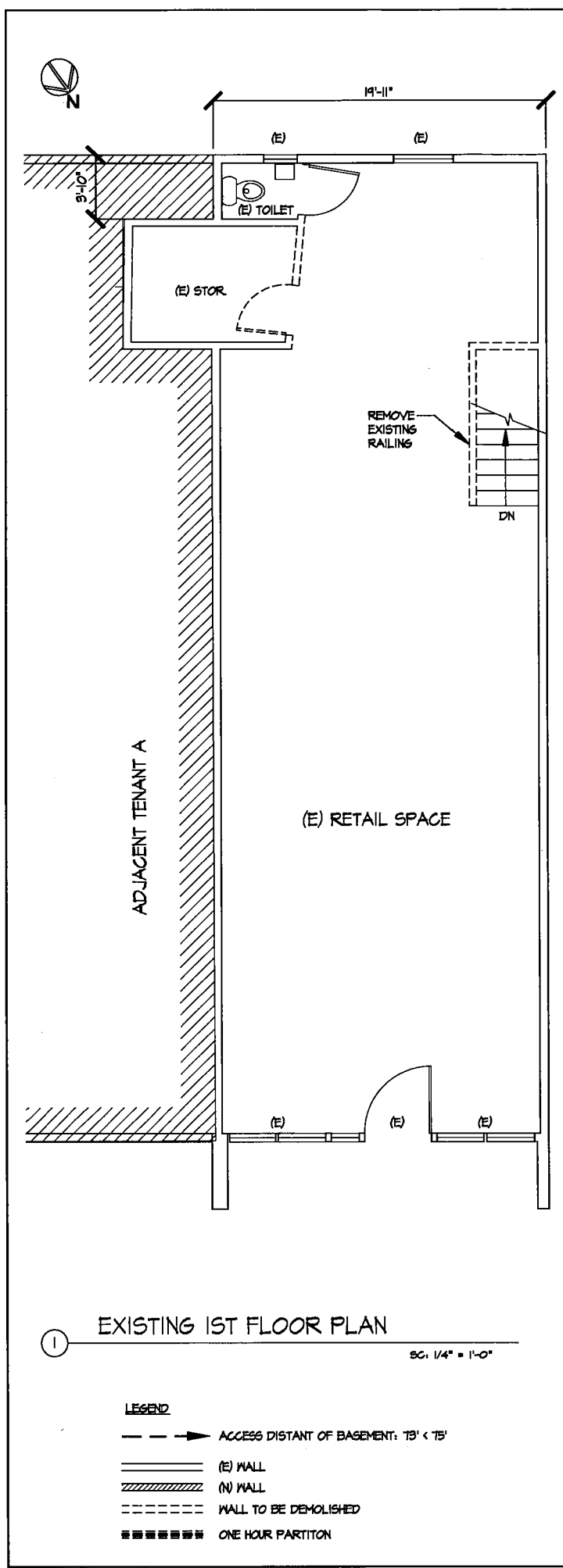
No.	Date	Description
	10/22/14	DESIGN REVISION

Stamp:



Sheet Title
FRONT AND REAR ELEV. SIGNAGE

Sheet No.
A-3



BUILDING INFORMATION

ADDRESS: 1963 OCEAN AVE., SAN FRANCISCO CA 94127

BLOCK: 6915 LOT: 20
BUILT: 1948
LOT AREA: 50'x90' = 4,500 SF
ZONING: NCT - OCEAN AVE. NEIGHBORHOOD COMMERCIAL TRANSIT

FLOOR: 1ST / BASEMENT
BUILDING TYPE: V-B

	OCCUPANCY	AREA (SF)	OCCUPANT LOAD
EXISTING	1ST FLOOR RETAIL	M 1160.4	36
	1ST FLOOR STORAGE	S-2 55.5	0
	BASEMENT OFFICE	B 931	4
PROPOSED	1ST FLOOR RETAIL	M 559	18
	1ST FLOOR OFFICE	B 104	1
	1ST FLOOR STORAGE	S-2 118	1
	BASEMENT LOUNGE	B 925	21
	BASEMENT STORAGE	S-2 118	1
BASEMENT OFFICE	B 388	3	
PROPOSED TOTAL OCCUPANT LOAD = 44			

TOTAL OCCUPANT LOAD 45 < 50
PER PLUMBING CODE 422.2, 1 UNISEX BATHROOM IS OK

SCOPE OF WORK

1. ESTABLISH RETAIL OFFERING TOBACCO PARAPHERNALIA (E-CIGARETTES & SUPPLIES)

CODE INFORMATION

2013 CALIF. BLDG. CODE AND SAN FRANCISCO BUILDING CODE AMENDMENTS
2013 CALIF. ELEC. CODE AND SAN FRANCISCO ELECTRICAL CODE AMENDMENTS
2013 CALIF. PLUMBING CODE AND SAN FRANCISCO PLUMBING CODE AMENDMENTS
2013 CALIF. MECH. CODE AND SAN FRANCISCO MECH. CODE AMENDMENTS
2013 CALIF. GREEN BLDG. CODE AND SAN FRANCISCO GREEN BUILDING CODE AMENDMENTS
2013 CALIFORNIA ENERGY CODE

SCHEDULE OF DRAWINGS

A-1: BUILDING INFO., SITE PLAN, EXIST. GROUND FLOOR PLAN

A-2: EXISTING BASEMENT FLOOR PLAN, PROPOSED BASEMENT FLOOR PLAN & GROUND FLOOR PLAN

A-3: FRONT AND REAR ELEVATION AND SIGNAGE



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Project Title:
HAPPY VAPE

1963 OCEAN AVE.
SAN FRANCISCO

Consultants:

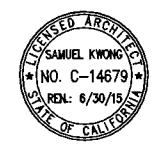
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Drawn By: YK

ISSUANCES & REVISIONS:

No.	Date	Description
	9/9/14	DESIGN REVISION
	10/22/14	DESIGN REVISION

Stamp:



Sheet Title
BLDG. INFO, SITE PLAN, EXIST. 1ST FLOOR PLAN

Sheet No.
A-1

Dear Commissioner,

My wife and I decided to open a small business on 1963 Ocean Ave, the former Aquatic Central, after conducting extensive market research. We found that there was a void in the new vaping industry. Although vaping products are available in various distribution outlets, the experience of vaping is not permitted in the interior premise; however, the health department does not regulate outdoor or backyard areas. By allowing patrons the unique experience of vaping outdoors, the customer is able to sample various flavors. This allows the customer to make a more informed purchase. In addition, with the health department's enforcement of hookah activity in eateries throughout San Francisco, it created a void for people who wanted the hookah experience as well but could no longer get it at a restaurant.

While conducting our community outreach in the Ocean Avenue area over a nine month period, we found many people were happy to see that we would be filling a vacant storefront in an area that the City and County of San Francisco refers to as "dead block." The Ocean Avenue Association Community Benefit District "...supports our proposal to open The Happy Vape on Ocean Avenue. Notably we also have the support of Reverend Gordon of the Ingleside Presbyterian Church and he has stated that "...the project will fill a vacancy with a retail store on the block with 5 vacancies, which will provide more pedestrian traffic to the Ocean Ave corridor..." In addition there are 20 other neighbors who have submitted support letters stating that this project is necessary, desirable and compatible with its surroundings.

Project sponsors also have a "letter of determination" completed by the planning department, which states that vaping enforcement is under the jurisdiction of the health department.

Unfortunately, there are some myths and inaccurate information circulating, which has instilled fear in some of our neighbors. We feel this negative energy to be irresponsible on the part of a few obstructionists. There is no conclusive scientific data that confirms vaping is harmful to the health of the vaper and bystanders. Other concerned neighbors have some valid points and we are willing to compromise with them.

Although there are less than ten letters of opposition, we have respected their opinions and have responded to each one via email. We have also met with many community groups: OMI Cultural Participation Project, Ingleside Terrace Home Association, Street Life Committee, and Ocean Avenue Association, some of which are in support and some of which choose to stay neutral. Citizens of Ocean Avenue feel that this business will improve the quality of life and the safeguards put in place will negate any negative impact. We propose to limit the hours of operation in the outdoor area to 8pm daily. We propose to limit the capacity in the outdoor area to 10 people. Most sampling will only take 5 to 10 minutes. We will also raise the age of entry to 21 years of age. We will provide educational material and notification material so that customers will be more sensitive to the immediate surroundings and respect the neighbors who reside nearby.

Please approve this and let's move upwards and onwards together.

Studies and research links for your information.

Vapor emission studies:

<http://jpet.aspetjournals.org/content/91/1/52.abstract>

<http://www.biomedcentral.com/content/pdf/1471-2458-14-18.pdf>

<http://www.clivebates.com/?p=2300#more-2300>

<http://www.ncbi.nlm.nih.gov/pubmed/23033998#>

http://clearstream.flavourart.it/site/wp-content/uploads/2012/09/CSA_ItaEng.pdf

<http://www.healthnz.co.nz/ECigsExhaledSmoke.htm>

<http://pubs.rsc.org/en/content/articlelanding/2014/em/c4em00415a#!divAbstract>

<http://informahealthcare.com/doi/abs/10.3109/08958378.2013.793439>

<http://tobaccocontrol.bmj.com/content/early/2013/03/05/tobaccocontrol-2012-050859.short>

E-cigarette as a gateway to tobacco smoking:

<http://tobaccoanalysis.blogspot.com.au/2013/10/first-study-to-examine-e-cigarette.html>

<http://www.forbes.com/sites/jacobsullum/2014/07/17/survey-shows-adults-who-use-e-cigarettes-to-quit-smoking-prefer-allegedly-juvenile-flavors/>

E-cigarettes Helping people quit and as an effective smoking cessation tool studies:

<http://www.addictionjournal.org/press-releases/e-cigarette-use-for-quitting-smoking-is-associated-with-improved-success-rates->

<http://www.plosone.org/article/info:doi/10.1371/journal.pone.0103462>

<http://link.springer.com/article/10.1007/s11606-014-2889-7>

[\[tabac.ch/fra/images/stories/documents/stop_tabac/seigel%20e%20cigs%20am%20j%20prev%20med%202011.pdf\]\(http://stop-tabac.ch/fra/images/stories/documents/stop_tabac/seigel%20e%20cigs%20am%20j%20prev%20med%202011.pdf\)](http://stop-</p></div><div data-bbox=)

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<http://onlinelibrary.wiley.com/enhanced/doi/10.1111/add.12623/http://onlinelibrary.wiley.com/enhanced/doi/10.1111/add.12623/>

E-cigarette studies:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/311887/Ecigarettes_report.pdf

<http://www.ashscotland.org.uk/media/6093/E-cigarettesbriefing.pdf>

<http://www.american.com/archive/2013/november/smoking-kills-and-so-might-e-cigarette-regulation>

<http://vaping.com/data/vaping-survey-2014-initial-findings>

<http://www.bbc.com/news/health-28554456>

<http://ecigarettereviewed.com/wp-content/uploads/2013/11/Research-on-Safety-of-Electronic-Cigarettes-Dr.-Konstantinos-Farsalinos-E-Cigarette-Summit.pdf>

<http://www.legaliser.nu/sites/default/files/files/Electronic%20cigarettes%20achieving%20a%20balanced%20perspective.pdf>

Long term studies of e-cigarette use:

<http://www.sciencedirect.com/science/article/pii/S0306460313003304?np=y>

<http://www.ncbi.nlm.nih.gov/pubmed/25301815>

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SAN FRANCISCO PLANNING DEPARTMENT

Letter of Determination

September 26, 2014

Marsha Garland
Garland Public & Community Relations
535 Green Street
San Francisco, CA 94133

Site Address:	1963 Ocean Avenue
Assessor's Block/Lot:	6915/020
Zoning District:	Ocean Avenue Neighborhood Commercial Transit
Staff Contact:	Marcelle Boudreaux, (415) 575-9140 or marcelle.boudreaux@sfgov.org

1650 Mission St.
Suite 400
San Francisco,
CA 94103-2479

Reception:
415.558.6378

Fax:
415.558.6409

Planning
Information:
415.558.6377

Dear Ms. Garland:

This letter is in response to your request for a Letter of Determination regarding the property at 1963 Ocean Avenue, a vacant retail use with proposal to establish a retail use selling e-cigarettes and related materials and steam stone hookah lounge with outdoor activity area (dba "Happy Vape"). This parcel is located in the Ocean Avenue Neighborhood Commercial Transit (NCT) Zoning District and 45-X Height and Bulk District.

CURRENT PROPOSAL

Per Planning Code Section 790.123, Tobacco Paraphernalia Establishment is defined as an establishment with greater than 10 linear feet or 10% of sales area devoted to display and sales of tobacco paraphernalia and (per Section 737.69) requires Conditional Use Authorization. Additionally, per Section 737.24, an outdoor activity area also requires a Conditional Use Authorization.

On February 7, 2014, the Project Sponsor submitted a Conditional Use Authorization application (Case No. 2014.0206C) for the subject property to establish a Tobacco Paraphernalia Establishment on the ground floor, a steam stone hookah lounge on the basement level and an outdoor activity area at the rear to allow sampling of e-cigarettes.

LETTER OF DETERMINATION REQUEST

The request seeks answers to the following: are steam stone hookahs allowed for indoor and outdoor use; is vaping allowed for indoor and outdoor use; are sales of packaged snacks and soft drinks allowed on the premises; and, would the use be considered a "cigar bar."

RESPONSE

In regards to allowed areas for steam stone hookahs, note that while the Planning Department would consider the hookah use as part of the overall Tobacco Paraphernalia Establishment use, the Department of Public Health (DPH) is responsible for regulating hookah establishments.

Marsha Garland
Garland Public & Community Relations
535 Green Street
San Francisco, CA 94133

September 26, 2014
Letter of Determination
1963 Ocean Avenue

In regards to allowed areas for vaping, it is the Planning Department's understanding of recent legislation enacted by DPH that vaping/e-cigarette smoking is now regulated in a similar manner to tobacco smoking. Please review Public Health Code Sections 19(N) and 19(F) and note that DPH is responsible for regulating such activity.

In regards to packaged drinks and snacks (food handling) being sold on the same premises as the Tobacco Paraphernalia Establishment and hookah use, please note that DPH is responsible for regulating such activity.

In regards to whether the proposed hookah use would be considered a "cigar bar"; this use would be considered as part of the Tobacco Paraphernalia Establishment use.

APPEAL: If you believe this determination represents an error in interpretation of the Planning Code or abuse in discretion by the Zoning Administrator, an appeal may be filed with the Board of Appeals within 15 days of the date of this letter. For information regarding the appeals process, please contact the Board of Appeals located at 1650 Mission Street, Room 304, San Francisco, or call (415) 575-6880.

Sincerely,



Scott F. Sanchez
Zoning Administrator

cc: Marcelle Boudreaux, Planner
Business Contacts: *Owner* - Cong Phuong Nguyen (948 Moscow St, San Francisco, CA 94112);
Manager - Blake He (blakehe@gmail.com)
Property Owner: Timoleon and Corinne Zaracotas
Neighborhood Groups

Chris Phung, Business Owner
1910 Ocean Ave (Linda's Ocean Nails)

Re: Support for Happy Vape, 1963 Ocean Avenue, Conditional Use Permit
Application

Dear Ms Chris Phung,

I urge you to support the conditional use permit application for 1963 Ocean Avenue for the following reasons:

- 1.) The project will fill a vacancy with a retail store, which will provide more pedestrian traffic to the Ocean Avenue Corridor;
- 2) The establishment is an upscale electronic vaporizer retail and steam stone hookah lounge that will be adult only and most of the activities will be in the sub-level and outdoor patio. It eliminate the impact on the people that walks by the establishment.
- 3.) The new social activity of sharing a common experience brings people together and creates an opportunity for people to connect and interact;
- 4.) The project aims to provide alternatives to smoking.
- 4.) The establishment will not be a smokeshop and it will not sell tobacco products or paraphernalia such as rolling papers, doobie clips, scales, drug kits, bongs and other assorted paraphernalia.



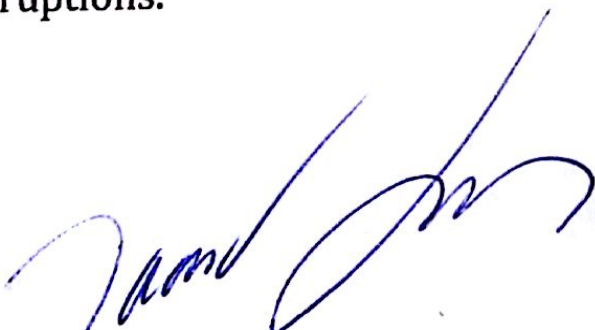
Fog Lifter, Business Owner
1901 Ocean Ave (Fog Lifter Cafe)

Re: Support for Happy Vape, 1963 Ocean Avenue, Conditional Use Permit Application

Dear Fog Lifter Owners,

I urge you to support the conditional use permit application for 1963 Ocean Avenue for the following reasons:

- 1.) The establishment will provide an alternative to smoking;
- 2.) The project will fill a vacancy with a retail store, which will provide more pedestrian traffic to the Ocean Avenue Corridor;
- 3.) The new social activity of sharing a common experience brings people together and creates an opportunity for people to connect and interact;
- 4.) The establishment will not be a smokeshop and it will not sell tobacco products or paraphernalia such as rolling papers, doobie clips, scales, drug kits, bongs and other assorted paraphernalia.
- 5.) The establishment will have carbon coal filter in the Steam Stone Hookah lounge to eliminate odor emissions.
- 6.) The establishment will have a tent over the outdoor patio sample vaping area to reduce disruptions.


Fog Lifter Cafe
9/17/2014

Gary, Business Owner
393 Ashton Ave (Ingleside Barber shop)

Re: Support for Happy Vape, 1963 Ocean Avenue, Conditional Use Permit Application

Dear Mr. Gary,

I urge you to support the conditional use permit application for 1963 Ocean Avenue for the following reasons:

- 1.) The project will fill a vacancy with a retail store, which will provide more pedestrian traffic to the Ocean Avenue Corridor;
- 2.) The establishment will not be a smokeshop and it will not sell tobacco products or paraphernalia such as rolling papers, doobie clips, scales, drug kits, bonges and other assorted paraphernalia;
- 3.) The establishment is an upscale electronic vaporizer retail and steam stone hookah lounge that will be adult only;
- 4.) The establishment will have carbon coal filter in the lounge to eliminate odor emissions.

Mary J. Linnard

Helen He, Business Owner

1930 Ocean Ave (Helen Beauty Skin Care)

Re: Support for Happy Vape, 1963 Ocean Avenue, Conditional Use Permit Application

Dear Ms He,

I urge you to support the conditional use permit application for 1963 Ocean Avenue for the following reasons:

- 1.) The establishment will provide an alternative to smoking;
- 2.) The project will fill a vacancy with a retail store, which will provide more pedestrian traffic to the Ocean Avenue Corridor;
- 3.) The establishment will not be a smokeshop.
- 4.) The business can in theory help reduce cigarette butts in the neighborhood.
- 5.) The establishment is an upscale electronic vaporizer retail and steam stone hookah lounge.
- 6.) Everything that will be vaped or smoked in the establishment are tobacco free and nicotine free, it will not have carcinogens.

A handwritten signature in black ink, appearing to be "Helen He", written in a cursive style.

JJ, Business Owner
1907 Ocean Ave (Cut to Contrast Barbershop)

Re: Support for Happy Vape, 1963 Ocean Avenue, Conditional Use Permit
Application

Dear Mr. JJ,

I urge you to support the conditional use permit application for 1963 Ocean Avenue for the following reasons:

- 1.) The establishment will provide an alternative to smoking;
- 2.) The project will fill a vacancy with a retail store, which will provide more pedestrian traffic to the Ocean Avenue Corridor;
- 3.) With the on site "vaping" component in the outdoor patio area, it will allow patrons to taste and sample various flavors in order to make an informed product purchase;
- 4.) The new social activity of sharing a common experience brings people together and creates an opportunity for people to connect and interact;
- 5.) The establishment will not be a smokeshop and it will not sell tobacco products or paraphernalia such as rolling papers, doobie clips, scales, drug kits, bongs and other assorted paraphernalia;
- 6.) The establishment is an upscale electronic vaporizer retail and steam stone hookah lounge that will be adult only and most of the activities will be in the sub-level and outdoor patio. It eliminate the impact on the people that walks by the establishment.



JERRY TUPAS

JULY 29, 2014


Joey Cassina, Business Owner
Ocean Avenue Tattoo
1907 Ocean Ave

Re: Support for Happy Vape, 1963 Ocean Avenue, Conditional Use Permit
Application

Dear Mr. Cassina:

I urge you to support the conditional use permit application for 1963 Ocean Avenue
for the following reasons:

- 1.) The establishment will provide a healthy alternative to smoking;
- 2.) The project will fill a vacancy with a retail store, which will provide more
pedestrian traffic to the Ocean Avenue Corridor;
- 3.) The new social activity of sharing a common experience brings people together
and creates an opportunity for people to connect and interact.


JOEY
CASSINA
OCEAN
AVENUE
TATTOO
7/24/14

Johnston Yau
Legend Billiards
1948 Ocean Ave
San Francisco, CA 94127
(415) 335-9228
yaujs@hotmail.com

August 5th 2014

Blake He
Happy Vape
1963 Ocean Ave
San Francisco, CA 94127
(415) 513-2620

Dear Mr. Blake He,

Thank you for contacting me with your business proposal to open an electronic vaporizer retail store and steaming stone hookah lounge. After watching your presentation at the meeting of the Ingleside Association, I am convinced that your business will do well at the desired location. Rest assured that you have our full support.

Good Luck!

Sincerely yours,


Johnston Yau

Mr. Larry & Mr. Rory, Business Owner
Bay Area Gold & Silver (Neighbor to the right)

Re: Support for Happy Vape, 1963 Ocean Avenue, Conditional Use Permit
Application

Dear Mr. Larry & Mr. Rory:

I urge you to support the conditional use permit application for 1963 Ocean Avenue
for the following reasons:

- 1.) We will have security cameras surveillance and we will be the extra sets of eyes
and ears for the neighborhood. Increase security.
- 2.) Bring a new culture to the ocean ave corridor .



LARRY LI

7/8/14

Li Zhi Song, Business Owner
Ocean Acupuncture and Health Center (neighbor to doors to the left)

Re: Support for Happy Vape, 1963 Ocean Avenue, Conditional Use Permit
Application

Dear Ms. Li Zhi Song

I urge you to support the conditional use permit application for 1963 Ocean Avenue for the following reasons:

- 1.) The establishment will provide a healthy alternative to smoking;
- 2.) The project will fill a vacancy with a retail store, which will provide more pedestrian traffic to the Ocean Avenue Corridor;
- 3.) The new social activity of sharing a common experience brings people together and creates an opportunity for people to connect and interact.

Li Zhi Song

Manual De Vera, Business Owner
1735 Ocean Ave (Allstate)

Re: Support for Happy Vape, 1963 Ocean Avenue, Conditional Use Permit Application

Dear Mr. De Vera,

Please support the conditional use permit application for 1963 Ocean Avenue for the following reasons:

- 1.) The establishment will provide a healthy alternative to smoking;
- 2.) The establishment will not be a smokeshop and it will not sell tobacco products or paraphernalia such as rolling papers, doobie clips, scales, drug kits, bongs and other assorted paraphernalia;
- 3.) The project will fill a vacancy with a retail store on the street that has 5 vacancies and 2 storefronts that are used as storage, which will bring more traffic and new economic interest into the neighborhood;
- 4.) The business will create 3-4 jobs;
- 5.) Everything that will be vaped or smoked in the establishment are tobacco free and nicotine free, it will not have carcinogens.

A handwritten signature in black ink, appearing to read "M. De Vera", is located in the lower right quadrant of the page. The signature is fluid and cursive, with a large initial "M" and a long, sweeping underline.



October 23, 2014

Marcelle Boudreaux

Re: Happy Vap/Blake He

Dear Marcelle,

I was approached by Blake He to write a letter stating that I had spoken to my Board of Directors regarding support for his potential business, Happy Vap. My board voted and we've decided to stay neutral at this time. We respect Blake's entrepreneurial spirit and his desire to occupy a space on Ocean Avenue, but we feel as an Arts and Culture non-profit, we would not be able to contribute or collaborate effectively with a business of this nature. Our mission statement is to collaborate with other organizations that promote the arts in the OMI.

We wish him luck with his endeavors and look forward to supporting possible projects or business in the future.

Sincerely,

Maria Fe Picar
The OMI Cultural Participation Project
Executive Director

Ray, Kevin, Kelvin, Business Owners

1725 Ocean Ave (Midas Collection)

Re: Approval for 1963 Ocean Avenue "Happy Vape" Conditional Use Permit Application

Dear Commissioners:

Please approve the conditional use permit application for 1963 Ocean Avenue for the following reasons:

- 1.) The establishment will provide an alternative to smoking.
- 2.) The project will fill a vacancy with a retail store on the street that has 7 vacancies, which will bring more traffic and new economic interest into the neighborhood
- 3.) The business will create 4 new jobs.
- 4.) With the on site "vaping" component in the outdoor patio area, it will allow patrons to taste and sample various flavors in order to make an informed product purchase.
- 5.) The establishment will have an awning over the outdoor patio sample vaping area to reduce disruptions.



Ben Li Business owner.

Mr. Ye, Business Owner

~~1900 Ocean Ave (Pho Ha Tien)~~

395 Ashton Ave. (E-C Mart) Y.F

Re: Support for Happy Vape, 1963 Ocean Avenue, Conditional Use Permit Application

Dear Mr. Ye,

我願意支持1963 Ocean Avenue conditional use permit的申請, 而原因有幾個:

- 1.) 該商店將會提供非香煙的產品選擇
- 2.) 該計畫將會採用一個Ocean Avenue上空了很久的商業埔位, 而且還會有助增加稍費者到這段的Ocean Avenue
- 3.) 這計畫是一個高尚的電子煙店及steam stone lounge的概念, 而針對的客戶群全都是已成年的人, 並不會批准或容許未滿18歲的青年在店內
- 4.) 這商店已計畫使用靜炭過濾器來確保店裡排出的空氣不會帶有味道而影響論居

Yi Feng Ye



Ocean Avenue Association
1728 Ocean Ave PMB 154
San Francisco, CA 94112

October 20, 2014

Marcelle Boudreaux
San Francisco Department of City Planning
marcelle.boudreaux@sfgov.org
415..575.9140

Dear Marcelle,

The Ocean Avenue Association supports Mr. Blake He's proposal to open the Happy Vape on Ocean Avenue.

The OAA's decision to support the Happy Vape conditional use application should not be construed as an endorsement of the applicant's chosen business nor its compatibility with the surrounding neighborhood. The Board has no position on the matters of public policy raised by members of the community with regard to the nature of the applicant's business. We do not doubt the sincerity of those views. The OAA's purview, however, does not extend to making choices among lawful business that otherwise comply with the City's licensing and regulatory process.

OAA's support is based on the board's view that Happy Vape's operations are consistent with the objectives of the OAA to promote vibrant business along the Ocean Avenue commercial corridor. The management team has shown a commitment to supporting the Ocean Avenue retail district and improving the cleanliness and safety of the commercial area. The OAA board also believes that Mr. He is receptive to the concerns and input of neighbors.

Please contact me if your have questions about this recommendation.

Daniel Weaver
Executive Director

Randy Tagle, Renowned Barber
Cut To Contrast Barbershop
1907 Ocean Ave (b/t Ashton Ave & Keystone Way)

Re: Support for Happy Vape, 1963 Ocean Avenue, Conditional Use Permit
Application

Dear Mr. Tagle:

I urge you to support the conditional use permit application for 1963 Ocean Avenue
for the following reasons:

- 1.) The establishment will provide a healthy alternative to smoking;
- 2.) The project will fill a vacancy with a retail store, which will provide more
pedestrian traffic to the Ocean Avenue Corridor;
- 3.) The new social activity of sharing a common experience brings people together
and creates an opportunity for people to connect and interact.

 7/24/14

Reverend Roland Gordon, Pastor & OAA Board Member
1345 Ocean Ave (Ingleside Presbyterian Church)

Re: Support for Happy Vape, 1963 Ocean Avenue, Conditional Use Permit Application

Dear Reverend Gordon,

Please support the conditional use permit application for 1963 Ocean Avenue for the following reasons:

- 1.) The establishment will provide a healthy alternative to smoking;
- 2.) The project will fill a vacancy with a retail store on the block with five vacancies, which will provide more pedestrian traffic to the Ocean Avenue Corridor;
- 3.) The business will create two - three more jobs;
- 4.) With the on site "vaping" component in the outdoor patio area, it will allow patrons to taste and sample various flavors in order to make an informed product purchase;
- 5.) The establishment will not be a smokeshop and it will not sell tobacco products or paraphernalia such as rolling papers, doobie clips, scales, drug kits, bongos and other assorted paraphernalia;
- 6.) The establishment is an upscale electronic vaporizer retail and steam stone hookah lounge that will be adult only and most of the activities will be in the sub-level and outdoor patio. It eliminate the impact on the people that walks by the establishment;
- 7.) The establishment will have a tent over the outdoor patio sample vaping area to reduce disruptions;
- 8.) Everything that will be vaped or smoked in the establishment are tobacco free and nicotine free, it will not have carcinogens.

Sincerely,
Blake He

Blake,
you have my support. Blessings!

"Rev. G."

Sherri Stratton, Business Owner
Serge-A-Lot
1949 Ocean Ave

Re: Support for Happy Vape, 1963 Ocean Avenue, Conditional Use Permit
Application

Dear Ms. Stratton:

I urge you to support the conditional use permit application for 1963 Ocean Avenue for the following reasons:

- 1.) The establishment will provide a healthy alternative to smoking;
- 2.) The project will fill a vacancy with a retail store, which will provide more pedestrian traffic to the Ocean Avenue Corridor;
- 3.) The business will create two - three more jobs;
- 4.) With the on site "vaping" component in the outdoor patio area, it will allow patrons to taste and sample various flavors in order to make an informed product purchase;
- 5.) The new social activity of sharing a common experience brings people together and creates an opportunity for people to connect and interact.



7-24-14

Tim Zaracotas, Business Owner
Aster Travel (Neighbor to the left)

Re: Support for Happy Vape, 1963 Ocean Avenue, Conditional Use Permit
Application

Dear Mr. Zaracotas:

I urge you to support the conditional use permit application for 1963 Ocean Avenue
for the following reasons:

- 1.) The establishment will provide a healthy alternative to smoking;
- 2.) The project will fill a vacancy with a retail store, which will provide more
pedestrian traffic to the Ocean Avenue Corridor.

This is to confirm that I do
support the opening of the
Happy Vape, my next door to my
business of Aster Travel Inc. -

S.F. 7-8-14

Tim C. Zaracotas

Tito Nuila, Business Owner
1719 Ocean Ave (Daytona Auto Body Shop)

Re: Support for Happy Vape, 1963 Ocean Avenue, Conditional Use Permit Application

Dear Mr. Nuila,

Please support the conditional use permit application for 1963 Ocean Avenue for the following reasons:

- 1.) The establishment will provide a healthy alternative to smoking;
- 2.) The project will fill a vacancy with a retail store, which will provide more pedestrian traffic to the Ocean Avenue Corridor;
- 3.) With the on site "vaping" component in the outdoor patio area, it will allow patrons to taste and sample various flavors in order to make an informed product purchase;
- 4.) The establishment will not be a smokeshop and it will not sell tobacco products or paraphernalia such as rolling papers, doobie clips, scales, drug kits, bongs and other assorted paraphernalia;
- 5.) The establishment is an upscale electronic vaporizer retail and steam stone hookah lounge that will be adult only and most of the activities will be in the sub-level and outdoor patio. It eliminates the impact on the people that walk by the establishment;
- 6.) Everything that will be vaped or smoked in the establishment are tobacco free and nicotine free, it will not have carcinogens.

TITO nuila

Tom Phan, Business Owner
1947 Ocean Avenue

Re: Support for Happy Vape, 1963 Ocean Avenue, Conditional Use Permit
Application

Dear Mr. Phan:

I urge you to support the conditional use permit application for 1963 Ocean Avenue for the following reasons:

- 1.) The establishment will provide a healthy alternative to smoking;
- 2.) With the on site "vaping" component in the outdoor patio area, it will allow patrons to taste and sample various flavors in order to make an informed product purchase;
- 3.) The project will fill a vacancy with a retail store, which will provide more pedestrian traffic to the Ocean Avenue Corridor;
- 4.) The new social activity of sharing a common experience brings people together and creates an opportunity for people to connect and interact.

Tom Phan

7-24-14


Walee Gon, Business Owner & OAA Board Member
545 Faxon Ave (Faxon Garage)

Re: Support for Happy Vape, 1963 Ocean Avenue, Conditional Use Permit Application

Dear Mr. Gon,

Please support the conditional use permit application for 1963 Ocean Avenue for the following reasons:

- 1.) The establishment will provide a healthy alternative to smoking;
- 2.) The project will fill a vacancy with a retail store on the street that has 5 vacancies and 2 storefronts that are used as storage, which will bring more traffic and new economic interest into the neighborhood;
- 3.) The business will create 3-4 jobs;
- 4.) With the on site "vaping" component in the outdoor patio area, it will allow patrons to taste and sample various flavors in order to make an informed product purchase;
- 5.) The establishment will not be a smokeshop and it will not sell tobacco products or paraphernalia such as rolling papers, doobie clips, scales, drug kits, bongs and other assorted paraphernalia;
- 6.) The establishment will have carbon coal filter in the lounge to eliminate odor emissions;
- 7.) The establishment will have a tent over the outdoor patio sample vaping area to reduce disruptions;
- 8.) Everything that will be vaped or smoked in the establishment are tobacco free and nicotine free, it will not have carcinogens.


Walee Gon 7/29/14

Mr. Louie and Ms. Louie, Business Owner
Dri-Clean Express (Neighbor 2 doors to the right)

Re: Support for Happy Vape, 1963 Ocean Avenue, Conditional Use Permit
Application

Dear Mr. Louie & Ms. Louie:

I urge you to support the conditional use permit application for 1963 Ocean Avenue for the following reasons:

- 1.) The project will fill a vacancy with a retail store, which will provide more pedestrian traffic to the Ocean Avenue Corridor;
- 2.) The new social activity of sharing a common experience brings people together and creates an opportunity for people to connect and interact.

A handwritten signature in black ink, consisting of a series of loops and a long horizontal stroke extending to the right.

We were asked that “With four other stores selling electronic cigarettes, why should you be here?”

- We offer a unique experience and services to the neighbors and the people of San Francisco that no other stores are offering.
- We are not only providing products for sale, but a unique experience for our patrons whether it be shopping, relaxing in the lounge or trying flavors in the outdoor sampling area, bringing people together to create greater economic interest to the area.
- We are the only store in the area dedicated to only e-cigarettes.
- Any and all persons under 18 will be removed from the premise.
- Our mission is to provide products that will help cigarette smokers reduce their nicotine intake levels gradually, that is an appealing replacement for traditional cigarettes.
- We carry a much wider selection and better quality products than the liquor stores in the area.
- We are not just selling e-cigarettes just as another item, each and every item is tested personally by the staff to deem whether it is qualified to be on the shelf or not.
- We are planning for incentive programs to encourage customers trying to quit cigarettes stay on track.
- We provide our patrons with information and demonstrations on safe handling and upkeep of various products to ensure their safety.
- The Steam Stone Hookah lounge is also an integral part of our business plan and is one of few in existence in the city.
- The other stores are 3 liquor store and a 7-Eleven, electronic cigarettes are accessory sales for these stores. Anyone could go into these stores including kids and they get exposed to cigarettes along with electronic cigarettes because the stores put them in the same area. Kids associate the electronic cigarettes with traditional cigarettes and that could really confuse kids.

Liquor Stores and Vape Stores In the area:

Homrun Liquors

1551 Ocean Ave, San Francisco, CA 94112 (0.3 mile away)

Wiley's Liquor

1015 Ocean Ave, San Francisco, CA 94112 (0.6 mile away)

A & N Liquor

1521 Ocean Ave, San Francisco, CA 94112 (0.3 mile away)

7-Eleven

2000 Ocean Ave, San Francisco, CA 94127

Juicebox Vapor

Parkside

907 Taraval St, San Francisco, CA 94116

1.7 miles away from 1963 Ocean Ave.

Dream Cloud Vapors

Excelsior

4971 Mission St, San Francisco, CA 94112

1.6 miles away from 1963 Ocean Ave.

Boudreaux, Marcelle (CPC)

From: Donna Howe <donna.howe@comcast.net>
Sent: Thursday, May 15, 2014 2:24 AM
To: Boudreaux, Marcelle (CPC)
Subject: Opposition to proposed permit for 1963 Ocean Ave

Follow Up Flag: Flag for follow up
Flag Status: Flagged

To: Marcelle Boudreaux
From: Donna Howe, 85 Entrada Court

Message:

I am a long time resident of the Ingleside Terraces. I am the third generation of our family to have lived at Entrada Court, and my son and his family are the fourth and fifth generations and currently reside nearby on Urbano Drive. That being said, **I wish to voice my strong opposition to the permit application reference the establishment of a business offering tobacco paraphernalia at the vacant retail space at 1963 Ocean Avenue.**

There are several schools (Commodore Sloat Elementary School, St. Francis Preschool, Stratford Academy, Voice of Pentecost Academy, Aptos Junior HS, and Lick-Wilmerding) nearby. I have serious concerns about the negative social and health impact a tobacco shop will have on the neighborhood.

There are already several cannabis dispensaries along the Ocean Ave. corridor between Junipero Serra and Howth. So far, the city has not seen fit to honor the wishes of our neighbors by failing to discourage the clustering of dispensaries; **if a tobacco shop were to be permitted to open and operate nearby it would be a clear indication that "the City" Planning Department does not support efforts to draw residents and family-friendly businesses to our historic neighborhood.**

For a number of years I maintained a residence in the east bay city of Fremont. The Smoke Shop there was a constant source of problems in the Niles District. That was in the days before ecigarettes, so it was full of such products as rolling papers, "doobie clips", scales, drug kits, bonges, and other assorted tobacco paraphernalia.

Establishing a similar business on Ocean Avenue can only bring negative outcomes that will far outweigh the generation of any commercial revenue for this city that I love. It would be naive to think the proposed business would offer only ecigarettes, cigarettes, cigars, snuff, chew and loose tobacco, all of which, I believe, are easily procured at a variety of other locations. There is no need for such a business in our neighborhood. Although I am sure it would be popular with college students from City College of San Francisco and San Francisco State University, it would also be a distraction from their educational pursuits and not likely to be popular with their parents.

I hope my work schedule will permit me to attend any community outreach meetings regarding this proposal, but I do wish to go on record now with the Planning Commission as being opposed to permitting the proposed business.



Blake He <blakehe@gmail.com>

1963 Ocean Ave

Blake He <blakehe@gmail.com>

Thu, Jul 31, 2014 at 11:24 PM

To: donna.howe@comcast.net

Dear Ms. Howe:

Your correspondence of May 15, 2014 to Planner Marcelle Boudreaux regarding my project at 1963 Ocean Avenue has just been forwarded to me. I appreciate your input and would like to mitigate your concerns.

I, too, have a vested interest in the Ocean Avenue community. I live in the area, went to school in the area and actually immigrated directly to the area with my family as a child. Now I am raising my own child in the neighborhood.

Many people misunderstand vape shops and think they are also "head" shops, marijuana dispensaries and/or tobacconists, which is not the case especially in my situation.

I was once a heavy smoker and e-cigarettes have helped me reduce my smoking enormously. As the father of a toddler they have further benefitted me and my family by providing a smoke free environment for my son to grow up in. I am very conscious of a healthy environment, have been a swimming coach, and curse the day I started smoking. Now I am grateful for vaping and know many others who feel the same way. Vaping is leading them and me to a healthier life style, one that eventually will be totally free of tobacco.

Rest assured the products that will be available in my store, as well as the sample vaping in the outdoor area, will not contain nicotine nor carcinogens. It is because of my own concern for healthy living that I want to start this business.

We will not be selling to children and there will be signs posted throughout our space saying that no one under 18 will be allowed in. We will also have a well-trained staff.

Happy Vape, which is to be the name of my business, is in the business of *harm reduction*. We have no intention of selling snuff, rolling papers, doobie clips, scales, drug kits, bongs and other tobacco and drug paraphernalia. We do not want to create problems; we want to help solve problems and I do not understand how my business would be a distraction from educational pursuits for students from SF State and City College.

There are many vacancies along Ocean Avenue and my goal is to fill one of them. I will be happy to share my business plan with you if that would be helpful and can forward that via e-mail.

I am available to meet with you any time that is convenient and, as I said, am happy to forward my business plan should you deem that necessary.

Blake He

Happy Vape

Electronic vaporizer retail &
Steaming stone hookah lounge
(415)513-2620
1963 Ocean Ave.
San Francisco, CA 94127



Blake He <blakehe@gmail.com>

1963 Ocean Ave

Donna Howe <donna.howe@comcast.net>

Fri, Aug 1, 2014 at 3:06 PM

To: Blake He <blakehe@gmail.com>

Thanks for your reply and the clarification. I have forwarded it to the participants in the Ingleside Terrace googlegroup. I do not need to see your business plan but appreciate your transparency.

Donna Howe

[Quoted text hidden]



Blake He <blakehe@gmail.com>

1963 Ocean Ave

Blake He <blakehe@gmail.com>

Thu, Jul 31, 2014 at 11:15 PM

To: sfwendy@gmail.com

Dear Wendy:

Your e-mail of May 10, 2014 to Planner Marcelle Boudreaux regarding my project as 1963 Ocean Avenue was forwarded to me.

First of all thank you for taking the time to express your concerns.

Rest assured the products that will be available, as well as the sample vaping in the outdoor area, will not contain nicotine nor carcinogens. It is because of my own concern for healthy living that I want to start this business.

We will not be selling to children and there will be signs posted throughout saying that no one under 18 will be allowed in. We will also have a well-trained staff.

With regard to the marijuana dispensaries and tattoo parlors, it is a matter of choice as to whether or not to patronize those businesses just as it is to patronize a vaping store.

I was once a heavy smoker and this product has helped me reduce my smoking enormously. As the father of a toddler it has further benefitted me and my family by providing a smoke free environment for my son to grow up in. I am very conscious of a healthy environment, have been a swimming coach, and curse the day I started smoking. Now I am grateful for vaping and know many others who feel the same way. Vaping is leading them and me to a healthier life style, one that eventually will be totally free of tobacco.

I commend you for a healthy lifestyle. I simply want to provide an alternative to smoking. Many people have said it has helped and we don't want to ignore those people who find vaping works.

If you would like additional information, we could meet or discuss this further through e-mails.

Thank you.

Blake He

Happy Vape

Electronic vaporizer retail &
Steam stone hookah lounge
(415)513-2620
1963 Ocean Ave.
San Francisco, CA 94127

Boudreaux, Marcelle (CPC)

From: Wendy Portnuff <sfwendy@gmail.com>
Sent: Saturday, May 10, 2014 3:44 PM
To: Boudreaux, Marcelle (CPC)
Subject: Conditional Use Permit for Tobacco Paraphanalia at 1963 Ocean Avenue

Dear Ms. Boudreaux,

I live in Ingleside Terraces, which is adjacent to the location above on Ocean Avenue. Furthermore, I walk past the location almost daily. I object strongly to the introduction of Tobacco Products to this part of our neighborhood. These electronic cigarettes are highly suspect for health reasons. They contain known carcinogens. I do not wish to be exposed to them, and I do not want them to be readily available to neighborhood youth in this part of the city. It's bad enough that there are marijuana stores and tatoo parlors here. Please do not approve yet another storefront that challenges our ability to remain healthy and to be role models for our children.

Wendy Portnuff
The Professional Woman's Guide to Healthy Travel
www.wendypornuff.com
415-269-4398



Blake He <blakehe@gmail.com>

1963 Ocean Ave

Blake He <blakehe@gmail.com>

Thu, Jul 31, 2014 at 11:19 PM

To: board@westwoodpark.com

Dear Ms. Favetti:

Your July 3 letter on behalf of the Westwood Park Association regarding my project at 1963 Ocean Avenue has just been forwarded to me by planner Marcelle Boudreaux.

Like you and your members I, too, have a vested interest in the Ocean Avenue community. I live in the area, went to school in the area and actually immigrated directly to the area with my family as a child. Now I am raising my own child in the neighborhood.

There are many vacancies along Ocean Avenue and my goal is to fill one of them. I will be happy to share my business plan with you if that would be helpful and can forward that via e-mail. Ideally, I would like an opportunity to present to your association at one of your meetings.

Many people misunderstand vape shops and think they are also "head" shops and/or tobacconists, which is not always the case.

I was once a heavy smoker and e-cigarettes have helped me reduce my smoking enormously. As the father of a toddler they have further benefitted me and my family by providing a smoke free environment for my son to grow up in. I am very conscious of a healthy environment, have been a swimming coach, and curse the day I started smoking. Now I am grateful for vaping and know many others who feel the same way. Vaping is leading them and me to a healthier life style, one that eventually will be totally free of tobacco.

Rest assured the products that will be available in my store, as well as the sample vaping in the outdoor area, will not contain nicotine nor carcinogens. It is because of my own concern for healthy living that I want to start this business.

We will not be selling to children and there will be signs posted throughout our space saying that no one under 18 will be allowed in. We will also have a well-trained staff.

Happy Vape, which is to be the name of my business, is in the business of **harm reduction**. Based on this perhaps we can start a fresh dialog that will allow me to present directly to your association.

I look forward to hearing from you.

Blake He

Happy Vape

Electronic vaporizer retail &
Steam stone hookah lounge
(415)513-2620
1963 Ocean Ave.
San Francisco, CA 94127



Blake He <blakehe@gmail.com>

1963 Ocean Ave

r and k favetti <woloso1@yahoo.com>

Thu, Aug 7, 2014 at 7:49 PM

To: Blake He <blakehe@gmail.com>

Cc: Marcelle.Boudreaux@sfgov.org, Dan Weaver <info.oacbd@gmail.com>

Dear Mr. He,

The Westwood Park Board has thoroughly reviewed your email dated July 31, 2014 and has not changed its position. I have attached our letter for reference.

Sincerely,
Kate Favetti, President
Westwood Park Association

On Thu, 7/31/14, Blake He <blakehe@gmail.com> wrote:

Subject: 1963 Ocean Ave
To: board@westwoodpark.com
Date: Thursday, July 31, 2014, 11:19 PM

Dear Ms.

Favetti:

Your July 3 letter on behalf of the Westwood Park Association regarding my project at 1963 Ocean Avenue has just been forwarded to me by planner Marcelle Boudreaux.

Like

you and your members I, too, have a vested interest in the Ocean Avenue

community. I live in the area, went to school in the area and actually

immigrated directly to the area with my family as a child.

Now I am

raising my own child in the neighborhood.

There

are many vacancies along Ocean Avenue and my goal is to fill one of

them. I will be happy to share my business plan with you if that would

be helpful and can forward that via e-mail. Ideally, I would like an

opportunity to present to your association at one of your meetings.

Many people misunderstand vape shops and think they are also "head" shops and/or tobacconists, which is not always the case.

I

was once a heavy smoker and e-cigarettes have helped me

WESTWOOD PARK



July 3, 2014

Marcelle Boudreaux, AICP
Planner, Southwest Quadrant
Planning Department, City and County of San Francisco
1650 Mission Street, Suite 400, San Francisco, CA 94103

RE: Letter of Opposition – Vaporizer Lounge and Store located at 1963 Ocean Avenue

Dear Ms. Boudreaux,

I am writing on behalf of the Westwood Park Association Board in opposition to the proposed vaporizer lounge and store at 1963 Ocean Avenue.

Members of our diverse communities surrounding Ocean Avenue have been working for many years to revitalize Ocean Avenue and to attract much needed neighborhood businesses and services to the Ocean Avenue retail corridor. We recently had a number of community meetings on the Ocean Avenue Corridor where residents were asked about what businesses and services they wanted to see on the Ocean Avenue. I can assure you that a vaporizer lounge and store was *not* on the list. By way of reference, the Planning Department representative on this effort is Lily Langlois.

It is our understanding that e-cigarette smoking devices and cartridges as well as nicotine cartridges will be sold, and, there will be a smoking lounge with vaporizing devices for smoking. Food, music and videos/movies will be shown in the lounge area to attract customers.

Currently, we have 4 locations where e-cigarettes and nicotine products are sold – 7-Eleven, Homrun, A&N Liquors, and No Limit – more than adequate for this area. Although the business owners have indicated that smoking nicotine will not be allowed on the premises, enforcement will be difficult.

We have precious few store fronts for the size of our neighborhoods. A vaporizer lounge and store does not propel our revitalization efforts forward nor does it provide the much needed and requested businesses and services to benefit our community.

I am joined by the Westwood Park Association Board members Kathy Beitiks, Anne Chen, Greg Clinton, Tim Emert, Caryl Ito and Anita Theoharis in opposing the proposed vaporizer lounge and store at 1963 Ocean Avenue.

Sincerely,

A handwritten signature in cursive script, appearing to read "Kate Favetti".

Kate Favetti, President
Westwood Park Association



Blake He <blakehe@gmail.com>

1963 Ocean Ave(Happy Vape)

Blake He <blakehe@gmail.com>
To: staceyinteractive@gmail.com

Wed, Oct 22, 2014 at 7:09 PM

Dear Mr. Stacey,


I am send you a fact sheet regarding our project. Our business plan is well thought out and has been shared with the community over a nine month period. Our benefits far outweigh any possible negative impacts. Please contact me so I may share with you our vision for providing synergy to this desolate area the city refers to as a "Dead Block". Thank you very much.

Blake He

Happy Vape

Electronic vaporizer retail &
Steam stone hookah lounge
(415)513-2620
1963 Ocean Ave.
San Francisco, CA 94127

2 attachments

 **Fact Sheet.pdf**
709K

 **Happy Vape Business Plan.docx**
41K

From: John Stacey
To: Boudreaux, Marcelle (CPC); Yee, Norman (BOS); Secretary, Commissions (CPC)
Subject: 1963 Ocean Avenue Vape Shop
Date: Monday, October 20, 2014 8:47:39 AM

I am writing to let you know of my opposition to the proposed Vape Shop, requesting to be located at 1963 Ocean Ave in San Francisco.

My reasons are fairly straight-forward:

- Ocean Avenue merchants appear to be moving in without much interest from the city on what the street is *becoming*. There are two relatively new tattoo parlors, about six nail shops, at least three massage parlors, two marijuana distributors, a bong shop, and (wait for it...) soon to be a VAPE shop!
- The neighbors deserve better. The (few) upstanding merchants on the street deserve better. Our community deserves better than having our main street turn into San Francisco's location for cheap sex, legal drugs, and various inhaled stimulants
- I realize I probably sound like a staunchy old republican, but I'm not: I am a 47 year old democrat - and own a home just off of Ocean. We have two teen-aged children that walk and drive through the "circus" daily. My wife and I call Ocean "Bangkok."
- In the 15 years that we've lived in our house, we've seen crime rise (including a shooting about 100 yards from this proposed shop). We've seen fast food litter pile up. We've seen drunken and disorderly behavior. We hear the subwoofers. We listen to the sounds of inebriates fighting on the sidewalks.
- It should stop. The city of San Francisco owes it to the local residents to do it's job... and have a commercial zoning plan for Ocean that is more calculated than "we'll rent to anyone the law allows."
- We pay substantial property taxes, and we vote.
- Please carefully consider my plea, as well as those from the neighbors in the community.

I live at 25 Cerritos, and I oppose the permitting of the Vape Shop.

Thank you for your time.

John Stacey
mobile 415-218-3431



Blake He <blakehe@gmail.com>

1963 Ocean Ave(Happy Vape)

Blake He <blakehe@gmail.com>
To: dellabear88@gmail.com

Wed, Oct 22, 2014 at 7:05 PM

Dear Ms. Go,


Thank you for your interest in our project. However you may have some misinformation, I will send you a fact sheet with pertinent information regarding our project. We do not offer tobacco products. Our diversity of products and services will stimulate pedestrian traffic. The Vaping will be designated to our outdoor backyard area enclosed by a tent. Thus there is no need to cross the street because of any adverse impact caused by our establishment. If you have additional concerns please share them with me. Thank you very much.

Blake He

Happy Vape

Electronic vaporizer retail &
Steam stone hookah lounge
(415)513-2620
1963 Ocean Ave.
San Francisco, CA 94127

2 attachments

 **Fact Sheet.pdf**
709K

 **Happy Vape Business Plan.docx**
41K

From: [deftabear](#)
To: [Boudreaux, Marcelle \(CPC\)](#)
Subject: 1963 Ocean Ave - Conditional Use Permit Application -- Tobacco Paraphernalia
Date: Monday, October 20, 2014 10:21:06 AM

Thank you for the notice of public hearing for this project.

I reside at 50 Urbano Dr. I am opposed to this project. There are already plenty of shops on Ocean Ave offering tobacco, e-cigarettes, hookah, and medical marijuana. It is creating an atmosphere on Ocean Ave that is not conducive to pedestrian traffic or business. The smells make me cross the street. My children are uncomfortable walking along these blocks of Ocean Avenue.

Adrienne Go



Blake He <blakehe@gmail.com>

1963 Ocean Ave(Happy Vape)

Wed, Oct 22, 2014 at 7:35 PM

Blake He <blakehe@gmail.com>
 To: Robert Karis <rckaris2@gmail.com>

Dear Mr. Karis,

E-cigarette does not lead young people (20 something) to be addicted to nicotine or cigarette. "First Study to Examine E-Cigarette Gateway Hypothesis Can Find Only One Nonsmoker Who Initiated with E-Cigs and Went on to Smoke" is a study that directly counters the article you included from the CDC.

<http://tobaccoanalysis.blogspot.com.au/2013/10/first-study-to-examine-e-cigarette.html>

I am also curious and concerned about the vapors from e-cigarettes, so I did some research. The result of the research is that the vapors from e-cigarettes are far below the standard what scientists are consider as toxic. I have also included a research article that explored the long term effects of the vapors.

<http://www.healthnz.co.nz/E-CigsExhaledSmoke.htm>

http://clearstream.flavourart.it/site/wp-content/uploads/2012/09/CSA_ItaEng.pdf

<http://www.ncbi.nlm.nih.gov/pubmed/23033998#>

<http://tobaccocontrol.bmj.com/content/early/2013/03/05/tobaccocontrol-2012-050859.short>

<http://pubs.rsc.org/en/content/articlelanding/2014/em/c4em00415a#divAbstract>

<http://jpet.aspetjournals.org/content/91/1/52.abstract>

<http://www.biomedcentral.com/content/pdf/1471-2458-14-18.pdf>

<http://ntr.oxfordjournals.org/content/early/2013/12/10/ntr.ntt203.short?rss=1>

<http://www.ecigarette-research.com/web/index.php/2013-04-07-09-50-07/2014/167-no-ecigs>

We are in the business of **harm reduction**. Many surveys and researches shows that E-Cigarette is a great way for people to fight their cigarette addiction. Some researchers are saying that e-cigarettes are the most effective way of helping people quit smoking cigarettes.

<http://www.sciencedirect.com/science/article/pii/S0306460313003304>

<http://vaping.com/data/vaping-survey-2014-initial-findings>

<http://www.plosone.org/article/info:doi/10.1371/journal.pone.0103462>

<http://www.addictionjournal.org/press-releases/e-cigarette-use-for-quitting-smoking-is-associated-with-improved-success-rates->

<http://nicotinepolicy.net/documents/letters/MargaretChan.pdf>

<http://link.springer.com/article/10.1007/s11606-014-2889-7>

Sincerely,

Blake He

Happy Vape

Electronic vaporizer retail &
 Steam stone hookah lounge
 (415)513-2620
 1963 Ocean Ave.
 San Francisco, CA 94127

2 attachments

Fact Sheet.pdf
 709K

Happy Vape Business Plan.docx
 41K

From: Robert Karis
To: Boudreaux, Marcelle (CPC); Secretary, Commissions (CPC)
Cc: Yee, Norman (BOS); Low, Jen (BOS)
Subject: 1963 Ocean Avenue, Case No.: 2014.0206C
Date: Monday, September 22, 2014 10:43:56 AM

Dear Ms. Boudreaux,

The proposed Happy Vape store at 1963 is a Conditional Use, which means it has to demonstrate that it is necessary or desirable. This business is neither necessary or desirable.

I am opposed to the vape store for several reasons:

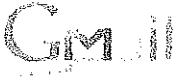
1) They are part of an effort by tobacco companies and others to addict young people, 20 somethings, to nicotine, which is a harmful substance
http://www.cdc.gov/media/releases/2014/p0825-e-cigarettes.html?s_cid=cdc_homepage_whatsnew_002 E-cigarette ads are targeted towards young people, as is easily demonstrated by googling images of e-cigarette ads.

2) The vapors from e-cigarettes can be harmful, even when they don't contain nicotine http://www.nytimes.com/2014/05/04/business/some-e-cigarettes-deliver-a-puff-of-carcinogens.html?_r=1
E-liquids use propylene glycol as a solvent. In ordinary usage, propylene glycol is safe. But when it is heated, as it is in e-cigarettes, propylene glycol is oxidized and gives rise to a variety of toxic substances, particularly formaldehyde in unsafe amounts. Some earlier studies reported only low doses of formaldehyde, but they may not have used a high enough voltage, 4.8 volts in this study. 4.8 volts is easily and frequently obtained with the devices sold in vape shops, as the higher voltage also results in more nicotine and more effect from the e-cigarette. It is not surprising that heating propylene glycol (P.G.) C₃H₈O₂ yields formaldehyde CH₂O, or, to show the chain structure of P.G.,: CH₂OH-CHOH-CH₃ + 2O₂ > 2CH₂O + 2H₂O + CO₂. In addition, e-cigarettes contain toxic metals and nanoparticles which result in disease causing inflammation.

3) E-cigarettes may be useful in a few cases as part of a comprehensive stop smoking program <http://www.cdc.gov/tobacco/campaign/tips/quit-smoking/> but the purpose of a stand alone vape shop is to to increase, not decrease, nicotine usage.

As the Planning Department and Commission have a duty to benefit our neighborhoods, I trust they will agree that a vape shop on Ocean Avenue is not necessary or desirable.

Yours truly,
Robert Karis
Ingleside Terraces



Blake He <blakehe@gmail.com>

1963 Ocean Ave(Happy Vape)

Blake He <blakehe@gmail.com>
To: drgeorgewumd@aol.com

Wed, Oct 22, 2014 at 7:07 PM

Dear Mr. Wu,


We are not vaping any nicotine on our premises. We have no affiliation with medical marijuana. Enclosed is a fact sheet of what we actually offer. Please feel free to contact us if you have any additional concerns. Thank you very much.

Blake He

Happy Vape

Electronic vaporizer retail &
Steam stone hookah lounge
(415)513-2620
1963 Ocean Ave.
San Francisco, CA 94127

2 attachments

 **Fact Sheet.pdf**
709K

 **Happy Vape Business Plan.docx**
41K

From: [George Wu](#)
To: [Boudreaux, Marcelle \(CPC\)](#)
Subject: Vape shops
Date: Saturday, October 18, 2014 7:00:15 PM

These Vape shops requesting conditional use permitting are neither necessary nor desirable. Addictive drugs including nicotine and marijuana have no place in family friendly neighborhoods.

What message are we sending to our children?!!!! Are our supervisors THAT desperate to find tax revenues?!!!!

George Wu, MD

Sent from my iPad

From: SMGraz2001@aol.com
To: [Boudreaux, Marcelle \(CPC\)](#); [Yee, Norman \(BOS\)](#); [Secretary, Commissions \(CPC\)](#)
Cc: smgraz2001@aol.com; calbearsph@gmail.com; rckaris@gmail.com; board@balboaterrace.org
Subject: 1963 Ocean Ave. Proposed Vape Shop
Date: Wednesday, October 22, 2014 12:45:54 PM

Hello SF Planning Commission, Mr. Norman Yee and Ms. Marcelle Boudreaux,

I would like to state my OPPOSITION to the proposed new Vape Shop at 1963 Ocean Ave. I realize that the Vape Shop is applying for a conditional use. At this point, I do not think that this type of business is necessary or desirable on Ocean Ave. corridor. E-Cigarettes can be purchased on Taraval and 19th Ave, which is quite close. On the health issue, E-Cigarettes contain nicotine and the vaporized byproducts include unhealthy chemicals, heavy metals and nanoparticles that accumulate in the lungs. Nicotine is addictive and habit forming. Ingestion of the non-vaporized concentrated ingredients in the cartridges can be poisonous.

There is a garden area in the back that the business wants to use for smokers. Homes are directly located on the other side of the fence. Is this fair to the neighbors?

Lastly, this proposed location is across from a school with children. So, I would appreciate your consideration in not approving this Vape Shop.

Sincerely, Susan Grazioli
Balboa Terrace Director



Blake He <blakehe@gmail.com>

1963 Ocean Ave (Happy Vape)

1 message

Blake He <blakehe@gmail.com>
To: linda.mcgilvray@gmail.com

Fri, Oct 24, 2014 at 3:53 AM

Dear Linda,

First and foremost we would like to thank you for the opportunity to present our business model to your organization. Current research indicates that e-cigarettes being harmful is inconclusive. The vaping component will be conducted in an enclosed tent in the outdoor activity area and therefore there is no adverse impact to worry about. Minors are not allowed on premise and we will not be doing external advertising, please be assured that many of your worries will not happen. Regarding the cluster of businesses needed to synergize that Ocean street corridor, we feel that we are part of the solution and not the problem. Our business model is sustainable, where many business have tried to open and have closed shortly after opening because of the lack of pedestrian traffic.

Please feel free to contact me in the future if you desire to do so.


Sincerely,

Blake He

Happy Vape

Electronic vaporizer retail &
Steam stone hookah lounge
(415)513-2620
1963 Ocean Ave.
San Francisco, CA 94127

2 attachments

 **Fact Sheet.pdf**
709K

 **Happy Vape Business Plan.docx**
41K

From: [Linda McGilvray](#)
To: [Boudreaux, Marcelle \(CPC\)](#)
Subject: Re: the Vape Shop at 1963 Ocean. . .
Date: Wednesday, October 22, 2014 5:56:43 PM

Dear Ms. Boudreaux,

The neighbors in Ingleside Terraces are very concerned about this proposed shop. It has been researched and found that these vapors and e cigarettes are not all that harmless to people. The neighbors with adjoining properties are certainly opposed to such activities that would pollute the air right outside the back of their homes. There also are a couple of private schools in the area that might be influenced by the wares. Trying to improve the quality of retail establishments on Ocean Avenue has been the focus, even though a few questionable shops have opened. Please consider the plight of the neighbors in considering licensing this shop.

Thanks for your consideration.

Linda McGilvray
Board member of ITHA
Oct. 22, 2014

From: Robert Karis
To: Boudreaux, Marcelle (CPC)
Cc: Yee, Norman (ROS); Secretary, Commissions (CPC)
Subject: 1963 Ocean Avenue, Case No.: 2014.0206C, letter of opposition
Date: Thursday, October 23, 2014 12:18:55 PM
Attachments: FDA-Deeming-Comments-San Francisco_DPH.pdf

Dear Ms. Boudreaux:

The attached document demonstrates why the San Francisco Planning Commission should deny the Conditional Use application for a vape shop at 1963 Ocean Avenue.

The document by Barbara A. Garcia, MPA, Director of Health, San Francisco Department of Public Health, is dated August 5, 2014. This letter was written on behalf of the SFPDH in response to regulations proposed by the United States Food and Drug Administration. Please include the document "FDA-Deeming-Comments-San Francisco-DPH.pdf" and my email in the case report for project 2014.0206C. Comments in the document pertaining to e-cigarettes, which I have highlighted, include the following:

Section 3, p.2:

FDA and other independent scientists have found numerous potentially dangerous chemicals and carcinogens as well as varying levels of nicotine that are inconsistent with the amount indicated on the labels of e-cigarette solutions....there is a lack of credible information on the full range of chemicals being produced by the large number of different e-cigarettes currently on the market.

Section 3, p.3:

CDC reported that e-cigarette use more than doubled among U.S. middle and high school students between 2011-2012. There is evidence that e-cigarettes help youth to initiate smoking habits – only 20% of middle school e-cigarette users reported never having smoked conventional cigarettes. Youth are also impressionable and can succumb to marketing ploys such as the numerous fruity and candy flavored e-cigarettes and to youth-oriented company advertising.

We recognized that these products pose a threat to the public health and are clearly serving as starter products for young people in our community....Surveys of local youth and adults show that the industry has created a great deal of confusion about these products and the general public repeats back the unsubstantiated claims made by e-cigarette marketers- eerily similar to claims made by the tobacco industry a generation earlier.

Current e-cigarette advertisements target youth with marketing strategies such as celebrity endorsements, and messaging that promote freedom, rebelliousness, and glamour with e-cigarette use.

Section 5, p.3:

Currently, e-cigarette liquid refill containers are not required to be sold in child-resistant packaging and that may encourage children to ingest the product's

poisonous content. Some e-cigarette refill product packaging features cartoons, colorful labeling, or illustrates edible ingredients representing particular flavors, such as cherry, chocolate, or bubble gum. The contents themselves can have the aroma of the edible ingredient pictured on the label. Any of these factors can prompt a child to investigate and the contents can be extremely dangerous, if not lethal.

CDC analyzed calls to U.S. Poison Centers from 2010 to 2014 related to e-cigarette exposures. The results showed that e-cigarettes accounted for an increasing proportion of the calls, 0.3% in September 2010 to 41.7% in February 2014. Half of the calls made regarding exposure were for incidents involving children ages 0-5. The prevalence of poisonings and the potential danger to children promoted the American Association of Poison Control Centers and its member centers to issue a statement warning e-cigarette users to keep the devices and liquids away from children. One teaspoon (5 ml) of a 1.8% nicotine solution can be lethal for a person weighing 200 pounds. Most nicotine solutions range between 1.8% and 2.4%, and the refill bottles contain 10-30 ml of solution.

It is obvious from reading this document why a vape store, whose purpose is to increase the use of e-cigarettes, vaporizing devices, and e-liquids, and to addict our relatives and neighbors to nicotine and to expose them and people near them to the harmful chemicals contained in the e-cigarette vapors (actually fumes), is not desirable in our neighborhood. The letter from the SFDPH focuses on youth, but college students and older residents of our neighborhood are also adversely affected by the advertising, availability, and unhealthy effects of these products. E-cigarettes result in previous non-smokers using e-cigarettes and possibly cigarettes.

E-cigarettes are reported to be about as effective as nicotine patches for smoking cessation. However, e-cigarettes contain a coil heated to 600 degrees Fahrenheit (which, of course, is not true of nicotine gum or patches), resulting in the emission of harmful fumes that have been found to contain formaldehyde, heavy metal nanoparticles, and other breakdown products which are deposited in the lungs. Vape shops sell devices with larger batteries than e-cigarettes. This allows higher voltages than found in e-cigarettes, which results in higher temperatures, more nicotine delivered to the user, more production of harmful breakdown products from the propylene glycol solvent, and very likely more metallic nanoparticles from the coil.

Due to insightful legislation passed by the San Francisco Board of Supervisors in recent years, with input from the DPH, tobacco paraphernalia establishments, including e-cigarettes and e-liquids, require Conditional Use Authorization. This allows neighborhoods in San Francisco to limit the number of these stores. Ocean Avenue has four stores nearby that sell e-cigarettes; the three liquor stores and the 7-Eleven. There are two vape stores within a 1.5 mile radius of 1963 Ocean Ave.

I ask that the Planning Commission agree that the health of our neighbors is infinitely more important than the interests of a new business, and vote to deny this Conditional Use Application. A vape shop on Ocean Avenue is not necessary or desirable.

Yours truly,
Robert Karis
Ingleside Terraces

Addendum:

The four stores on Ocean Avenue that sell e-cigarettes are:

No Limit Liquor & Food Mart, 1015 Ocean Ave.

A & N Liquors, 1521 Ocean Ave.

Homrun Liquors, 1551 Ocean Ave.

7-Eleven, 2000 Ocean Ave.

The two vape shops within a 1.5 mile radius of 1963 Ocean Ave. are:

Juicebox Vapor, 907 Taraval St. at 19th Ave.

Dream Cloud Vapors, 4971 Mission St., near Geneva Ave.



Happy Vape
1963 Ocean Avenue
San Francisco, CA 94127
415/513/2620

Owner: Blake He, Cong Phuong Nguyen

Hours of Operation: Monday - Sunday 11 am - 12 am
(Proposed)

Location: 1963 Ocean Avenue, San Francisco, CA 94127

General Information: Happy Vape is a yet to open electronic vaporizer retailer and steam stone hookah lounge. Our goal is to provide a healthier alternative to tobacco products, share information about the safe handling of our products, and to provide a positive engaging experience for our customers.

Happy Vape plans to achieve both the retail and lounge idea through the use of its 2 story building. We are proposing that the ground level of Happy Vape will be used as the retail floor for electronic vaporizers and e-liquids and bottom floor be used as the steam stone hookah lounge.

After much research and speaking with the city health and planning department, in order to sale electronic vaporizers and e-liquids and contain the steam stone hookah lounge, Happy Vape has applied for the required

conditional use permit for tobacco paraphernalia. The owners found that their plans was permissible, that *the property at 1963 Ocean Ave. is zoned Ocean Ave NCT. As per planning code section 790.123, tobacco paraphernalia establishment is permitted use within this zoning district, subject to section 227 procedure.*

Happy Vape has also checked with Janine Young, senior inspector of the Health department and Lieutenant Mary Tse from fire department and was told that the steam stone hookah complies with city requirements in the space suggested.

The steam stone hookah lounge is where we hope people can come together and share an experience. Whether that be enjoying the range of flavors available while listening to music, watching sports, chatting with friends, or just a place to kill time in between classes for college students.

Happy Vape is happy to comply with the current regulations not allowing indoor vaping, signs stating "No Vaping Indoors" will be posted throughout the store. But in order to provide our customers a chance to sample the products before purchasing, Happy Vape is proposing the use of its outdoor patio area as the e-liquid sampling area, hopefully providing a better experience for our customers.

Happy Vape has no interests in selling to minors nor allowing minors to be on the premise. In order to do this, signs for "18 and over" will be posted throughout the store.

Happy Vape will have ADA compliant counters and bathroom for patrons with special needs.

Happy Vape has four support letters from our commercial neighbors, two from the left and two from the right of our store. Happy Vape has tried to engage the neighbors in the back on two occasions. The neighbor has yet to respond, but we will continue to reach out to them.

Goal:

To obtain Conditional use permit.

Please send support letters and/or e-mails to:

Cc: blakehe@gmail.com

Cc: marshagarland@att.net

Consultants:

Garland Public & Community Relations
535 Green Street
San Francisco, CA 94133

Questions: Marsha Garland 415/531/2911
Stefano Cassolato 415/875/0818

Happy Vape
1963 Ocean Avenue, San Francisco, CA 94127

Business Plan
Executive Summary

Description of the Company:

Happy Vape will be a destination space, both a retail and a lounge, for people who have made a commitment to quit smoking and/or to significantly reduce their consumption of tobacco. Collaterally Happy Vape will help non-smokers live in a cleaner and better smelling environment. Happy Vape will sell e-cigarettes and vaping liquids, also known as juices.

Uniquely, the business will feature a relaxing lounge area where people can socialize and discuss their progress at curtailing and overcoming their tobacco addiction.

Associated with the lounge area Happy Vape plans to serve healthy packaged all natural or organic snacks and healthy packaged drinks. Also Happy Vape wants to sell instant coffee fused with ganoderma extract. (See below for information on ganoderma, a mushroom extract.)

There will be no alcohol sales and no food prepared on the premises.

Periodically Happy Vape will sponsor seminars on quitting smoking and addictive behavior.

Happy Vape is in the business of ***harm reduction***.

Products and Services:

Our goal is to sell the best available vaporizers, e-juices, e-cigarettes and batteries.

Happy Vape plans to carry a wide variety of e-juice flavors, re-buildable atomizers and drip tips.

We are also planning to sell t-shirts with graphic designs to inspire and motivate people to do things outside their norm.

Hookah Steam Stones & Hookah Lounge

Hookah Steam Stones are a new concept in the hookah world. Instead of smoking, Steam Stones allow you to inhale vapor. Hookah Steam Stones are available in a variety of flavors. Steam stones are a great way to smoke without the nicotine.

Happy Vape will have a hookah lounge on the lower level of the premises. There will be an attendant at all times. There will be couches along the walls and all genres of music playing in the background. There will be televisions mounted on the walls, with baseball, basketball and football games and occasional movie nights.

The lounge will be a place where patrons will socialize and practice an ancient culture in a modern way with the steam stones. The steam stones as pointed out above have no tobacco and no carcinogens.

We have no plans to sell cigarettes, snuff, rolling papers, doobie clips, scales, drug kits, bongs and other tobacco and drug paraphernalia.

Testimonials:

Gavin Wagner: "Very easy to use, convenient, effective and the different flavor choices are great."

Yuan Ning: "I was on the e-cigarette with the black cherry flavor for about 3-4 months and now I am not smoking or vaping."

Albert Lau: "I got off cigarettes and used e-cigs for about 7 months, now I vape on and off."

Jame Ching: "I use e-cigarettes to help me quit smoking, I mix using e-cigarettes and cigarettes throughout my days and it has help me go from a pack a day to half a pack a day."

Justin Cheuck: "E-cigarettes drastically cut down my consumption of cigarettes. I use e-cigarettes only in the day time and I have 2-3 cigarettes in the evening time."

Hyoweon Yang: "It was so much easier than cold turkey, so easy to quit anyone can do it."

Lisa Dungan: "I've struggled with my nicotine addiction for 45 years. ecigs have enabled me to completely stop smoking for over 3 years. NO more coughing or any ill effects that cigarettes had caused. So thankful to have rid myself of the habit!"

Marketing and Sales Techniques:

In store sales and online through our website. We will offer same day delivery. Sell through E-Bay and Google and have regular shipping.

The Competition:

Dream Cloud Vapors, 4971 Mission Street, San Francisco, CA 94112, 1.6 miles away

Juicebox Vapor, 907 Taraval Street, San Francisco, CA 94116, 1.7 miles away

7-Eleven, 2000 Ocean Avenue (E-Cigarettes only), one block away

Target Market:

All ages except no one under 18. Smokers.

Operations:

Open Daily, 11 am - 12 midnight.

Outdoor Activity Area 11 am – 8 pm.

Handicapped Access

Brands:

Joyetech, KangerTech, iTaste, Vision, Aspire. The E-juice/e-liquid we will carry is Virgin Vapor, one of the few companies that supplies organic e-juices. We are looking into carrying other brands also.

Owners' Bios:

Blake He was born in Canton China. His family moved to the United States on May 14, 1998. Blake attended Aptos Middle School at 105 Aptos Avenue just off Ocean Avenue. Blake grew up in the Ocean Avenue area because the cousin who sponsored his family lived there. Blake has seen a lot of positive changes in the neighborhood and wants to contribute. He truly feels Ocean Avenue has a lot of potential because it's right off the freeway and there's a lot of foot and car traffic, especially with colleges on both ends. It creates wide range of race and economic diversity.

After middle school Blake started working for the Mayor's Youth Employment and Education Program (MYEEP) teaching kids how to swim. He continued working for MYEEP throughout his time at the Philip & Sala Burton High School teaching kids how to swim in the summer and tutoring kids after school. Blake attended San Francisco City College Phelan Campus after high school.

Blake He is married and has a small child. He and his family live in the Ocean Avenue neighborhood. His previous employment was working for D & J Engineering and Air Conditioning. There he obtained his Universal HVAC Permit and Fire Director Certificate, joined the Local 39 Union and worked at Charles Schwab as an Utility Engineer.

Cong Phuong T Nguyen, co-owner of Happy Vape, is the wife of Blake He. She was an international student from Hanoi, Vietnam. She attended San Francisco State University where she majored in International Business. After college and various part-time jobs she started her career in the banking industry where she worked with both Wells Fargo and Chase.

Cong is now a stay at home mother to the He's baby boy Jayce. They decided to open a business hoping that she can remain a stay at home mother and dedicate herself to raising their son the way they envision.

Health Benefits of Ganoderma:

Ganoderma curbs high blood pressure, tames inflammation, builds stamina, and supports the immune system.

Ganoderma shows promise in reducing cholesterol levels and easing allergy-related inflammation of the airways, according to preliminary evidence from animal-based studies. Here's a look at more of the science behind ganoderma's health-enhancing effects.

1) Cancer and the Immune System

Often used as an immune stimulant by people with cancer, ganoderma has been shown to strengthen immunity as well as combat cancer-cell proliferation. In a 2003 study of 34 people with advanced-stage cancer, for instance, taking ganoderma in supplement form three times daily for 12 weeks led to a significant increase in T-cells (known to play a central role in immune defense).

2) Antioxidant Benefits

Several small studies have suggested that regular use of ganoderma supplements may increase your levels of antioxidants, compounds thought to protect against disease and aging.

3) Relief of Urinary Tract Symptoms

In a 2008 study of 88 men with urinary tract symptoms, researchers found that ganoderma was significantly superior to a placebo in providing symptom relief.

Other Common Uses

Acne, Allergies, Adrenal Fatigue, Arthritis, Candida, Common Cold, Herpes, HIV, Hair Loss, Lyme Disease, Ulcerative Colitis, Uterine Fibroids , Vitiligo, Weight Loss

BBC World News July 30, 2014 Report:

30 July 2014 Last updated at 19:34 ET

E-cigarettes 'less harmful' than cigarettes

Researchers say national policies need to be made once all evidence is reviewed

E-cigarettes are likely to be much less harmful than conventional cigarettes, an analysis of current scientific research suggests.

Scientists argue replacing conventional cigarettes with electronic ones could reduce smoking-related deaths even though long-term effects are unknown.

In the journal *Addiction*, researchers suggest e-cigarettes should face less stringent regulations than tobacco.

But experts warn encouraging their use without robust evidence is "reckless". Instead of inhaling tobacco smoke, e-cigarette users breathe in vaporised liquid nicotine.

About two million people use electronic cigarettes in the UK, and their popularity is growing worldwide.

'Fewer toxins'

The World Health Organization and national authorities are considering policies to restrict their sales, advertising and use.

An international team examined 81 studies, looking at:

- safety concerns
- chemicals in the liquids and vapours
- use among smokers and non-smokers

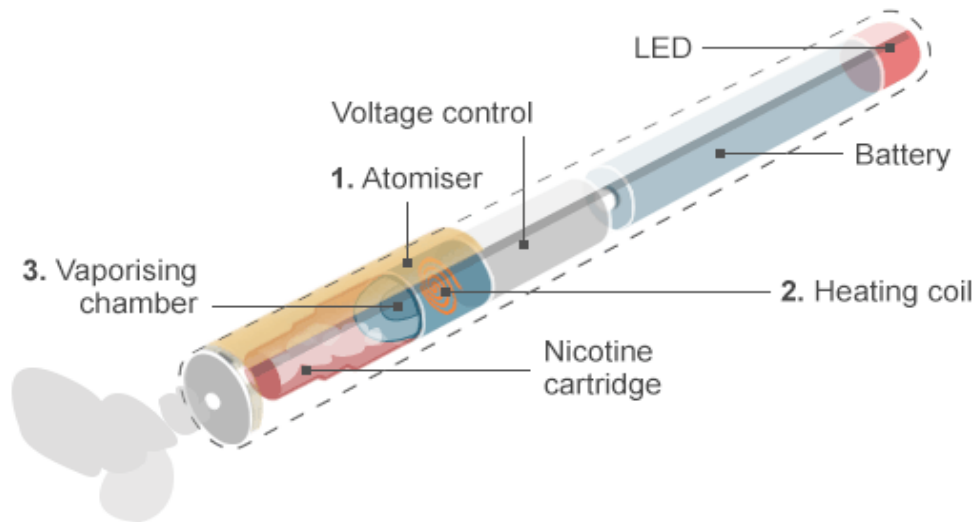
Scientists say risks to users and passive bystanders are far less than those posed by cigarette smoke, but caution that the effects on people with respiratory conditions are not fully understood

And they say electronic cigarettes contain a few of the toxins seen in tobacco smoke, but at much lower levels.

They report there is no current evidence that children move from experimenting with e-cigarettes to regular use, and conclude the products do not encourage young people to go on to conventional smoking habits.

And their analysis suggests switching to e-cigarettes can help tobacco smokers quit or reduce cigarette consumption.

What's inside an e-cigarette?



Prof Peter Hajek, of Queen Mary University in London, an author on the paper, told the BBC: "This is not the final list of risks, others may emerge.

"But regulators need to be mindful of crippling the e-cigarette market and by doing so failing to give smokers access to these safer products that could save their lives.

"If harsh regulations are put in place now, we will damage public health on a big scale." Researchers conclude there should be more long-term studies comparing the health of smokers with e-cigarette users.

'Proportionate regulations'

Prof Martin McKee, of the London School of Hygiene and Tropical Medicine, who was not involved in this analysis, told the BBC: "Health professionals are deeply divided on e-cigarettes.

"Those who treat smokers with severe nicotine addiction see them as offering a safer alternative to cigarettes.

"In marked contrast, many others, such as the 129 health experts who recently wrote to the World Health Organization, are extremely worried given the serious concerns that remain about their safety, the absence of evidence that they help smokers quit, and the way they are being exploited by the tobacco industry to target children.

"This report concedes there are huge gaps in our knowledge - yet, incredibly, encourages use of these products. This seems little short of reckless."

Martin Dockrell, at Public Health England, said: "Increasing numbers of smokers are turning to these devices as an aid to quitting and there is emerging evidence that they are effective for this purpose.

"In order to maximise the benefits to public health while managing the risks, regulation of e-cigarettes needs to be proportionate and designed to ensure the availability of safe and effective products, and to prevent the marketing of e-cigarettes to young people and non-smokers."

Neighborhood Outreach

We had 2 pre-application meetings at the project site. We invited all the neighbors within 300 feet radius of the project site, all the neighborhood groups in the Ocean View area and the West of Twin Peaks area.

We presented to the OAA board members on July 16, 2014 and we attended on Aug 20, 2014 and Oct 15, 2014 to participate and answer questions.

We presented our proposed project at the Ocean Avenue Street Life Committee on July 8, 2014 and August 13, 2014.

We attended the Ingleside Terraces Homes Association board meeting on Oct 16, 2014 to participate and answer questions.

We met with Kate Favetti and Caryl Ito from Westwood Park Association on Oct 27, 2014.

During our outreach, we reached out to all the schools and churches around the area in August (24th-29th).

List of schools:

Lick Wilmerding High School

Aptos Middle School

Commodore Sloat Elementary School

St. Francis Preschool

Straford Academy

Voice of the Pentecost Academy

Why should Ocean Avenue be deprived of a retail vape store, when there are 21 vape stores in the city serving other districts.

List of all the Vape Stores in San Francisco (21 Vape Stores):

Vapor Smoke Shop

Union Square

435 Stockton St, San Francisco, CA 94108

7.5 miles away from 1963 Ocean Ave.

It Is Vapor 13

1347 Polk St, San Francisco, CA 94109

7.7 miles away from 1963 Ocean Ave.

Vape Tech

Russian Hill

1042 Columbus Ave, San Francisco, CA 94133

9 miles away from 1963 Ocean Ave.

Frisco Vapor - Electronic Cigarette Store

Marina/Cow Hollow

1881 Lombard St, San Francisco, CA 94123

7.5 miles away from 1963 Ocean Ave.

Juicebox Vapor

Parkside

907 Taraval St, San Francisco, CA 94116

1.7 miles away from 1963 Ocean Ave.

Gone With The Smoke Vapor

Tenderloin

569 Geary St, San Francisco, CA 94102

6.6 miles away from 1963 Ocean Ave.

Viper Vapor

Lower Haight

260 Divisadero St, San Francisco, CA 94117

4.8 miles away from 1963 Ocean Ave.

Vapor Den

Mission

16 Guerrero St, San Francisco, CA 94103

4.9 miles away from 1963 Ocean Ave.

Dream Cloud Vapors

Excelsior

4971 Mission St, San Francisco, CA 94112

1.6 miles away from 1963 Ocean Ave.

Vapeguyz

Union Square, SoMa

865 Market St, San Francisco, CA 94103

7.3 miles away from 1963 Ocean Ave.

Cloud City Vapors

Corona Heights

376 Castro St, San Francisco, CA 94114

4.3 miles away from 1963 Ocean Ave.

Vape Supreme

Japantown, Lower Pacific Heights

1630 Post St, San Francisco, CA 94115

6.1 miles away from 1963 Ocean Ave.

Vapory Shop

Mission

2707 Folsom St, San Francisco, CA 94110

4.1 miles away from 1963 Ocean Ave.

SF Vapor

Mission Terrace, Outer Mission

4994 Mission St, San Francisco, CA 94112

1.7 miles away from 1963 Ocean Ave.

Big Bam Vapes

North Beach/Telegraph Hill, Russian Hill

752 Vallejo St, San Francisco, CA 94133

8.8 miles away from 1963 Ocean Ave.

Vapor Smoke Shop

Union Square

435 Stockton St, San Francisco, CA 94108

7.9 miles away from 1963 Ocean Ave.

Tower Vapor

SoMa

1601 Mission St, San Francisco, CA 94102

5.2 miles away from 1963 Ocean Ave.

It Is Vapor San Francisco

Nob Hill

1347 Polk St, San Francisco, CA 94109

7.7 miles away from 1963 Ocean Ave.

SOS Vapes

Inner Richmond

3829 Geary Blvd, San Francisco, CA 94118

5.2 miles away from 1963 Ocean Ave.

DTSF VAPORS

Chinatown

515 Grant Ave, San Francisco, CA 94108

7.4 miles away from 1963 Ocean Ave.

Vapor Den Cow Hollow

Marina/Cow Hollow

2764 Octavia, San Francisco, CA 94123

7.1 miles away from 1963 Ocean Ave.







Neighborhood Vacancy Problem

There are a total of 34 commercial storefronts on the 1900 block of Ocean Ave. 5 of them are vacant and 2 are use as storage. That's **20.6%** vacancy on the 1900 block of Ocean Ave.

-According to Invest In Neighborhoods San Francisco, Ocean Avenue Profile:

- Ocean Ave from Ashton to Manor are mostly “dead blocks”; few businesses bring foot traffic. (That is 1900 block and 2000 block of Ocean Avenue)
- High Retail Leakage.
- Lack of public space to congregate.
- Residents complain about lack of diverse offerings; many don't patronize shops and instead shop at West Portal, Stonestown.

-Supervisor Katy Tang introduced a legislation that if a storefront is vacant for more than 270 days must now pay a \$765 annual fee to The City.

-According to Katy Tang's legislation:

- “Empty storefronts are sinister. In addition to being eyesores these vacant commercial storefronts have a detrimental impact on the economic viability of the commercial corridors in which they are located.”
- “Vacant storefronts often attract illegal activity, such as squatting, vandalism, and dumping.”
- “Such activity not only repels would-be customers and patrons from commercial corridors, but also places an undue burden on city agencies.”

FRANCISCAN HOBBIES

明月髮廊
Tel: 587.9800

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1929

1929
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Kimura Gallery

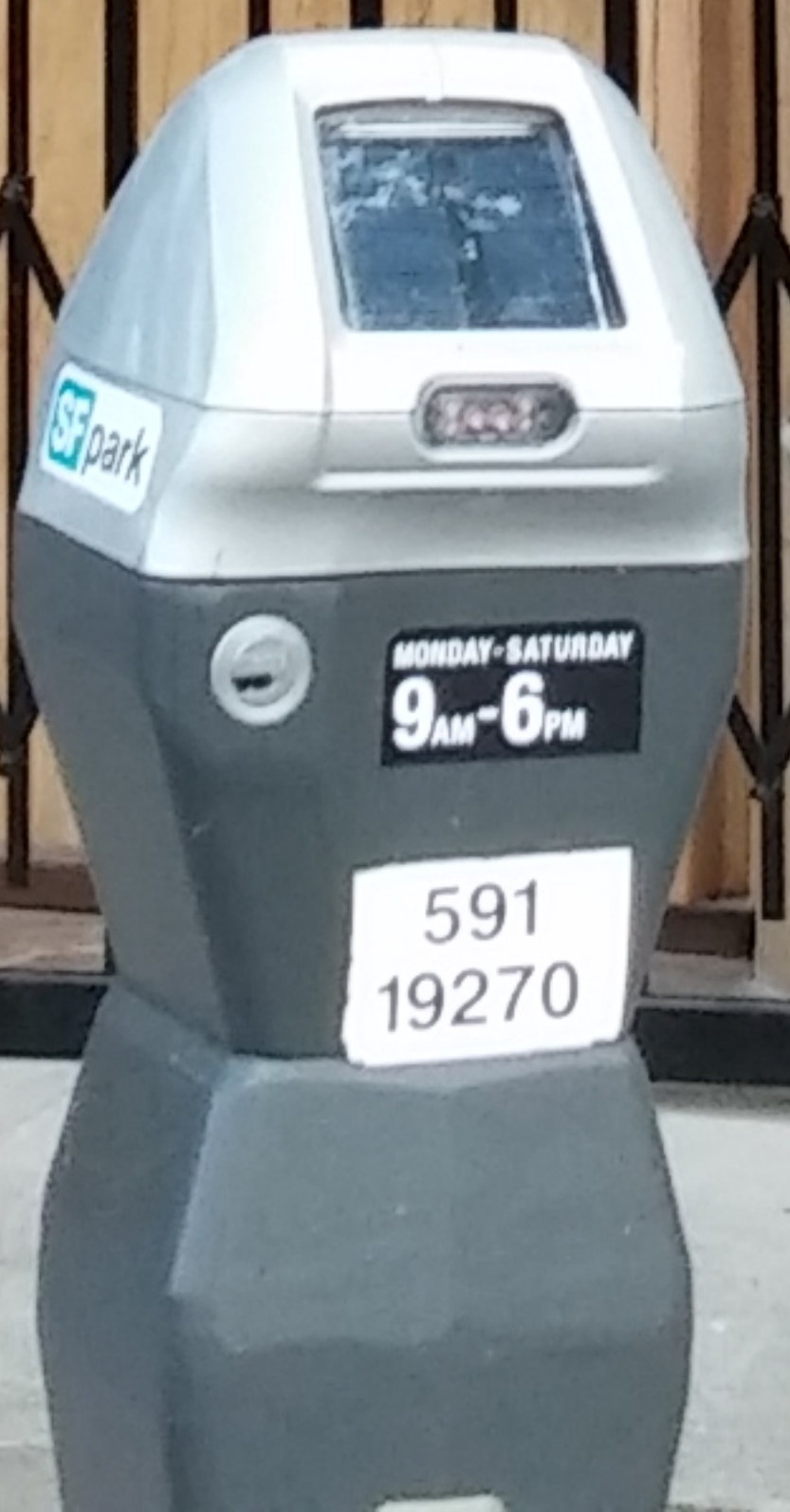
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NO TRESPASSING





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OPEN DAILY



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**BEAN
QUERIA**
OPEN DAILY 10-10

NACHOS
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COMPLETE LUNCH
& DINNER
PLATES
415-586-7013

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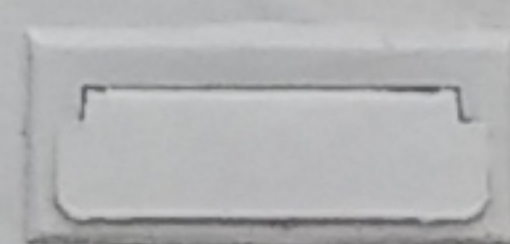
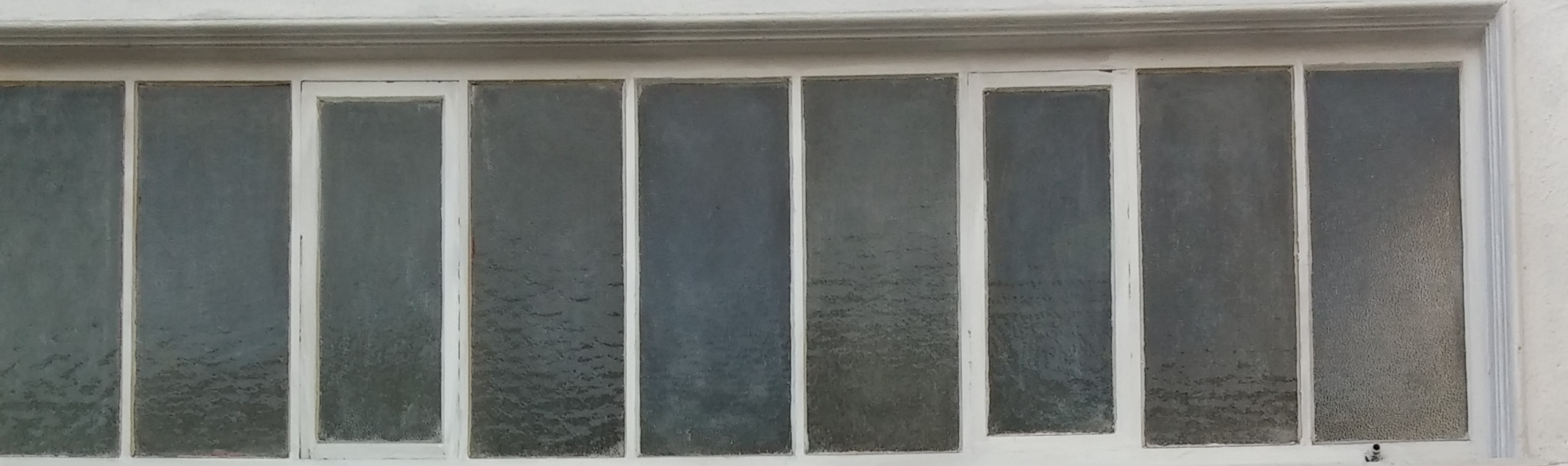
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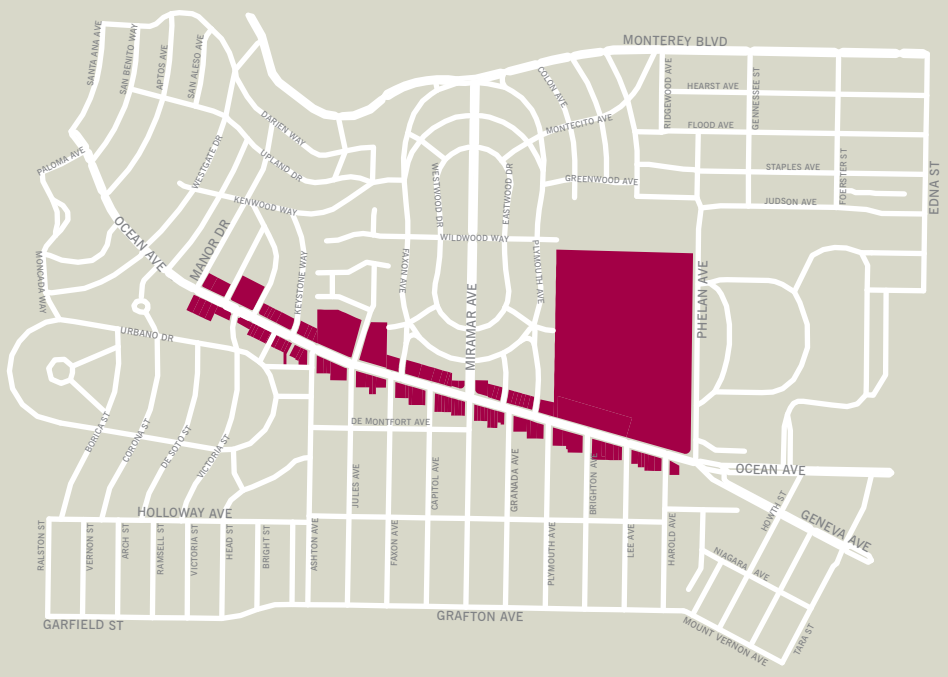
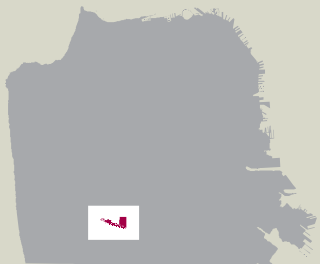


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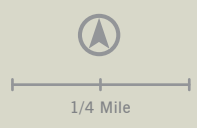




OCEAN AVENUE



OCEAN AVENUE
 FROM PHELAN
 AVENUE TO
 MANOR DRIVE



Neighborhood Features

SEE MORE ON PAGE 3

The OMI (Oceanview, Merced Heights and Ingleside neighborhoods) is located between City College of San Francisco and San Francisco State University in the southwestern part of San Francisco. It is a middle-class district of single-family, owner-occupied homes. Approximately 75% percent of the land area in the OMI is residential. While the population has been mostly African-American, in recent years the neighborhood has witnessed an influx of Asian-American and other ethnic groups, making it one of San Francisco's most diverse neighborhoods. The neighborhood is served by the Balboa Station BART, Interstate-280, three Muni Metro lines and several bus lines.

Ocean Avenue, the main street of the OMI, has over 160 storefronts and was recently transformed by Avalon Bay's 173 unit market rate housing with a new Whole Foods market on the ground floor. Pending development projects include the Municipal Transit Agency's redevelopment of the Phelan Bus Loop and City College's new Performing Arts Center. The district is beginning to attract new tenants while continuing to offer a range of affordable shopping and dining options.

In 2010, Ocean Avenue Association became a Community Benefit District (CBD) with a management focusing on cleaning and maintenance, safety, marketing, and streetscape improvements. The CBD also serves as an advocate for the 11-block district. Other nonprofit organizations in the area provide an array of programs supporting youth development, the arts and culture, education and advocacy for residents in the community.



Invest in Neighborhoods is a City initiative to provide focused, customized assistance to meet the specific needs of San Francisco's neighborhood commercial corridors.

This assessment is a snapshot of existing conditions in Ocean Avenue as of February 2013. It will help to inform the City's investments in the neighborhood, and provide a resource for neighborhood stakeholders.

Contents include:

- Neighborhood Features
- Commercial District Health
- Key Takeaways
- Demographics
- Land Use
- Business Mix
- Transportation
- Existing Plans & Interventions

Note: This document includes some subjective descriptions of the neighborhood based on findings gathered through direct observation and interviews with key neighborhood stakeholders.

Commercial District Health

SEE MORE ON PAGE 4

Ocean Avenue has a relatively low commercial vacancy rate. Sales tax captured in the district has grown 32% since 2006, compared with 17% growth citywide. The corridor's growth opportunities include lawn and garden supplies, home furnishings, general merchandise, clothing, shoes, and jewelry, luggage and leather goods.

Between 2009 and 2012 vehicle theft/theft from vehicles increased by 66%, while robbery and assault incidents showed slight increases. Hot spots of criminal activity existed on Ocean Avenue at the intersections at Jules Ave and at Phelan Ave. (Source: SFPD incidents data, November 2009-October 2012) Community stakeholders report that prostitution is a major issue.

Demographics

SEE MORE ON PAGE 7

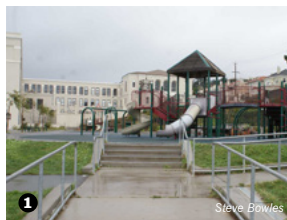
Over 15,180 people live within a one-quarter mile radius of the Ocean Avenue corridor. Its population is older than San Francisco's but similarly diverse. It has both a higher proportion of residents young residents under 18 years old and older residents over 60 years old. The Ocean Avenue corridor has a majority of Asian residents. Its proportion of white residents is lower and its proportion of Latino residents is the same as found in San Francisco overall. The majority of Ocean Avenue corridor's 5,060 residential structures are single-family. Homeowning households predominate and most households are family households. Households income in the Ocean Avenue corridor are higher than that of the City overall and most households own cars.

READ NEIGHBORHOOD FEATURES SUMMARY ON PAGE 2



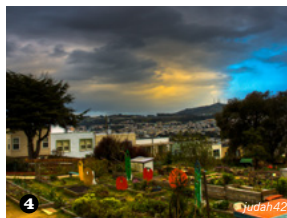
Notable Places

- 1 Aptos Park
- 2 Balboa Park
- 3 BART and Muni Stations at Balboa Park
- 4 Brooks Park
- 5 City College of San Francisco
- 6 Diego Rivera Theatre at City College



Pipeline Projects

- A 50 Phelan Way 71 units
- B 1415 Ocean Avenue 6 units
- C 1446 Ocean Avenue 13 units



Cultural Events

Annual OMI-NIA Family Festival

Merchant & Resident Groups

- Ocean Avenue Association
- OMI-NIA Neighbors in Action
- Westwood Park Neighbors Association



COMMERCIAL DISTRICT HEALTH

READ COMMERCIAL DISTRICT HEALTH SUMMARY ON PAGE 2



Glenn Hering

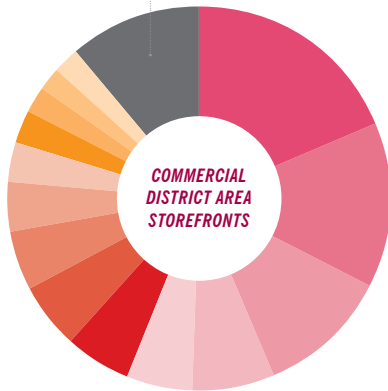
Ocean Avenue Storefronts

TOTAL STOREFRONTS

% VACANT

144

11%

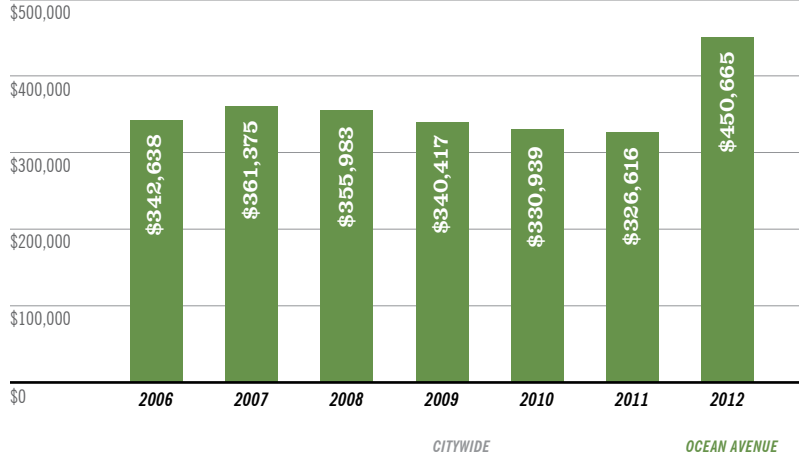


Eating and Drinking Places	27
Personal Services	20
Other Retail	16
Medical Services	10
Business or Professional Services	8
Other Non-Retail Services	8
Trade Shops (with Retail Component)	8
Churches	7
Dry Cleaners, Laundry	6
Grocery Stores / Small Markets	5
Fitness / Gyms	4
Auto Repair	3
Gas Station / Service Station	3
Liquor Store	3
Vacant Storefronts	16

Source: November 2012 parcel inventory within Commercial District Area (see boundary map on page 6) conducted by Planning Department / OEWD.

Sales Tax

OCEAN AVENUE TRADE AREA



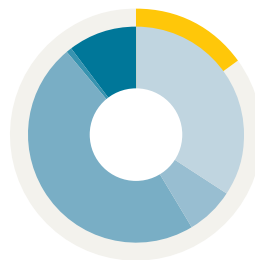
Sales Tax Change
2006-2012

▲ 17%

▲ 32%

Demographics

OCEAN AVENUE 1/4 MILE DEMOGRAPHIC AREA



White	34%
Black	7%
Asian	47%
Native American / Hawaiian or Pacific Islander	1%
Other / Two or More	10%
% Latino	15%

District Population

No. of Households

Median Household Income

15,180

5,060

\$86,304

Observations About Physical Conditions

Storefronts look rundown. ☹️

Fast pace of car traffic; drivers do not slow down. ☹️

Lack of public space to congregate. ☹️

Lack of street level parking. ☹️

Recent Accomplishments



Launch of Ocean Avenue Association in 2011 provides organizational structure and a voice for the neighborhood.



The City helped attract and finance Champa Garden, a full-service restaurant that will open in the district in summer 2013.



New national retailers serve longstanding community needs (Chase Bank, Whole Foods).

“Long term we want more attractive streets to bring out more street life. We want to help improve store facades, plant more trees and sidewalk landscaping and improve the quality of our public spaces... as well as providing more children-friendly places.”

Neighborhood Advocate

STRENGTHS

- Economically diverse; low, middle and high income families and professionals.
- High rates of homeownership and many multi-generational households.
- One of the most ethnically diverse communities in the city.
- Active residents; long time neighborhood associations and organizations.
- Creation of Ocean Avenue CBD has given businesses and property owners a voice.
- Library is an anchor that attracts foot traffic.
- Over \$350 million in public/private investment in new development projects.
- Low commercial vacancy rate.
- Regional and national retailers and banks are interested in the area.
- Over 35,000 students attending nearby campuses of City College and SFSU.
- Wide sidewalks and bike lanes for most of the district.
- Excellent access to public transportation (BART, K Muni, Buses) and Interstate 280.

OPPORTUNITIES

- Opportunity to capture more local purchasing power by attracting businesses that meet local needs.
- Façade improvements could improve the pedestrian and shopping environment.
- Create public spaces for people to gather; triangles at Geneva (dog park).
- A number of opportunity sites for additional development.
- Attract stores and services that focus on large student population.

CHALLENGES

- Ocean Ave from Ashton to Manor are mostly “dead blocks”; few businesses bring foot traffic.
- High retail leakage.
- Storefronts look run down.
- Residents complain about lack of diverse offerings; many don’t patronize shops and instead shop at West Portal, Stonestown.
- Nonprofit service providers occupy valuable ground floor retail.
- Fast pace of car traffic negatively affects the pedestrian environment.
- Lack of public space to congregate.
- Lack of street level parking.



OCEAN AVENUE

Study Area Boundaries



NOTE:

Demographic data presented on page 7 represents the area within 1/4 mile of the Ocean Avenue commercial district.

Business mix data presented on page 9 corresponds with the Trade Area indicated on the map.

Ocean Avenue storefronts data presented on page 4 corresponds with the Commercial District Area indicated on the map.

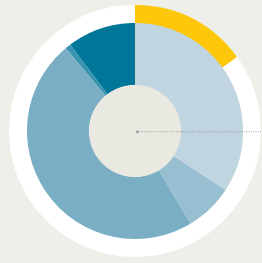
OCEAN AVENUE: DEMOGRAPHICS

READ DEMOGRAPHICS SUMMARY ON PAGE 2

Population

15,180

vs. 805,240 Citywide



Population Density

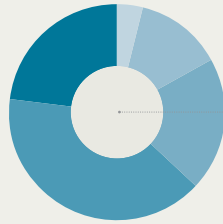
26 per acre

vs. 27 Citywide

Median Age

46.1

vs. 38.5 Citywide



Race / Background

	CITYWIDE	OCEAN AVENUE
White	48%	34%
Black	6%	7%
Asian	33%	47%
Native American / Hawaiian or Pacific Islander	1%	1%
Other / Two or More	11%	10%
% Latino	15%	15%
Male / Female Ratio	51/49%	51/49%
Foreign Born	36%	35%
Linguistic Isolated Households	14%	19%

Age

	CITYWIDE	OCEAN AVENUE
Under 5	4%	4%
5 to 17	9%	13%
18 to 34	30%	20%
35 to 59	37%	40%
60 and over	19%	23%

No. of Households

5,060

vs. 345,810 Citywide

% of Households Without a Car

6%

vs. 29% Citywide

Households

	CITYWIDE	OCEAN AVENUE
Family Households	44%	66%
Single-Person Households	39%	17%
Non-Family Households	17%	17%
Average Household Size	2.3	3.3
Average Family Household Size	3.1	3.5

Median Household Income

\$86,304

vs. \$71,420 Citywide

Unemployment

7.8%

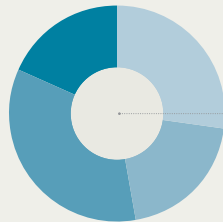
vs. 7% Citywide

Income

	CITYWIDE	OCEAN AVENUE
Median Family Household Income	\$86,670	\$102,300
Per Capita Income	\$45,478	\$35,461
% Poverty	12%	6%
Unemployment	7.0%	7.8%

Education

A higher percentage of college graduates or more.



Education

	CITYWIDE	OCEAN AVENUE
High School or Less	29%	27%
Some College / AA Degree	20%	20%
College Degree	31%	34%
Post Graduate	20%	18%

No. of Housing Units

5,300

vs. 376,940 Citywide

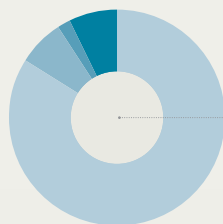
Housing

	CITYWIDE	OCEAN AVENUE
Renting Households	62%	27%
Rental Vacancy Rate	3.4%	4.2%
Median Rent	\$1,260	\$1,936

Residential Density

8 units per acre

vs. 12 Citywide



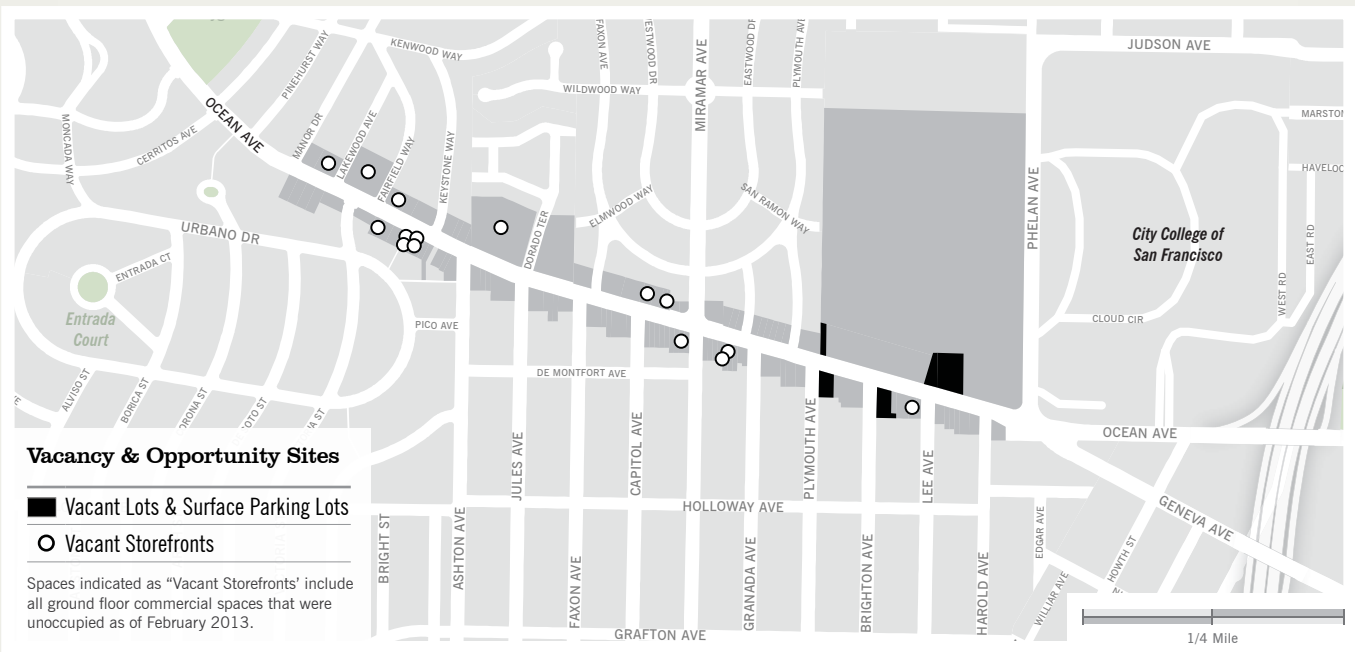
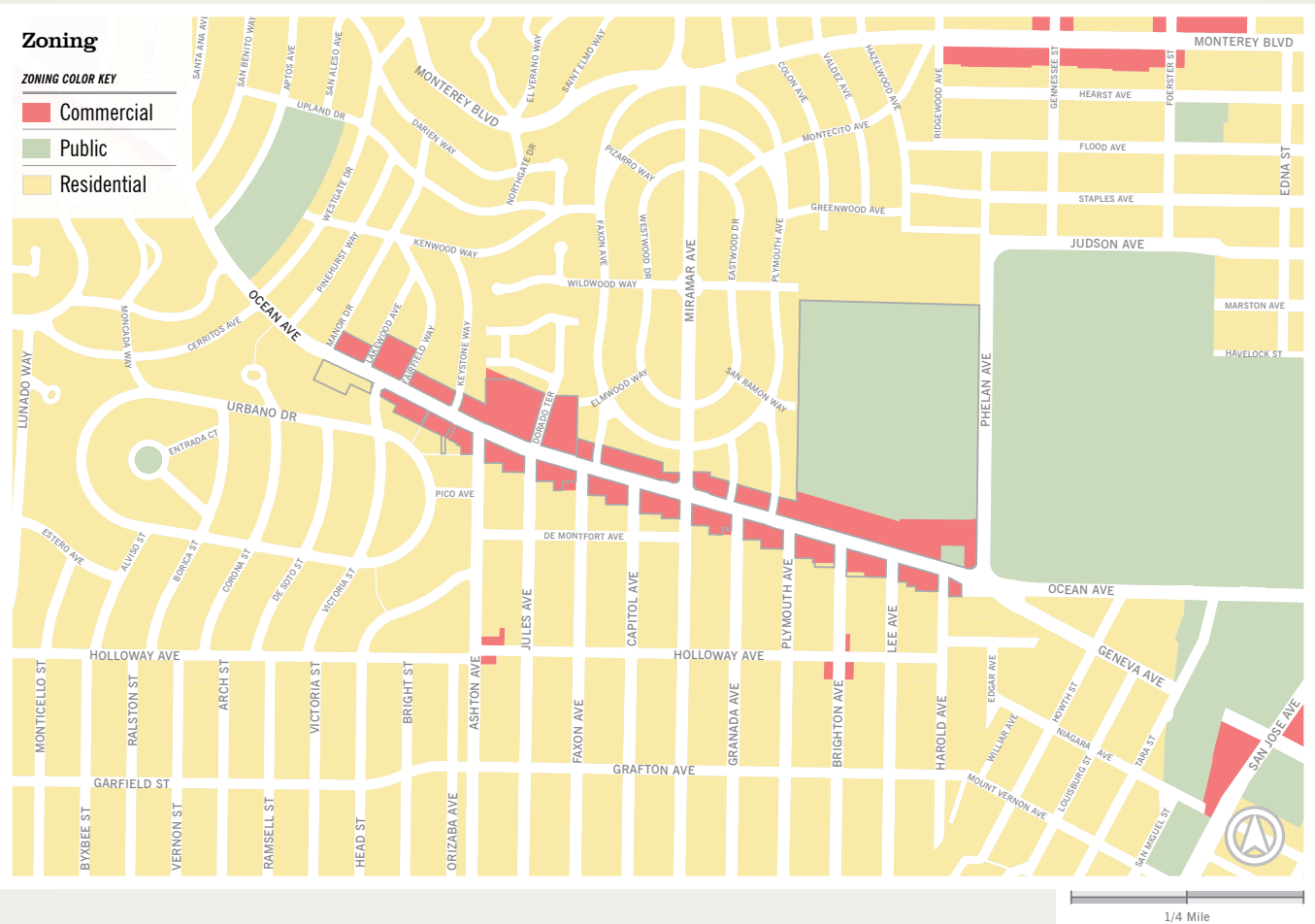
Housing Type

	CITYWIDE	OCEAN AVENUE
Single Family Housing	33%	84%
2 - 4 Units	21%	7%
5 - 9 Units	10%	2%
10 units or more	35%	7%

OCEAN AVENUE: LAND USE

Neighborhood Zoning

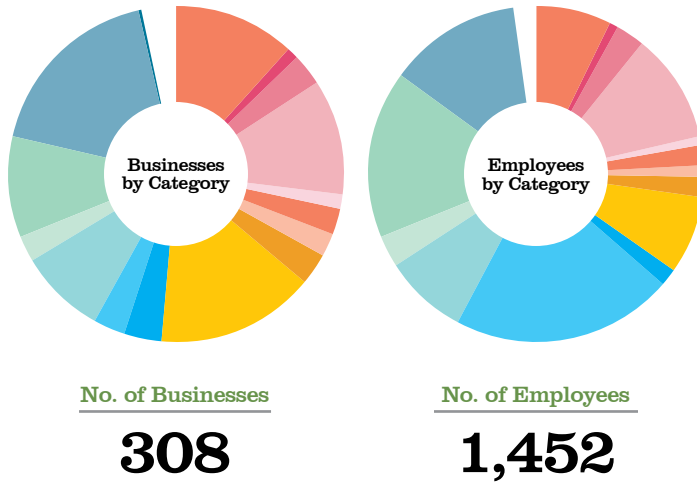
NC-T OCEAN AVENUE NEIGHBORHOOD COMMERCIAL TRANSIT DISTRICT



OCEAN AVENUE: BUSINESS MIX

Summary of Business by Categories, 2011

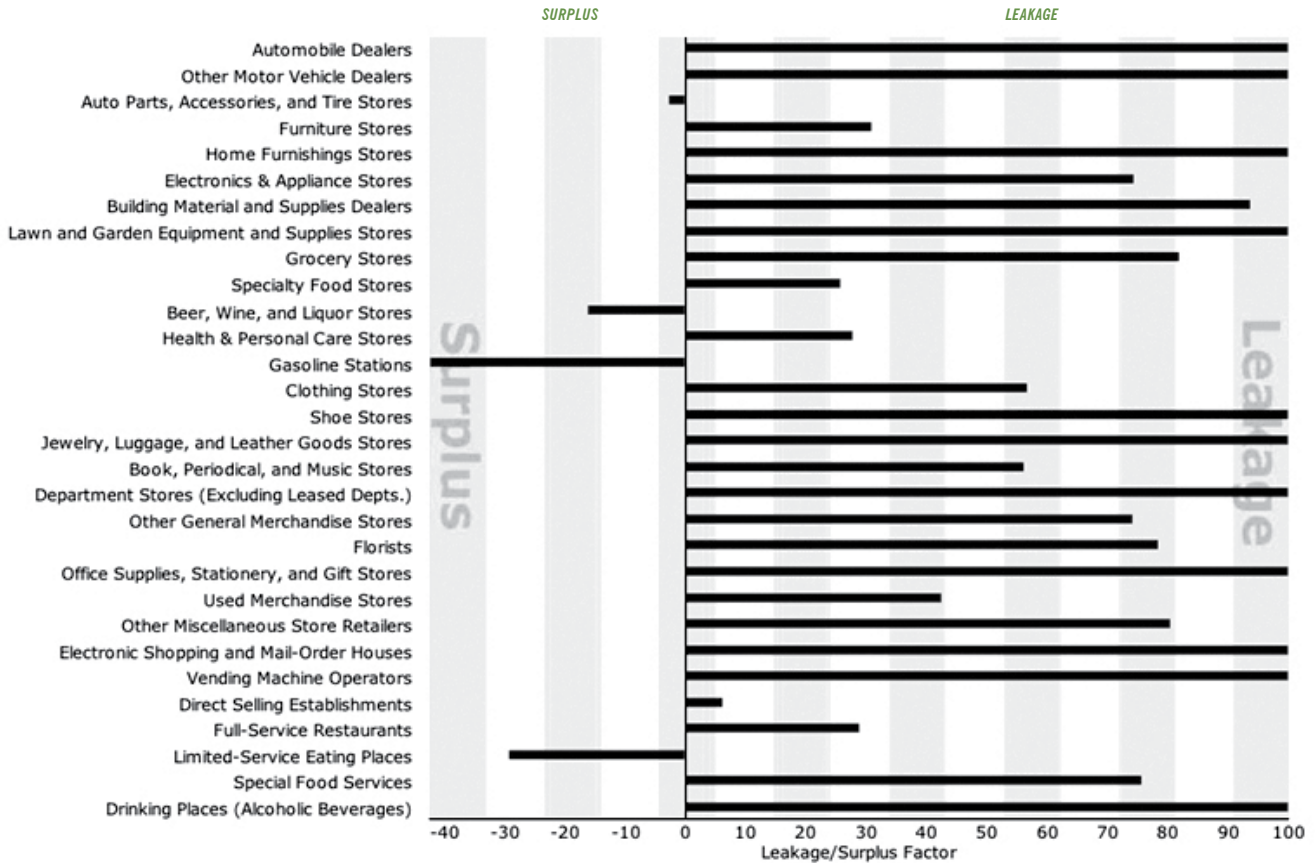
Source: Business data provided by Infogroup, Omaha NE Copyright 2012, all rights reserved. ESRI forecasts for 2011.



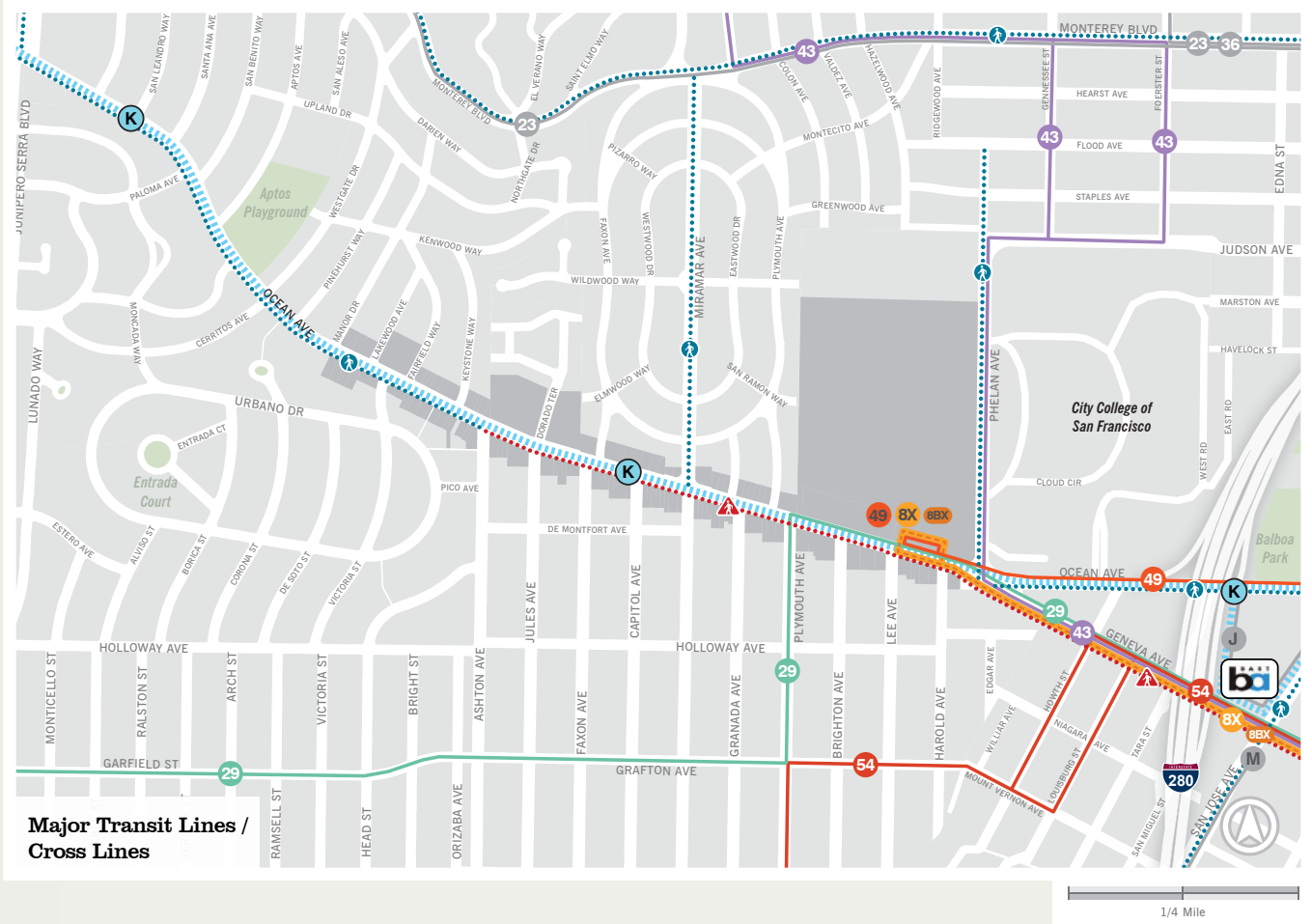
NAICS BUSINESS CATEGORY	BUSINESSES	EMPLOYEES
Construction	36	107
Manufacturing	4	13
Wholesale Trade	9	38
Retail Trade	34	154
Transportation & Warehousing	4	13
Information	8	28
Finance & Insurance	7	17
Real Estate, Rental & Leasing	9	27
Professional, Scientific & Tech Services	47	111
Admin. Support, Waste Mgmt. & Remediation Services	11	24
Educational Services	10	308
Health Care & Social Assistance	25	118
Arts, Entertainment & Recreation	8	43
Accommodation & Food Services	30	238
Other Services (except Public Administration)	54	183
Public Administration	1	2
Unclassified Establishments	10	29

Leakage / Surplus Factor by Industry Group, Ocean Avenue

The *Leakage / Surplus Factor* summarizes the relationship between supply (retail sales by businesses in the commercial district) and demand (consumer spending by households within a quarter-mile radius of the commercial district). As the *Leakage / Surplus Factor* trends toward +100, the market is experience leakage, meaning there is less retail activity relative to local demand. As the factor trends toward -100, this means that the market is in surplus and retail activity is in excess of local demand.



OCEAN AVENUE: TRANSPORTATION



Major Transit Line

K Ingleside



Cross Lines

- 8, 8BX, 49 on Ocean and Phelan Avenue
- 43 on Phelan Avenue
- 29 on Plymouth Street

Parking

- Metered Spaces **120**
- Unmetered Spaces **43**

Walking

-  Key Walking Streets (see map)
-  High Priority Segments (see map)

Bicycling

- Bicycle Racks **15**



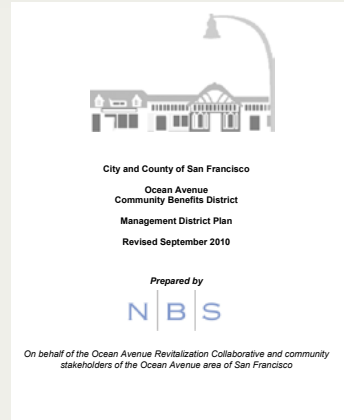
OCEAN AVENUE: EXISTING PLANS & INTERVENTIONS

Ocean Avenue Community Benefit District Management District Plan

DATE: 2010 **SOURCE:** Office of Economic and Workforce Development

SUMMARY: This document lists and describes information for the Ocean Avenue Community Benefit District. Property owners establish community benefit districts or business improvement districts to provide a constant funding source for various improvements, services and activities that benefit properties within a defined geographical area. The improvements, services and activities include providing enhanced cleaning and maintenance services, improving security, providing for economic development to promote and revitalize the area and other programs found to benefit the area. The ongoing revenue stream for the improvements, services and activities comes from the annual assessments that are levied upon properties within the area.

URL: <http://www.oewd.org/media/docs/CBD%20docs/Ocean%20Avenue/OceanAvenueManagementPlan.pdf>



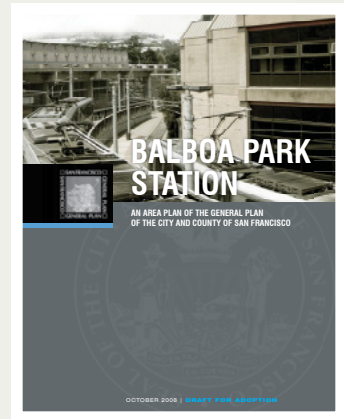
Balboa Park Station Area Plan

DATE: 2000 **SOURCE:** SF Planning

SUMMARY: This document sets forth objectives and policies informed by three key principles;

1. Improve the area's public realm;
2. Make the transit experience safer and more enjoyable; and
3. Improve the economic vitality of the Ocean Avenue Neighborhood Commercial District.

URL: http://www.sf-planning.org/ftp/general_plan/Balboa_Park_Station.htm





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District 7, Ocean Avenue



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To learn more about Invest in Neighborhoods please visit our website at <http://oewd.org/IIN.aspx>, or contact the Office of Economic and Workforce Development at (415) 554-6969 or moewd@sfgov.org and ask to speak with a member of the Invest in Neighborhoods team.

The *Invest in Neighborhoods* Commercial District Profiles have been brought to you by:



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Display Settings: Abstract**Full text links**Nicotine Tob Res. 2014 Oct 9. pii: ntu200. [Epub ahead of print]

A Longitudinal Study of Electronic Cigarette Use in a Population-based Sample of Adult Smokers: Association with Smoking Cessation and Motivation to Quit.

Biener L¹, Hargraves JL².

Author information

Abstract

Aims: Increasingly popular electronic cigarettes (e-cigarettes) may be the most promising development yet to end cigarette smoking. However, there is sparse evidence that their use promotes cessation. We investigated whether e-cigarette use increases smoking cessation and/or has a deleterious effect on quitting smoking and motivation to quit. **Methods:** Representative samples of adults in two U.S. metropolitan areas were surveyed in 2011/2012 about their use of novel tobacco products. In 2014, follow-up interviews were conducted with 695 of the 1374 baseline cigarette smokers who had agreed to be re-contacted (retention rate: 51%). The follow-up interview assessed their smoking status and history of electronic cigarette usage. Respondents were categorized as intensive users (used e-cigarettes daily for at least one month), intermittent users (used regularly, but not daily for more than one month), and non-users/tryers (used e-cigarettes at most once or twice). **Results:** At follow-up, 23% were intensive users, 29% intermittent users, 18% had used once or twice, and 30% hadn't tried e-cigarettes. Logistic regression controlling for demographics and tobacco dependence indicated that intensive users of e-cigarettes were 6 times as likely as non-users/tryers to report that they quit smoking (O.R. 6.07, 95% C.I. 1.11, 33.2). No such relationship was seen for intermittent users. There was a negative association between intermittent e-cigarette use and one of two indicators of motivation to quit at follow-up. **Conclusions:** Daily use of electronic cigarettes for at least one month is strongly associated with quitting smoking at follow up. Further investigation of the underlying reasons for intensive versus intermittent use will help shed light on the mechanisms underlying the associations between e-cigarette use, motivation to quit and smoking cessation.

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Highlights

Abstract

Keywords

1. Introduction

2. Material and methods

3. Results

4. Discussion

Role of funding sources

Contributors

Conflict of interest

Acknowledgment

References

Figures and tables

Table 1

Table 2

ADVERTISEMENT



Addictive Behaviors

Volume 39, Issue 2, February 2014, Pages 491–494



Short Communication

A longitudinal study of electronic cigarette users

Jean-François Etter^a, Chris Bullen^b[Show more](#)

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DOI: 10.1016/j.addbeh.2013.10.028

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Highlights

- Little is known about change in the behaviour of users of electronic cigarettes over time.
- We followed 477 users of electronic cigarettes during one month and 367 users over one year.
- We found that electronic cigarette use had no deleterious effects on smoking behaviour.

Abstract

Objective

To assess behavior change over 12 months in users of e-cigarettes (“vapers”).

Methods

Longitudinal Internet survey, 2011 to 2013. Participants were enrolled on websites dedicated to e-cigarettes and smoking cessation. We assessed use of e-cigarettes and tobacco among the same cohort at baseline, after one month (n = 477) and one year (n = 367).

Results

Most participants (72%) were former smokers, and 76% were using e-cigarettes daily. At baseline, current users had been using e-cigarettes for 3 months, took 150 puffs/day on their e-cigarette and used refill liquids containing 16 mg/ml of nicotine, on average. Almost all the daily vapers at baseline were still vaping daily after one month (98%) and one year (89%). Of those who had been vaping daily for less than one month at baseline, 93% were still vaping daily after one month, and 81% after one year. In daily vapers, the number of puffs/day on e-cigarettes remained unchanged between baseline and one year. Among former smokers who were vaping daily at baseline, 6% had relapsed to smoking after one month and also 6% after one year. Among dual users (smokers who were vaping daily at baseline), 22% had stopped smoking after one month and 46% after one year. In dual users who were still smoking at follow-up, cigarette consumption decreased by 5.3 cig/day after one month (from 11.3 to 6.0 cig./day, p = 0.006), but remained unchanged between baseline and 1-year follow-up.

Conclusions

E-cigarettes may contribute to relapse prevention in former smokers and smoking cessation in current smokers.

Keywords

Electronic cigarette; E-cigarette; Nicotine; Smoking

Corresponding author at: Institute of social and preventive medicine, University of Geneva, CMU, case postale, CH-1211 Geneva 4, Switzerland. Tel.: + 41 22 379 04 59; fax: + 41 22 379 04 52.

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E-cigarette use for quitting smoking is associated with improved success rates

People attempting to quit smoking without professional help are approximately 60% more likely to report succeeding if they use e-cigarettes than if they use willpower alone or over-the-counter nicotine replacement therapies such as patches or gum, finds a large UCL survey of smokers in England [1]. The results were adjusted for a wide range of factors that might influence success at quitting, including age, nicotine dependence, previous quit attempts, and whether quitting was gradual or abrupt.

The study, published in *Addiction*, surveyed 5,863 smokers between 2009 and 2014 who had attempted to quit smoking without the aid of prescription medication or professional support. 20% of people trying to quit with the aid of e-cigarettes reported having stopped smoking conventional cigarettes at the time of the survey.

The research, chiefly funded by Cancer Research UK, suggests that e-cigarettes could play a positive role in reducing smoking rates. “E-cigarettes could substantially improve public health because of their widespread appeal and the huge health gains associated with stopping smoking,” says Professor Robert West of UCL’s Department of Epidemiology & Public Health, senior author of the study. “However, we should also recognise that the strongest evidence remains for use of the NHS stop-smoking services. These almost triple a smoker’s odds of successfully quitting compared with going it alone or relying on over-the-counter products.” [2]

Another survey by the same team found that most e-cigarette

use involves first generation ‘cigalike’ products rather than second generation ones that use refillable cartridges and a wider choice of nicotine concentrations and flavours [3]. Dr Jamie Brown of UCL’s Department of Clinical, Educational and Health Psychology, lead author of both reports, says: “We will continue to monitor success rates in people using e-cigarettes to stop smoking to see whether there are improvements as the devices become more advanced.”

Some e-cigarette users may want to continue using them indefinitely. “It is not clear whether long-term use of e-cigarettes carries health risks but from what is known about the contents of the vapour these will be much less than from smoking,” says Professor West.

“Some public health experts have expressed concern that widespread use of e-cigarettes could ‘re-normalise’ smoking. However, we are tracking this very closely and see no evidence of it. Smoking rates in England are declining, quitting rates are increasing and regular e-cigarette use among never smokers is negligible.” [4]

-Ends-

Notes to Editors

Paper reference: Brown J, Beard E, Kotz D, Michie S, and West R (2014) Real-world effectiveness of e-cigarettes when used to aid smoking cessation: A cross-sectional population study. *Addiction* 109: [doi: 10.1111/add.12623](https://doi.org/10.1111/add.12623).

For a copy of the paper, or to speak to Dr Brown or Professor West, contact Harry Dayantis in the UCL press office, T: +44(0)20 3108 3844, M: +44(0)7747 565056, E: h.dayantis@ucl.ac.uk

Information about the free services provided by the NHS to help people stop smoking can be found at the following URL: <http://www.nhs.uk/smokefree>

Professor West is author of a new guide to stopping smoking called *The SmokeFree Formula* (Orion Books). See www.smokefreeformula.com for more information.

References

1 Brown, Beard, Kotz, Michie & West, ‘Real-world effectiveness of e-cigarettes when used to aid smoking

cessation: a cross-sectional population study', will be published in *Addiction* on Wednesday 21 May at 00:01 London time / Tuesday 20 May at 19:01 US Eastern time.

2 The previous study investigating the effectiveness of NHS services is as follows: Kotz, Brown & West, 'Real-world effectiveness of smoking cessation treatments: a population study', published in *Addiction* on 20 December 2013: <http://dx.doi.org/10.1111/add.12429>, which was in line with meta-analysis of a large number of randomised controlled trials: Stead LF, Lancaster T. 'Combined pharmacotherapy and behavioural interventions for smoking cessation.' *Cochrane Database of Systematic Reviews*. 2012;10:CD008286: <http://dx.doi.org/10.1002/14651858.CD008286.pub2>

3 The 2012 survey on e-cigarette usage is: Brown, West, Beard, Michie, Shahab & McNeill, 'Prevalence and characteristics of e-cigarette users in Great Britain: Findings from a general population survey of smokers', published in *Addictive Behaviours* on 11 March 2014: <http://dx.doi.org/10.1016/j.addbeh.2014.03.009>

4 The data for the study come from The Smoking Toolkit Study which tracks smoking habits in adults over the age of 16 every month and publishes the results online at <http://www.smokinginengland.info/latest-statistics/> Each month a new sample of approximately 1800 adults are selected using a form of random location sampling and complete a face-to-face computer-assisted survey with a trained interviewer. The method has been shown to result in a sample that is nationally representative in its socio-demographic composition and proportion of smokers.

Funding

The Smoking Toolkit Study is currently funded by Cancer Research UK. Since its inception it has also been co-funded at various times by The Department of Health, Pfizer, Glaxo-SmithKline and J&J (who manufacture stop-smoking medicines and nicotine replacement therapy but not e-cigarettes). Jamie Brown's salary is funded by The Society for the Study of Addiction. Robert West's salary is funded by Cancer Research UK. The study team has not received, and has a policy of not accepting, funding from any e-cigarette manufacturers.

About UCL (University College London)

Founded in 1826, UCL was the first English university established after Oxford and Cambridge, the first to admit students regardless of race, class, religion or gender and the first to provide systematic teaching of law, architecture and medicine.

We are among the world's top universities, as reflected by our performance in a range of international rankings and tables. According to the Thomson Scientific Citation Index, UCL is the second most highly cited European university and the 15th most highly cited in the world.

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big survey 2014 - initial findings general

17 Jul 2014 – By [Neil McLaren \(/author/2\)](#)

As many of you will know, ECF conducted its annual big survey recently, and had a huge amount of responses, over 10,000 in just 2 weeks! What's more we had a completion rate of 97%, which is no mean feat when you consider there were 75 questions. We thank each and everyone of you for taking part and doing your bit to help the community, this data is extremely useful and helps paint a true picture of what vaping is like in 2014.

We are currently working on a research paper to give this data the weight it deserves, but it is our opinion that it needs to be released into the public domain immediately, and especially before the end of the FDA deeming regulation commenting period.

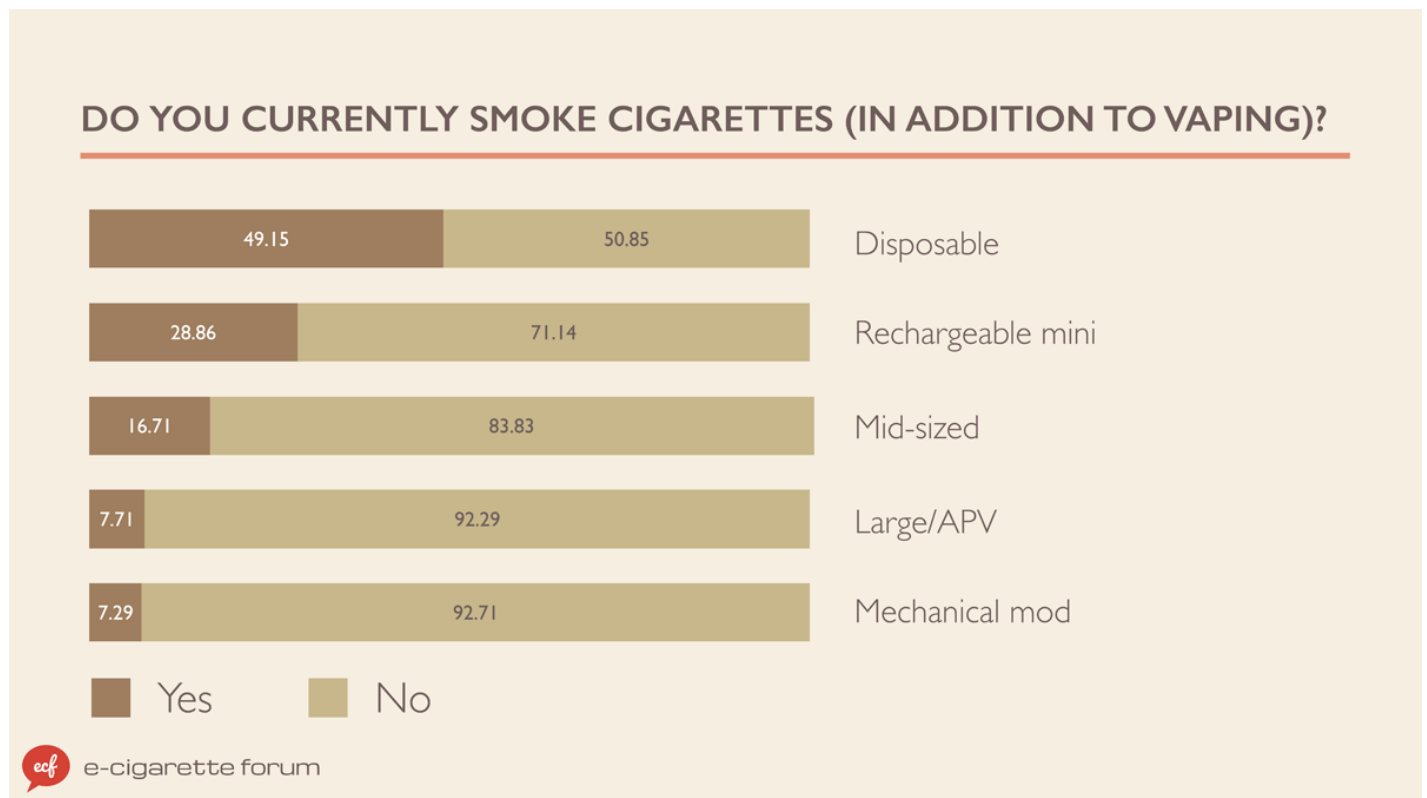
The picture it paints is contrary to many popularly held beliefs across the media and government, that we as vapers face on a daily basis, and many people won't want to hear it.

We encourage you to share and use this data wherever you can, especially the next time somebody says adults don't like flavours.

What you see here is some broad initial findings and points that stood out, some we suspected to be true, but didn't know for sure, others more surprising.

We will be updating **vaping.com/data** (<http://www.vaping.com/data>) over the coming days as we go deeper into the results. If there is anything you would like us to look more closely at for you please contact us on [info @ vaping.com](mailto:info@vaping.com)

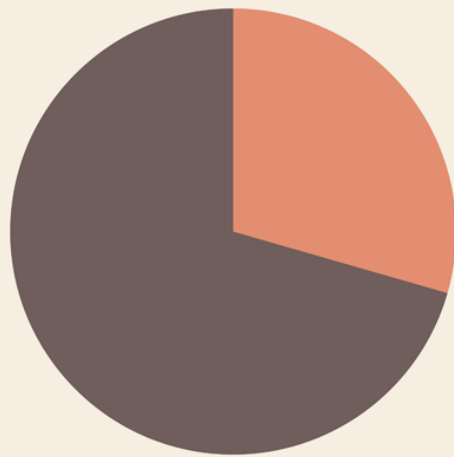
There are separate initial findings posts for **E-liquids** (<http://vaping.com/data/big-survey-2014-initial-findings-liquid>) and **Hardware**. (<http://vaping.com/data/big-survey-2014-initial-findings-hardware>)





92%

of vapers are worried that government regulations will remove products they use from the market



WOULD YOU KNOWINGLY PURCHASE A DEVICE MADE BY ONE OF THE MAJOR TOBACCO COMPANIES?

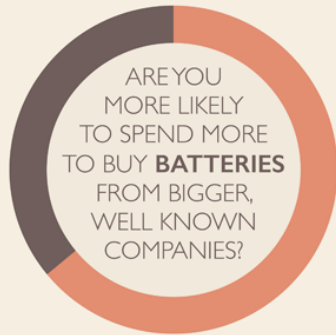
- 29.45% Yes
- 70.55% No

Current smokers vs quitters.

The dual user group are 53.85% unlikely to knowingly purchase a product from a tobacco company. Suggesting the successful act of quitting pushes a vaper further away in almost every respect from their former smoker behaviour.



VAPERS FEARS



65% YES



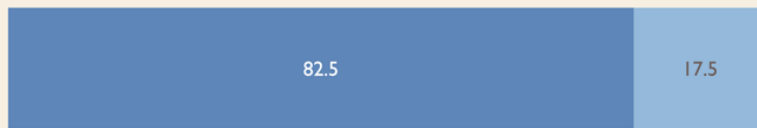
57.4% NO



VAPERS FEARS

Do negative vaping stories in the media concern you?

DUAL USERS



Both sets of vapers are concerned about the perception of vaping in the media.

However, it is the dual users who are most worried,

QUITTERS



■ Yes ■ No

THE RISE OF THE VAPESTORE

Where did you purchase your first e-cigarette?



18 Tweet 11 Like 0 +1

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2 comments • 3 months ago



Oliver Kershaw — Another thing they've not acknowledged (and probably don't know about) is that there is an annual dip which

70,000 is a lot of comments

2 comments • 2 months ago



Debra Knop Babski — if it wasn't for vaping I would of never stopped smoking. and I smoked for 40 years thank god for the vape

Docs Recommend Vaping to Quit Smokes

1 comment • 2 months ago



Bond d'Ananta — happy vaping everybody.....

Help Defeat Rep. Liz Thomson & strike a blow for Vapers everywhere

9 comments • 2 days ago



Ellie Choate — I was apalled and shocked by the angry attack on Dr Nitzgen who did nothing more than attempt to educate and

recently

→ (http://vaping.com/data)

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Big Survey 2014 - Initial Findings Eliquid (http://vaping.com/data/big-survey-2014-initial-findings-liquid)

Big Survey 2014 - Initial Findings General (http://vaping.com/data/vaping-survey-2014-initial-findings)

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WARNING: You must be over the legal age to purchase and/or use an electronic cigarette. Do not use an e-cigarette if you are below the legal smoking age or do not already smoke tobacco. If you have any allergy to nicotine or any combination of inhalants, or if you are pregnant or breast-feeding, or if you have heart disease, diabetes, high blood

pressure or asthma, please consult with your doctor before using any electronic cigarette products. Please note that nicotine is addictive and toxic by direct swallowing or in contact with the skin. Nicotine is known to cause birth defects and reproductive harm. Please keep it out of reach of children or pets.

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Briefing on e-cigarettes for policy makers



I am occasionally asked for a briefing on e-cigarettes and related policy issues – so here's one I produced recently, that I hope some readers of this blog might find useful – for example in talking to Directors of Public Health, NHS officials etc. This is the longer one... I also did a [shorter one with more recommendations](#).

E-cigarettes briefing – a disruptive public health technology threatened by excessive regulation

What are they? E-cigarettes generally consist of a battery, a heating coil and a liquid containing nicotine. A switch triggered by hand or by sucking pressure activates the battery to heat the coil, which vaporises the liquid. This is then inhaled and the nicotine absorbed into the blood via mouth, throat and lungs. The liquids contain nicotine, water, a 'diluent' such as propylene glycol or glycerol, and a flavouring, such as tobacco, mint, vanilla or fruit. There are now hundreds of flavours and these are an intrinsic part of the appeal. The devices and the liquids can be sold as integrated units or separately. Some look like cigarettes (1st generation 'cig-a-likes' in the jargon), some look like pens (2nd generation 'Ego' type), and the larger ones with tanks can look very distinctively different (3rd generation 'tanks' or 'mods'). The products have emerged only recently due to advances in batteries, which can now provide sufficient power and battery life in a small unit.

Public health case. There are 10 million smokers in the UK (~20% adults), about 110 million in the EU and around 1.3 billion worldwide – the current annual premature death toll attributed to smoking is 100,000, 700,000 and 6 million respectively. WHO estimates one billion premature deaths from smoking in the 21st Century on current trends. The public health proposition is that: e-cigarettes can substitute for cigarette use through market-based competition; provide a satisfactory alternative to smoking; and, in doing so, dramatically reduce risks to health, perhaps by 97-100% among those who switch. The alternative public health approach is to quit smoking and nicotine altogether – this is much slower and harder to achieve, and may leave ex-smokers with cravings and withdrawal and a sense of loss. Global tobacco sales are variously estimated at \$700-800 billion (Bloomberg), mainly cigarettes, whereas sales of vapour products are likely to be \$5 billion in 2014 (Euromonitor) – there is scope for a major structural change in the market for recreational nicotine.

The benefits to the smoker. From the smoker's perspective, e-cigarettes create a new value proposition: they offer many of the experiences of smoking (a nicotine hit, something to hold and gesture with, sensory experience etc) with few of the harms (long term risk much lower, less social disapproval, minimal odour nuisance) and at a lower cost. Prior to the emergence of e-cigarettes, the alternatives were broadly cast as 'quit or die' – this new value proposition fits between the two.

Harm arising from vaping. No-one claims vaping is entirely benign. Nor does it need to be to make very large inroads into the risks of disease if people switch. Studies of liquids and vapour chemistry reveal traces of contaminants and thermal breakdown products that are potentially harmful, but at levels generally two orders of magnitude lower than in cigarette smoke and unlikely to pose a material threat. The most comprehensive literature review so far concluded:

Current state of knowledge about chemistry of liquids and aerosols associated with electronic cigarettes indicates that there is no evidence that vaping produces inhalable exposures to contaminants of the aerosol that would warrant health concerns by the standards that are used to ensure safety of workplaces. ... Exposures of bystanders are likely to be orders of magnitude less, and thus pose no apparent concern.

[\(Burstyn I, 2013\) Peering through the mist: systematic review of what the chemistry of contaminants in electronic cigarettes tells us about health risks.](#)

Legitimate regulatory agenda. Burstyn rightly recommends continued surveillance and measures to reduce exposures to residual harmful substances

in vapour and e-liquids, and this would make a worthwhile regulatory agenda. There is no basis for believing that bystanders are at any material risk: in public places the issue is one of norm-setting and etiquette and should be a matter for owners and operators, not the law

Current use in the UK. A recent [GB survey by ASH](#) showed that 2.1 million people are using e-cigarettes and about one third are now ex-smokers – this represents a very substantial health gain. The Department of Health estimates a value of £74,000 per successful quit attempt (£60,000 health value per life-year and 1.24 life-years gained), so 700,000 switchers gives approximately £52 billion welfare benefit – with possibly a small deduction (1-3%) for detriments arising from extra vaping. More information of use of e-cigarettes is given at Appendix 1.

What is the potential? [One Wall Street analyst projects that vapour use will surpass smoking \(in the US\) within a decade](#) (by which she means 2023). Much will depend on whether regulation encourages or suppresses innovation – and her forecast is contingent on an effective pro-innovation regulatory framework. Other analysts are less bullish, but all see great potential. If half of smokers convert to vaping, it would be one of the most remarkable public health phenomena ever: in UK, 5 million smokers switching would create a health benefit of ~£370 billion, on the basis given above.

What are critics concerned about? Most opponents of e-cigarettes are slowly giving up the argument that ‘we don’t know what’s in them’ or concerns about the safety of the products themselves. They are instead concentrating on ‘population’ arguments. This is the idea that though vaping is very much less hazardous than smoking, at population level it could be *more dangerous* because it causes changes in the way people smoke, for example:

- It could be a ‘gateway’ to smoking for adolescents;
- It might divert people from quitting smoking because they don’t feel under so much social pressure if they can avoid smoking restrictions by vaping;
- By visible displays of smoking-like behaviour it might ‘renormalise’ smoking.

There is no basis to believe any of these effects are real rather than contrived tactical campaign arguments. The UK’s foremost expert in smoking cessation, Professor Robert West, puts it thus:

Evidence conflicts with the view that electronic cigarettes are undermining tobacco control or ‘renormalizing’ smoking, and they may be contributing to a reduction in smoking prevalence through increased success at quitting smoking ([Electronic cigarettes in England – latest trends 6 July 2014](#))

Fear of the tobacco industry. A further source of critics’ concern is the possible negative role of the tobacco industry. In practice it is hard to see what this could be: they are threatened by e-cigarettes, and will need to produce high quality attractive alternatives or risk losing share in the recreational nicotine market to other tobacco companies or non-tobacco e-cigarette companies. It is more likely that they will become important drivers of a wholesale switch from smoking to vaping.

The case of snus – a cautionary tale. Many of the same ‘population’ arguments were made on a precautionary basis in the case to ban ‘oral tobacco’ in 1992 throughout the EU, even though it is 95-98% less hazardous than smoking. On accession, Sweden was granted an exemption from the ban. In fact, this product – ‘snus’ or oral snuff – has become popular in Sweden and is the reason why Sweden has by far the lowest rate of smoking in the EU: 13% Swedish adults vs 28% EU average ([Eurobarometer, 2012](#)). Snus has three main effects in Sweden and Norway: it is used to quit smoking; it is used to substitute for smoking; it diverts young people from onset of smoking. Despite overwhelming evidence to justify lifting the EU ban on snus, the ban was re-affirmed in 2014.

To summarise: a market based public health phenomenon. The electronic cigarette has emerged through the interplay between consumers and innovative suppliers, with no public sector involvement or endorsement, no call on the taxpayer or NHS resources, and minimal regulation. Yet this product is already providing very substantial health benefits as a relatively benign alternative to smoking. It has empowered smokers to take control of their risks and has greatly enhanced the welfare of hundreds of thousands of UK citizens. It has challenged the tobacco industry, but also interests in the public sector and civil society who have played no role – or a hostile role – in its rise.

Regulatory issues

The primary risk to these otherwise highly positive developments is poor and excessive regulation. At the heart of the regulatory challenge there is a ‘double negative’: being tough on e-cigarettes is being tough on the competitive alternative to cigarettes. There is a danger that loss-averse regulators and officials will place excessive focus on the residual risks associated with vapour products, but in doing so render them less effective and appealing as alternatives to smoking and thereby potentially increase total health risks through the unintended consequence of continuing smoking. All the regulatory proposals advanced so far suffer from this weakness.

- **The UK’s favoured approach has been to regulate these vapour products as medicines.** This onerous regime applies costs, burdens and restrictions that would dramatically contract the range of products and number of suppliers, whilst acting as a barrier to innovation. It creates very high barriers to entry and is unsuitable for an evolving disruptive fast moving consumer goods industry. It is likely that only the largest companies could make and pass these requirements – so far only one, the subsidiary of British American Tobacco, has attempted it. The regime is wholly unnecessary: the products are not medicines in law or common sense, the vendors are not healthcare providers and users do not regard themselves as in treatment.
- **The EU’s favoured approach is to regulate using measures designed for tobacco products.** After the European Parliament rejected the

Council's proposal to regulate e-cigarettes as medicines (for many of the reasons given above), a closed trilogue process created 5,000 words of new regulation in three months – with no consultation or impact assessment and inadequate justification – with scientists pointing out numerous errors of fact and interpretation. The resulting directive (2012/40/EC – Article 20) has numerous flaws of arbitrary and unscientific policy and poor policy-making process, and is likely to be found in breach of key treaty principles if challenged in the European Court of Justice. The UK will now offer both the medical route and the approach negotiated under this directive as alternatives. The directive has entered into force and its provisions apply from 2016/17.

- **The US favoured approach is to treat e-cigarettes as tobacco products on the basis that the pure nicotine used is originally extracted from tobacco.** In April, the FDA announced its intention to apply tobacco legislation to e-cigarettes – that was designed with the primary purpose of slowing innovation and creating burdens for the cigarette manufacturers.
- **The WHO's favoured approach** is to classify these products as tobacco and to apply the restrictive measure of the WHO's tobacco treaty (the Framework Convention on Tobacco Control). The WHO would also include these products in UN targets to reduce tobacco consumption by 30% by 2025. In practice the only hope of coming close to meeting this target is to use vapour products to meet the targets, not to reduce them. 53 of the world's top experts in the field recently wrote to WHO to implore them to take a more positive approach. Their letter is appended at Appendix 2.

The best outcome would be an amendment or legal challenge to the EU directive to remove its most egregious features. The EU directive offers the best promise for a decent regulatory regime, but contains some absurd and unjustified measures, notably:

- **A ban on most advertising sponsorship and promotion.** The anti-competitive ban protects the incumbents from a disruptive challenger and is unjustified in a directive with a single market legal base, and disproportionate relative to tobacco. Most tobacco advertising is banned in the EU, but tobacco kills 700,000 per year. In contrast, vaping is likely to *reduce* premature deaths.
- **Limiting the strength of nicotine liquids to 20mg/ml.** Approximately 25-30% of consumers use liquids stronger than this. They may be more important for more heavily dependent smokers and those just switching. The threshold is arbitrary and pointless.
- **Limiting liquid container sizes.** We manage hazardous liquids (like bleach) by having packaging and labelling standards not by limiting the containers to tiny inconvenient sizes.
- **Requiring large warnings.** The directive requires cigarette-like warnings that contain misleading and off-putting information covering 30% of the pack. The warnings are not proportionate.
- **Numerous technical measures** that would fail a reasonable risk-benefit assessment.
- **A continuing ban on snus** – despite it being the reason, beyond doubt, for the best tobacco-related health outcomes in Europe in Sweden, it will remain banned throughout the rest of the EU. It is unscientific, unethical and probably unlawful to ban this product.

Conclusion: too big and too bossy. The tobacco products directive, at least as it applies to reduced risk alternative to smoking, is poor policy made in a poor process. The directive, and the way it was created, fits the Prime Minister's characterisation of the EU being 'too big and too bossy'. It is also a useful case study in the challenges for 'open policy-making'. It is not strictly an EU problem: UK officials have been closely involved in forming this policy and there are many lessons to be learned from the experience.

Appendices

1. [Data briefing by Professor Robert West and colleagues \(2 pages\)](#)

2. [Letter by 53 scientists and experts to WHO \(3-page letter + signatures\)](#)



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4 comments to Briefing on e-cigarettes for policy makers



[John Chamley](#)

August 2, 2014 at 1:30 pm · Reply

Considering that most e liquids are no longer 'toxic' according to EU CLP, the proposed EU regulations are even more disproportionate.

The press release below links to the BIBRA study on classification.

<http://www.ecita.org.uk/blog/index.php/how-toxic-is-e-liquid/>



John Chamley

[August 2, 2014 at 1:34 pm](#) · [Reply](#)

I should have added:

[Safety evaluation and risk assessment of electronic cigarettes as tobacco cigarette substitutes: a systematic review](#)

Konstantinos E. Farsalinos (corresponding author) and Riccardo Polosa.

Read the full text, now available.

This is the most comprehensive report I have read and will reinforce the tidal turn.

Chapeau to Konstantinos and Riccardo!



David Bareham

[August 6, 2014 at 9:37 am](#) · [Reply](#)

John: Response re: A6 from Correspondence contact for Kosmider paper;reads:

"There are data in our paper on ingredients in fluid A6. Please see Table 1. It contained PEG. There is also a note under the Table 2, showing that this sample was different, since it contained PEG. Unfortunately, I don't think we have any sample left as we used it for the study."

Dave.



Roger Hall

[August 10, 2014 at 10:56 am](#) · [Reply](#)

Taking just two of your stated egregious features it's highly pertinent to add that the Commission on Human Medicines Working Group on NCPs when drawing up their recommendations concluded that "The commission noted that the use of (nicotine threshold) levels was not evidence based, unscientific, difficult to enforce and likely to be confusing" and "would likely be detrimental to public health" and were also against the use of warning labels for similar reasons citing the fact that "the requirement to state that nicotine can damage your health is unlikely to be true".

<http://www.mhra.gov.uk/home/groups/comms-ic/documents/websiteresources/con286849.pdf>

The same arguments equally apply with the TPD in relation to ecigs surely?

Carbonyl Compounds in Electronic Cigarette Vapors—Effects of Nicotine Solvent and Battery Output Voltage

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- Received November 4, 2013.
- Accepted April 7, 2014.

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Abstract

Introduction: Glycerin (VG) and propylene glycol (PG) are the most common nicotine solvents used in e-cigarettes (ECs). It has been shown that at high temperatures both VG and PG undergo decomposition to low molecular carbonyl compounds, including the carcinogens: formaldehyde and acetaldehyde. The aim of the study was to evaluate how various product characteristics, including nicotine solvent and battery output voltage, affect the levels of carbonyls in EC vapor.

Methods: Twelve carbonyl compounds were measured in vapors from 10 commercially available nicotine solutions and from three control solutions composed of pure glycerin, pure propylene glycol, or a mixture of both solvents (50:50). EC battery output voltage was gradually modified from 3.2 to 4.8V. Carbonyl compounds were determined using HPLC/DAD method.

Results: Formaldehyde and acetaldehyde were found in 8 of 13 samples. The amounts of formaldehyde and acetaldehyde in vapors from lower voltage EC were on average 13- and 807-fold lower than in tobacco smoke, respectively. The highest levels of carbonyls were observed in vapors generated from PG-based solutions. Increasing voltage from 3.2 to 4.8V resulted in 4 to over 200 times increase in formaldehyde, acetaldehyde, and acetone levels. The levels of formaldehyde in vapors from high-voltage device were in the range of levels reported in tobacco smoke.

Conclusions: Vapors from EC contain toxic and carcinogenic carbonyl compounds. Both solvent and battery output voltage significantly affect levels of carbonyl compounds in EC vapors. High-voltage EC may expose users to high levels of carbonyl compounds.

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INTRODUCTION

Electronic cigarettes (e-cigarettes; ECs) have been gaining increasing popularity as nicotine delivery tools. It has been shown that number of EC users is growing rapidly ([Ayers, Ribisl, & Brownstein, 2011](#); [Kosmider, Knysak, Goniewicz, & Sobczak, 2012](#)). Scientific evidence is urgently needed to develop the best regulatory approach to ECs. The U.S. Food and Drug Administration (FDA) has authority to regulate ECs as tobacco or medicinal products, and such regulation is expected to be announced soon ([Benowitz & Goniewicz, 2013](#)). Recently, the European Parliament has voted that ECs will be regulated as tobacco products, but the U.K. Medicines and Healthcare products Regulatory Agency (MHRA) has announced that EC will be regulated as medicinal devices in the United Kingdom by 2016 ([Hajek, Foulds, Le Houezec, Sweanor, & Yach, 2013](#)). Studies are urgently needed to evaluate the presence of potentially toxic and hazardous compounds in vapors generated by ECs and which are inhaled by product users. Vapors are generated from solutions, commonly known as e-liquids or e-juices, which contain solvents (so-called e-liquid base), various concentrations of nicotine, water, additives, and flavorings. The most popular solvents used in e-liquids are glycerin (most commonly of vegetable origin, VG), propylene glycol (PG), or their mixture in various ratios. The “base” usually constitutes 70% to 80% of all components in the e-liquid.

When an EC user takes a puff, it activates heating element that vaporizes the e-liquid. This vaporization process occurs at various temperature ranges. It has been estimated that theoretical vaporization temperature of the heating element may reach up to 350°C (Balhas et al., 2014; Schripp, Markewitz, Uhde, & Salthammer, 2013). This temperature is sufficiently high to induce physical changes of e-liquids and chemical reactions between the constituents of e-liquids. At this temperature, solvents may undergo thermal decomposition leading to formation of potentially toxic compounds. Both VG and PG have been shown to decompose at high temperatures generating low molecular weight carbonyl compounds with established toxic properties (e.g., formaldehyde, acetaldehyde, acrolein, and acetone) (Paschke, Scherer, & Heller, 2002). Moreover, carbonyls such as formaldehyde and acetaldehyde may be present in the e-liquid (Farsalinos, Spyrou, Tsimopoulou, Romagna, & Voudris, 2014). Formaldehyde is classified by the International Agency for Research of Cancer (IARC) as a human carcinogen (Group 1), and acetaldehyde is classified as possibly carcinogenic to humans (Group 2B) (IARC, 2012). Acrolein causes irritation of the nasal cavity, damages the lining of the lung (U.S. EPA, 2003), and has been shown to contribute to cardiovascular disease (Park & Taniguchi, 2008). Acetone is a mucous membrane irritant that has been shown to induce damage on olfactory neuroepithelium in mice after inhalation (Buron, Hacquemand, Pourié, & Brand, 2009). It has been hypothesized that exposure to carbonyls may cause mouth and throat irritation, one of the most commonly reported side-effects of ECs (Bullen et al., 2010).

We previously evaluated 12 various brands of ECs and found that the generated vapors contained various carbonyls (Goniewicz et al., 2014). The limited literature to date described the presence of formaldehyde, acetaldehyde, acetone, acrolein, propanal, butanal, glyoxal, and methylglyoxal in EC vapors (Goniewicz et al., 2014; Laugesen, 2008; Schripp et al., 2013; Uchiyama, Inaba, & Kunugita, 2010). The studies reported that the levels of carbonyls in EC vapors are significantly lower than those found in tobacco smoke. However, these studies used early models of EC (also referred as “first generation”).

EC product categories have been evolving very rapidly and a “second generation” was recently introduced to the market. New products include “tank systems” that can be refilled by users with various e-liquids (Supplementary Figure 1). Some new EC models allow users to increase vaporization temperature by changing battery output voltage (Supplementary Figure 1). An EC generates vapor by heating an atomizing device normally containing a heater coil. To produce more heat, the device needs more power. Variable voltage EC are power control devices that allow the user to control the voltage that is applied to the atomizer. Variable voltage EC allows user to change the voltage of the device to increase the vapor production and nicotine delivery. There is also a huge variety of e-liquids on the market, which are manufactured and distributed by various companies. The aim of the study was to evaluate the extent to which nicotine solvent and battery output voltage affect the levels of carbonyls in the vapors of these second generation products.

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MATERIALS AND METHODS

Electronic Cigarette

The most popular device available on the Polish market as on January 2013 was selected for the study. Because the Internet is currently the main distribution channel for EC, we searched google.pl web browser and tracked the number of EC sell offers on Allegro.pl, which is the most popular online auction service in Poland. Based on the number of search hits and sell offers, we chose and purchased the eGo-3 brand (Volish, Ltd, Poland). The device has controlled maximum time for single puff of 10 s. We chose a model composed of a Crystal 2 clearomizer (Supplementary Figure 1), with a heating element with resistance of 2.4 ohms, a 900 mAh battery with voltage of 3.4V, and a battery voltage stabilization system. All batteries were charged for 24hr before each test. Only fully charged batteries were used for liquid generation, and batteries were replaced when the devices indicated a decrease in charging level from 100%–50% (white diode color) to 50%–10% (light blue diode color).

In order to test the effect of battery output voltage on carbonyl levels delivered to vapor, we used eGo-3 Twist battery. This 900 mAh battery has a dial that allows for gradually changing its voltage from 3.2 to 4.8V with precision of $\pm 0.07V$ (Supplementary Figure 1).

Nicotine Solutions (E-liquids)

Ten kinds of commercially available e-liquids with nicotine concentration from 18 to 24mg/ml were used to fill up the clearomizer (tank). All products except one had the labels or inserts that provided information about source of manufacturing, name of distributor, and ingredients (A1–A10; Table 1). However, only half of the product labels showed the concentrations of solvents and flavorings. Based on the labeling information, we grouped the products into VG based (only VG; A1–A3), VG:PG based (both VG and PG mixed in various ratios; A4–A6), and PG based (only PG; A7–A10). We collected 1ml of each e-liquid and refilled 10 clearomizers of the same type 24hr before aerosol generation. Each clearomizer was used only for one e-liquid. We followed instructions in the user’s manual and stored the clearomizers at room temperature in a horizontal position to equally distribute the solution inside the clearomizer.

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Table 1.**Characteristics of Nicotine Refill Solutions**

In addition to commercially available products, we prepared three sets of control e-liquids (C1–C3; [Table 1](#)). The control e-liquids were prepared by dissolving pure nicotine (>99%, Acros) in analytical-grade solvents and vortexing for 10min. The following control solutions were prepared: C1 with VG (88.2%), redistilled water (10.0%), and nicotine (1.8%); C2 with VG (44.1%), PG (44.1%), redistilled water (10.0%), and nicotine (1.8%); and C3 with PG (88.2%), redistilled water (10.0%), and nicotine (1.8%). None of the control e-liquid contained any flavorings or additives. These control e-liquids were used in experiments with adjustable battery voltage.

Generation of EC Vapors

Vapors from ECs were generated using the automatic smoking machine Palaczbot (University of Technology, Lodz, Poland) as described previously ([Goniewicz, Kuma, Gawron, Knysak, & Kosmider, 2013](#)). In the current study, all tests were performed with the following puffing conditions: puff duration 1.8 s, puff volume 70ml, and puff intervals 17 s as described previously ([Goniewicz et al., 2013](#)). A total of 30 puffs were taken from each EC in two series of 15 puffs with a 5-min interval between series. ECs were kept in a horizontal position in order to maintain natural conditions of puffing on EC. Because the device used in this study was manually activated, an operator of the smoking machine pressed the button manually 1 s before each puff was taken and released it immediately after the puff was completed. Vapors from each e-liquid were tested three times.

In experiments with adjustable battery voltage, vapors were generated using three different battery voltages: 3.2, 4.0, and 4.8V. Three tests were conducted for each of nine solvent:voltage combinations. We used new clearomizers of the same type per each voltage setting. Because we did not use the same battery for all tests, differences in carbonyl levels in vapors generated at 3.2V were compared with the levels in vapors generated at 4.8V using a *t* test. For statistical analysis, results below lower limits of quantitation (LLOQ; see below) were estimated as $LLOQ/\sqrt{2}$.

Analysis of Carbonyl Compounds

The method recommended by the U.S. Environment Protection Agency (EPA) was applied for determination of carbonyl compounds ([U.S. EPA, 2003](#)). Briefly, it involves direct extraction of these compounds from aerosol to solid phase, that is, silica gel saturated with 2,4-dinitrophenylhydrazine (DNPH). The silica sorbent tubes (300/150mg; SKC Inc.) were placed between EC mouthpieces and smoking machine to trap carbonyls from freshly generated vapors. The sorbent tubes were placed directly behind the EC mouthpiece to avoid potential losses of analyzed compounds. DNPH derivatives of carbonyl compounds were desorbed from sorbent tubes using 1ml of acetonitrile. Ten microliters of the extract was analyzed using high-performance liquid chromatography (HPLC) with Eclipse PAH chromatographic column (4.5×250mm, 5 μm, Zorbax, Agilent Technologies) and a diode array detector (DAD; 365nm wavelength) (AT 1200, Agilent Technologies, USA). An elution gradient with acetonitrile:water mobile phase was used, and chromatographic separation was performed at a constant temperature of 40°C. The method was calibrated and validated as per the International Conference on Harmonization guideline Q2 R1 ([International Conference on Harmonization, 2005](#)). All calibration and control samples were prepared by spiking the sorbent tubes with various amounts of stock solution of carbonyls and proceeding with whole analytical procedures. Blank samples were prepared by sampling air from the laboratory where all tests were performed. If any of the analyzed carbonyls were detected in blank samples, the background levels were subtracted from the levels detected in vapor samples. Precision and accuracy of the method varied from 4% to 12% and from 96% to 108%, respectively. In order to compare levels of carbonyls found in vapors with levels reported for tobacco smoke, results were recalculated per one series of 15 puffs from ECs. The LLOQ of the carbonyls were as follows: (ng/15 puffs): formaldehyde, 30; acetaldehyde, 15; acrolein, 30; acetone, 30; propionaldehyde, 20; crotonaldehyde, 40; butanal, 30; benzaldehyde, 40; isovaleric aldehyde, 20; valeric aldehyde, 20; o-methylbenzaldehyde, 35; and m-methylbenzaldehyde, 35.

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RESULTS**Levels of Carbonyl Compounds Released From Commercially Available Refill Solutions**

[Table 2](#) shows amounts of each analyzed carbonyl compounds in 15 puffs of vapor from 10 commercially available e-liquids. The values presented in [Table 2](#) are means with *SD* from three tests performed at the same voltage of 3.4V. All samples contained at least one carbonyl compound. Formaldehyde, acetaldehyde, acetone, and butanal were found in most of the analyzed samples. However, not all commercially available e-liquids emitted all these four carbonyls. Crotonaldehyde was detected in only one sample (A10), whereas acrolein was not detected in any sample.

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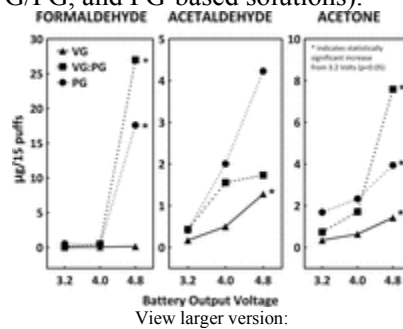
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Table 2.

Levels of Carbonyl Compounds in Vapors Generated From EC Refilled With Commercially Available (A1–A10) and Control (C1–C3) Nicotine Solutions (ng/15 puffs; mean \pm SD; $N = 3$)

Effect of Solvent and Battery Output Voltage on Carbonyl Yields Released to Vapors

[Figure 1](#) shows the effect of solvent and battery output voltage on amounts of formaldehyde, acetaldehyde, and acetone released to vapors with 15 puffs from EC refilled with three different control solutions (C1–C3). In general, PG-based e-liquids generated significantly higher levels of carbonyls than VG-based e-liquids ($p < 0.05$). Increased battery output voltage resulted in the higher levels of carbonyls in vapor. When low battery output voltage (3.2V) was used, the average amounts of formaldehyde released with 15 puffs from VG, VG/PG, and PG were (mean \pm SD) 0.02 ± 0.02 , 0.13 ± 0.11 , and 0.53 ± 0.19 μg , respectively. When battery output voltage was increased to 4.8V, the amounts of formaldehyde were 0.15 ± 0.06 ($p = .03$), 27.0 ± 7.9 ($p < .01$), and 17.6 ± 19.7 μg ($p = .21$), respectively. When low battery output voltage (3.2V) was used, the average amounts of acetaldehyde released with 15 puffs from VG, VG/PG, and PG were 0.17 ± 0.09 , 0.43 ± 0.50 , and 0.41 ± 0.28 μg , respectively. However, when the battery output voltage was increased to 4.8V, the amounts of acetaldehyde increased to 1.24 ± 0.12 ($p < .01$), 1.73 ± 1.21 ($p = .16$), and 4.23 ± 3.23 μg ($p = .11$), respectively. Levels of acetone also increased with increased battery output voltage (from 0.34 ± 0.09 , 0.73 ± 0.52 , 1.68 ± 0.30 to 1.43 ± 0.14 [$p < .01$], 7.59 ± 2.14 [$p = .01$], 3.94 ± 0.47 [$p < .01$] $\mu\text{g}/15$ puffs, respectively, for VG, VG/PG, and PG-based solutions).



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Figure 1.

Effects of nicotine solvent and battery output voltage on levels of carbonyl compounds released from ECs ($\mu\text{g}/15$ puffs; $N = 3$; puff duration 1.8 s, puff volume 70ml, puff intervals 17 s).

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DISCUSSION

We present novel findings on levels of carcinogenic and toxic carbonyl compounds in vapors from second generation of EC. Our findings show that vapors generated from various commercial and reference solutions expose EC users to toxic carbonyls, including the carcinogens formaldehyde and acetaldehyde. Our findings are consistent with previously published reports reporting presence of formaldehyde, acetaldehyde, acrolein, propanal, acetone, and butanal in EC vapors ([Goniewicz et al., 2014](#); [Laugesen, 2008](#); [McAuley, Hopke, Zhao, & Babaian, 2012](#); [Schripp et al., 2013](#)).

Our study found that the amounts of formaldehyde and acetaldehyde in vapors from lower voltage tank system ECs were on average 13- and 807-fold lower than in tobacco smoke, respectively. We previously reported that levels of these toxicants in vapors from the first generation of EC were 9- and 450-fold lower than in tobacco smoke, respectively ([Goniewicz et al., 2014](#)). [Schripp et al. \(2013\)](#) found that the levels were 7- and 59-fold lower compared with tobacco smoke. Our findings suggest only a slight reduction in toxicant emission from the second generation low-voltage EC compared with first generation ECs. Despite findings from chemical analysis, *in vitro* studies of the effects of EC vapor on cultured cells have shown that cell survival was not associated with the nicotine solvent ([Farsalinos Romagna, Alliffranchini, et al., 2013](#)). Therefore, clinical studies are needed in order to determine whether such levels of carbonyls may have the potential to cause disease to EC users. We also showed that levels of carbonyl compounds in EC vapors are strongly affected by product characteristics, like type of nicotine solvent and battery voltage. In general, the highest levels of carbonyls were observed in vapors generated from PG-based solutions. This finding suggests that PG in ECs is more susceptible to thermal decomposition than VG. The presence of carbonyls in flavor-free control solutions indicates that the primary sources of these toxicants are nicotine solvents. An interesting finding of our study is that no toxic carbonyls were detected in a single sample with reduced content of VG and PG. In this product (A6), the primary solvent was polyethylene glycol (PEG). It would suggest that PEG-based e-liquids might have reduced toxicity from decomposition products. Further research should explore this hypothesis.

The striking finding of our study is that levels of carbonyls rapidly increase with increased battery output voltage. Increasing battery output voltage leads to higher temperature of the heating element inside EC. In addition, the increased battery output voltage results in more e-liquid consumed per puff. Our findings show that increasing voltage from 3.2 to 4.8V resulted in 4 to over 200 times increase in formaldehyde, acetaldehyde, and acetone levels. The levels of formaldehyde in vapors from high-voltage devices were in the range of levels reported in tobacco smoke (1.6–52 µg/cigarette; [Counts, Morton, Laffoon, Cox, & Lipowicz, 2005](#)). This finding suggests that in certain conditions ECs might expose their users to the same or even higher levels of carcinogenic formaldehyde than tobacco smoke. This finding is essential for the product safety and in the light of forthcoming regulation of the devices.

We also noted some inconsistency in results related to acrolein presence in vapor with previously published findings. In our study, we did not find acrolein in any products. However, our previous research as well as research published by other authors suggest the presence of acrolein in EC vapor. However, in current study, we measured carbonyls only in two series of 15 puffs, whereas in previous report, we used much larger samples (150 puffs). Thus, this inconsistency might be attributed to differences in detection limits. The other explanation would be that generation of acrolein increases with the duration of EC use. Extensive puff-by-puff analysis would facilitate verification of this hypothesis.

The present study have some important limitations. We only looked at two factors that might affect toxicity of EC, namely nicotine solvent and battery output voltage. More research is needed to describe how other product characteristics affect toxicity of ECs. Future studies should examine the types of heating elements, flavorings and additives, and product storage conditions. Secondly, recent studies showed significant variations in puffing topography among users of various EC models ([Edmiston et al., 2014](#); [Farsalinos, Romagna, Tsiapras, Kyrzopoulos, & Voudris, 2013](#); [Vansickel et al., 2014](#)). Puffing topography may affect levels of carbonyls released from different ECs. There are some discrepancies between puffing regime used in our study and the results of clinical studies ([Farsalinos, Romagna, Tsiapras, et al., 2013](#)). Future studies should examine the effect of puffing on carbonyl levels released to EC vapors. The other limitation of this study is that we used the SKC sorbent tubes to trap carbonyl compounds. These tubes are meant to capture gas-phase, rather than particle-phase carbonyls. It is likely that at least some of the carbonyls (e.g., formaldehyde) are partitioned between the gas and particle phase in EC aerosol and may not have been trapped efficiently in the sorbent tubes. It is possible that what was measured actually represents a lower bound of what could have been emitted by the ECs.

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CONCLUSIONS

Vapors from ECs contain toxic and carcinogenic carbonyl compounds. Both solvent and battery output voltage significantly affect levels of carbonyl compounds in EC vapors. Levels of carbonyls rapidly increase with increased battery output voltage. New generation of high-voltage ECs may put their users in increased health risk from exposure to high levels of carbonyl compounds although the risk will still probably be much lower compared with smoking.

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SUPPLEMENTARY MATERIAL

Supplementary [Figure 1](#) can be found online at <http://www.ntr.oxfordjournals.org>

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DECLARATION OF INTERESTS

MLG received research funding from Pfizer, manufacturer of stop smoking medication. AS received research funds and travel expenses from Chic Group LTD, manufacturer of electronic cigarettes in Poland. Other authors declare no conflict of interest.

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Characterization of chemicals released to the environment by electronic cigarettes use (ClearStream-AIR project): is passive vaping a reality?³

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Abstract

Background Electronic cigarettes (e-CIG) have been marketed as a safer alternative habit to tobacco smoking. We have developed a group of research protocols to evaluate the effects of e-CIG on human health, called ClearStream. No studies have adequately evaluated the effects of e-CIG use on the release of chemicals to the environment. The purpose of this study was to identify and quantify the chemicals released on a closed environment from the use of e-CIG (ClearStream-AIR).

Methods A 60 m³ closed-room was used for the experiment. Two sessions were organized, the first using 5 smokers and the second using 5 users of e-CIG. Both sessions lasted 5 h. Between sessions, the room was cleaned and ventilated for 65 h. Smokers used cigarettes containing 0.6 mg of nicotine while e-CIG users used commercially available liquid (FlavourArt) with nicotine concentration of 11 mg/ml. We measured total organic carbon (TOC), toluene, xylene, carbon monoxide (CO), nitrogen oxides (NO_x), nicotine, acrolein, poly-aromatic hydrocarbons (PAHs) glycerin and propylene glycol levels on the air of the room.

Results During the smoking session, 19 cigarettes were smoked, administering 11.4 mg of nicotine (according to cigarette pack information). During the e-CIG session, 1.6 ml of liquid was consumed, administering 17.6 mg of nicotine. During the smoking session we found: TOC=6.66 mg/m³, toluene=1.7 µg/m³, xylene=0.2 µg/m³, CO=11 mg/m³, nicotine=34 µg/m³, acrolein=20 µg/ml and PAH=9.4 µg/m³. No glycerin, propylene glycol and NO_x were detected after the smoking session. During the e-CIG session we found: TOC=0.73 mg/m³ and glycerin=72 µg/m³. No toluene, xylene, CO, NO_x, nicotine, acrolein or PAHs were detected on room air during the e-CIG session.

Conclusions Passive vaping is expected from the use of e-CIG. However, the quality and quantity of chemicals released to the environment are by far less harmful for the human health compared to regular tobacco cigarettes. Evaporation instead of burning, absence of several harmful chemicals from the liquids and absence of sidestream smoking from the use of the e-CIG are probable reasons for the difference in results.

Introduzione

La rapida espansione, negli ultimi anni, del mercato della sigaretta elettronica, legata in parte alla possibilità di utilizzarla anche nei luoghi in cui è vietato fumare, ha fatto sorgere alcune perplessità sulla sua sicurezza in questi contesti. Ad oggi però queste perplessità si basano più su ragionamenti di tipo ipotetico che su valutazioni scientifiche. Scopo di questo esperimento, è quello di iniziare a comprendere e misurare qual è l'impatto del fumo elettronico sull'atmosfera di un ambiente chiuso, confrontandolo con il fumo tradizionale.

Protocollo

Per l'esperimento è stata predisposta una stanza, con un volume pari a circa 60 m³, all'interno della quale sono stati allestiti dei sistemi di campionamento dell'aria.

Al fine di garantire una maggiore sensibilità e per rimuovere la variabile legata al ricircolo d'aria, l'esperimento è stato condotto in un ambiente senza rinnovo d'aria esterna.

I parametri analizzati sono stati:

- CO
- NO_x
- Acroleina
- Idrocarburi Policiclici Aromatici (IPA)
- Carbonio Organico Totale (COT)
- Sostanze Organiche Volatili (SOV)
- Nicotina
- Glicerina
- Glicole Propilenico

Alcuni di questi parametri (CO, NO_x, COT) sono stati monitorati in continuo. Per tutti gli altri sono state impiegate delle fiale e delle membrane specifiche per catturare le varie famiglie di composti in esame in modo cumulativo.

Procedura

L'esperimento si è svolto in 2 sessioni, una per i fumatori ed una per i *vaper*¹, della durata di 5 h ciascuna ed ha coinvolto, per ogni sessione, 5 volontari.

¹Termine anglosassone gergale, utilizzato per indicare un utilizzatore abituale di sigaretta elettronica.

Introduction

The rapid expansion of the e-cigarette market in recent years, due in part to the fact that they can be used also in no smoking areas, has given rise to perplexities on their safety in these contexts. However, thus far, these perplexities are based more on hypothetical reasons rather than scientific evaluations. The aim of this experiment is to understand and to measure what kind of impact e-cigarettes use has on a closed environment atmosphere compared to traditional cigarette smoking.

Protocol

A 60 m³ volume room was used for the experiment. This room was fitted with air sampling systems.

In order to guarantee a higher sensitivity and remove air recirculation-dependant variables, the experiment was performed without renewal of indoor air.

The following parameters were analyzed:

- CO
- NO_x
- Acrolein
- Polycyclic Aromatic Hydrocarbons (PAHs).
- Total Organic Carbon (TOC)
- Volatile Organic Compounds (VOCs)
- Nicotine
- Glycerine
- Propylene Glycol

Some of these parameters (CO, NO_x, TOC) were monitored continuously. For all the other parameters, in order to capture the various types of compounds cumulatively, vials and specific membranes were used.

Procedures

The experiment was divided in two sessions: one for vapers¹ and one for smokers. Each session lasted 5 h and involved 5 volunteers.

Between the sessions the room was cleaned and ventilated for 65 h, in order to restore the original

¹English slang term indicating an electronic cigarette user.

Tra le due sessioni la stanza è stata pulita ed arieggiata per complessive 65 h al fine di ripristinare le condizioni di neutralità iniziali.

Sessioni di Campionamento

Nel corso delle due prove, dopo aver allestito la stanza per il campionamento e rilevato i parametri di partenza, 5 volontari hanno fumato le loro sigarette o usato la loro personale sigaretta elettronica, a seconda della sessione in corso.

Ai volontari è stato spiegato che avrebbero potuto fumare/*svapare*² nelle quantità e nei tempi più adatti alle loro personali esigenze, a condizione di svolgere questa attività sempre all'interno del locale predisposto per l'esperimento.

La permanenza nel locale è stata tassativamente limitata al tempo strettamente necessario a fumare/*svapare*.

L'accesso e la permanenza nel locale sono stati consentiti ad un massimo di 3 volontari contemporaneamente.

La porta della stanza è rimasta chiusa se non per il tempo necessario ad entrare o ad uscire.

Tutti i volontari hanno firmato un consenso informato prima di prendere parte allo studio.

Per la sessione fumatori, si è provveduto ad annotare il numero di sigarette fumate, mentre per la sessione *vaper* è stato valutato il peso del liquido consumato, con una bilancia di precisione.

Volontari

I volontari fumatori avevano un'età media di circa 21 anni con una storia media di 6.5 anni di fumo ed un consumo medio giornaliero di circa 17 sigarette. Il contenuto di nicotina delle sigarette fumate era pari a 0.6 mg per sigaretta. Nel corso della sessione di campionamento sono state fumate complessivamente 19 sigarette, che hanno dispensato ai fumatori circa 11.4 mg di nicotina, basandosi su quanto riportato sul pacchetto.

I *vaper* hanno dichiarato di usare la sigaretta elettronica in maniera esclusiva da circa 3 mesi (min 1, max 6) con un consumo giornaliero di liquido³ pari a 1.5 ml e un contenuto di nicotina medio di 11 mg/ml. Tutti i volontari, hanno usato un liquido commerciale (*Heaven Juice* tradizionale) prodot-

²Termine gergale largamente usato, derivato dall'inglese *to vape*, ed impiegato per indicare l'azione di chi fuma una sigaretta elettronica.

³Tutti i liquidi per sigaretta elettronica utilizzati nell'esperimento erano del tipo *Heaven Juice Tradizionale* di FlavourArt, contenenti circa il 40% di glicerolo USP, circa il 50% di glicole propilenico USP, da 0.9% a 1.8% di nicotina USP, <1% di componente aromatica, acqua depurata, secondo quanto ricavato dalla documentazione fornita del produttore.

neutral conditions.

Sampling Sessions

For the two tests, the room was initially prepared for the sampling and analyzed for baseline conditions. Then, 5 volunteers smoked their cigarettes or e-cigarettes, depending on the session.

Volunteers were allowed to smoke/*vape*² as much as and whenever they wanted, provided that they used the room set for the experiment.

The time that volunteers spent in the room was strictly limited to smoking/*vaping*.

Only a maximum of 3 volunteers were allowed in the room at the same time.

The door of the room was opened only to let volunteers in or out.

Informed consent was obtained by all subjects before participating to the study.

During the smokers' session, the number of smoked cigarettes was noted down. During the vapers' session, the weight of consumed liquid, was evaluated using a precision scale.

Volunteers

The mean age of smokers was about 21 years and they were smoking on average 17 cigarettes per day for 6.5 years. The nicotine content in the smoked cigarettes was 0.6 mg per cigarette. During the sampling session, a total of 19 cigarettes were smoked which dispensed about 11.4 mg of nicotine, according to the information on cigarette packs.

Vapers declared that they had been using e-cigarettes exclusively for about 3 months (min 1, max 6), with a liquid³ daily intake of 1.5 ml, and an average nicotine content of 11 mg/ml.

For e-cigarette users, a commercially available liquid (*Heaven Juice* traditional) produced by FlavourArt was used, and a commercial EGO Pulse device by Smokie's®.

During the sampling session, 1760 mg of liquid were vaporized, which is equal to 1.6 ml containing

²English term *to vape* indicating the act of e-smoking.

³Heaven Juice Traditional e-cigarette liquids by Flavour Art were used during the experiment. They contained about 40% of USP glycerol, 50% of USP propylene glycol, from 0.9% to 1.8% of USP nicotine, <1% aromatic component, purified water, according to the information provided by the producer.

Composti Analizzati Analyzed compounds	Supporto di campionamento Sampling medium	Litri campionati (teorici) Sampled liters (theoretical)	Metodo Method
Nicotina Nicotine	Fiala XAD-2 XAD-2 vial	600	NIOSH 2544
Glicoli - Glicerina Glycols - Glycerine	Filtro in fibra di vetro + fiala XAD-7 Glass fiber filter + XAD-7 vial	600	NIOSH 5523
Idrocarburi Policiclici Aromatici (IPA) Polycyclic Aromatic Hydrocarbons (PAHs)	Filtro in fibra di vetro + fiala XAD-2 Glass fiber filter + XAD-2 vial	600	NIOSH 5515
Acroleina Acrolein	Fiala di Silica gel + DPNH Silica gel vial + DPNH	60	NIOSH 2018
SOV VOCs	Fiala di carbone attivo Activated carbon vial	60	UNI EN 13649

Tab. 1: Metodi utilizzati per il campionamento dei composti. / Methods used for substances sampling.

to da *FlavourArt* e un dispositivo EGO Pulse di Smokie's®. about 17.6 mg of nicotine.

Durante la sessione di campionamento, sono stati vaporizzati 1760 mg di liquido, pari a circa 1.6 ml e contenenti circa 17.6 mg di nicotina.

Materiali e Metodi

Per le metodiche di campionamento sono state adottate diverse procedure sia della normativa UNI che NIOSH, impiegando differenti fiale SKC specifiche per i diversi componenti da ricercare. Per alcune molecole sono state utilizzate anche delle membrane filtranti in fibra di vetro o in PTFE con porosità di 0.8 μm (Tab. 1).

Ogni fiala è stata collegata ad un campionatore aspirante portatile, calibrato e impostato per aspirare uno specifico volume, in funzione della durata dell'esperimento e delle specifiche della metodica in uso.

A questi sistemi di campionamento cumulativo, sono stati affiancati, un rilevatore di CO, CO₂, NO_x, e un rilevatore di COT a ionizzazione di fiamma FID.

A fine esperimento, le fiale e le membrane sono state sigillate e trasportate presso i laboratori ABICH S.r.l.⁴ per le analisi.

Risultati

Le analisi dei campioni hanno evidenziato numerose e sostanziali differenze tra fumo di sigaretta e fumo elettronico, sia in termini di impatto sulla qualità dell'aria, sia anche in termini di tossicità. (Tab. 2).

Per il campionamento sono state impiegate delle membrane in PTFE e siamo rimasti colpiti dal co-

Materials and Methods

Considering the sampling methodologies different procedures both from UNI and NIOSH have been used. Different SKC vials specific for the different components to search were used. For some molecules, also fiberglass or PTFE 0.8 μm porosity membrane filters were used (Tab. 1).

Each vial was linked with a portable suction sampler, calibrated and set to aspirate a specific volume, depending on the duration of the experiment and on the method details.

In addition to these cumulative sampling systems, a CO and CO₂ and NO_x detector and a FID flame ionization TOC detector were used.

At the end of the experiment, the vials and the membranes were sealed and taken to the ABICH S.r.l.⁴ labs for the analysis.

Results

The sampling analysis underlined many and fundamental differences between cigarette smoking and e-cigarette smoking, both in terms of impact on air quality and also on toxicity. (Tab. 2).

PTFE membranes have been used for the sampling. We were surprised by the colour of the mem-

⁴ABICH S.r.l., Verbania (VB), Italia

⁴ABICH S.r.l., Verbania (VB), Italy

Parametro Parameter	Volume Campionato* Sampled Volume* [L]	Concentrazione Media* Mean Concentration* [mg/m ³]	
		Sigaretta Tradizionale Traditional Cigarette	Sigaretta Elettronica Electronic Cigarette
		Nicotina / Nicotine	600
Glicerina / Glycerine	600	< 0.001**	0.072
Glicolene Propilenico / Propylene Glycol	600	< 0.01**	< 0.01**
Acroleina / Acrolein	60	0.020	< 0.0016**

Tempo di campionamento: 300 minuti. / Sampling time: 300 minutes.

* dati relativi alle condizioni operative di riferimento (20°C e 0.101 MPa) riprodotte dall'attrezzatura / values refer to ideal working conditions (20°C and 0.101 MPa) simulated by the equipment

** inferiore alla soglia rilevabile dalla metodica / below the instrument sensitivity

Tab. 2: Sostanze rilevate. / Detected substances.

lore assunto dalle membrane alla fine delle sessioni. Questo, pur non costituendo un dato analitico di per sé, in qualche modo ci ha dato un'idea dei risultati che avremmo ottenuto (Fig. 3 e 4).

branes at the end of the sessions. Even if this does not constitute analytic data as such, it has given us an idea of the results that we could expect (Fig. 3 and 4).



Fig. 3: Membrana in PTFE al termine della sessione di fumo tradizionale. / PTFE membrane at the end of the cigarette smoking session.



Fig. 4: Membrana in PTFE al termine della sessione di fumo elettronico. / PTFE membrane at the end of the e-cigarette session.

CO (Monossido di Carbonio) [12] Il monossido di carbonio non ha mostrato alcuna variazione con il fumo elettronico, rimanendo al di sotto dei limiti di rilevabilità dello strumento, mentre il fumo di sigaretta ha prodotto un costante incremento della sua concentrazione durante tutta la durata del campionamento, raggiungendo un picco di 11 mg/m³, valore questo, al di sopra della soglia di legge (10 mg/m³)⁵ (Fig. 5).

Il monossido di carbonio è un gas tossico con una elevata affinità per l'emoglobina, compromettendo

⁵Decreto Legislativo 13 agosto 2010, n. 155. Attuazione della direttiva 2008/50/CE relativa alla qualità dell'aria ambiente e per un'aria più pulita in Europa.

CO (Carbon Monoxide) [12] The levels of carbon monoxide did not show any variation during e-cigarette smoking, remaining below the detection limits of the tool. On the contrary cigarette smoking produced a steady elevation in CO throughout the sampling period. It reached a peak of 11 mg/m³, which is above the legal threshold (10 mg/m³)⁵ (Fig. 5).

Carbon monoxide is a toxic gas with a high affinity for haemoglobin, compromising its ability to transport oxygen. Smokers, continue to exhale out high levels of CO several hours after smoking their

⁵Legislative decree 13th August 2010, n.155. Application of the directive 2008/50/CE concerning the quality air in the environment for a clearer air in Europe.

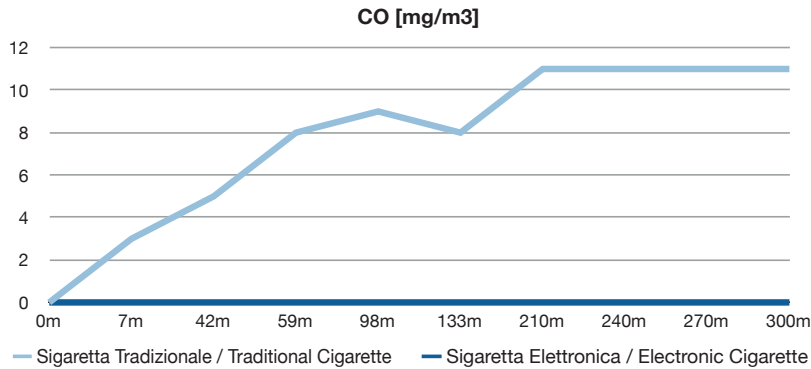


Fig. 5: Concentrazione di CO durante l'esperimento. / CO concentration during the experiment.

la sua capacità di trasportare ossigeno. Un fumatore continua ad emettere elevati livelli di monossido di carbonio, anche molte ore dopo aver fumato l'ultima sigaretta [5].

Nicotina Tra gli aspetti più interessanti, abbiamo osservato che la nicotina, pur presente nei liquidi utilizzati per l'esperimento, non è stata rilevata durante la sessione relativa al fumo elettronico. Per contro sono stati dosati $34 \mu\text{g}/\text{m}^3$ di nicotina, con il fumo tradizionale. Va precisato che, stando a quanto riportato sui pacchetti, la quota di nicotina inalata dai fumatori, ammonta complessivamente a circa 11.4mg, mentre i *vaper* hanno inalato nicotina per un totale di 17.6 mg. Tuttavia la quota di nicotina indicata sul pacchetto tiene conto solo della quota inalata, senza fornire alcuna informazione relativa a quella effettivamente presente nella sigaretta e liberata nell'aria durante la sua combustione.

Basandosi sui risultati osservati è possibile dedurre che il fumo di sigaretta produce una contaminazione da nicotina nell'aria, almeno 35 volte superiore a quella del fumo elettronico, il che equivale a dire che servono almeno 35 *vaper* per produrre un livello di nicotina equivalente a quello prodotto da un singolo fumatore.

Se inoltre avessimo bilanciato le prove, chiedendo ai fumatori, di consumare sigarette, in quantità tali da eguagliare il consumo di nicotina dei *vaper*, questi avrebbero dovuto fumare circa 29 sigarette, producendo una concentrazione di nicotina stimata in circa $52 \mu\text{g}/\text{m}^3$.

Argomentare sulle ragioni di questi risultati è estremamente difficile, si potrebbe ipotizzare che esista per i *vaper* una differente cinetica di assorbimento della nicotina, o più semplicemente che le quantità in gioco siano estremamente contenute se paragonate a quelle effettivamente liberate dal fumo tradizionale. Ma al di là di queste ipotesi, tutte da verificare, il risultato in sé rimane un fatto: 5 *vaper* che utilizzano la sigaretta elettronica, per 5 h, in una

last cigarette, even if the last cigarette was put out many hours before [5].

Nicotine Among all, the most interesting aspects we observed was that nicotine was not detected in air during the e-smoking session, although liquids used for experiments contained it. On the other hand, $34 \mu\text{g}/\text{m}^3$ of nicotine were found during the smoking session. It should be made clear that, according to the information on packs, the amount of nicotine inhaled by smokers was about 11.4mg, while the amount of nicotine inhaled by vapers was about 17.6 mg. However the amount of nicotine reported on packs is the inhaled amount. This information does not give details about the real amount of nicotine inside the cigarettes and released in the air during combustion and from side stream smoke.

Based on the observed results, we can conclude that cigarette smoking produces nicotine contamination in the air at least 35 times higher than e-smoking. This means that we need at least 35 vapers to produce nicotine level in air similar to the level produced by a single smoker.

Moreover if we had balanced the tests, asking cigarette smokers to consume the amount of cigarettes necessary to match the amount of nicotine used by vapers, the latter should have smoked about 29 cigarettes, producing an expected nicotine concentration of about $52 \mu\text{g}/\text{m}^3$.

It's extremely difficult to discuss about the reasons for these results. We could suppose that there is a different absorption kinetics for nicotine. Or maybe the amount in play is extremely low, when compared to the nicotine amount released during traditional smoking. However beyond all these hypotheses, which have not been verified, there is one fact: 5 vapers using e-cigarettes for 5 h in a small room without renewal of indoor air do not produce detectable levels of nicotine in the air.

Parametro Parameter	Volume Campionato* Sampled Volume* [L]	Concentrazione Media* Mean Concentration* [$\mu\text{g}/\text{m}^3$]	
		Sigaretta Tradizionale	Sigaretta Elettronica
		Traditional Cigarette	Electronic Cigarette
Metiletilchetone / Methyl ethyl ketone	60	4.2	4.4
1-etil-3-metil benzene / 1-ethyl-3-methylbenzene	60	0.2	3.4
Limonene / Limonene	60	12.5	0.1
Decano / Decane	60	0.4	4.2
Undecano / Undecane	60	4.2	0.7
Dodecano / Dodecane	60	3.7	0.3
Cedrene / Cedrene	60	0.3	0.9
Longifolene / Longifolen	60	18.3	30.3
Toluene / Toluene	60	1.7	-
O,m,p - Xilene / o,m,p - Xylene	60	0.2	-
1-etil-2-metil benzene / 1-ethyl-2-methylbenzene	60	4.9	-
1,2,4-trimetil benzene / 1,2,4-Trimethylbenzene	60	0.3	-
Mentene / Menthene	60	0.5	-
BHT (Butilidrossitoluene / Butylhydroxytoluene)	60	-	0.4
Terpene / Terpene (u.s.)	60	-	2.3
Longiciclene / Longicyclene	60	-	2.2
Cariofillene / Caryophyllene	60	-	1.0
n.i. totali / total u.s.	60	14.7	12.6

n.i. sostanza non identificabile / u.s. unidentifiable substance

Tempo di campionamento: 300 minuti. / Sampling time: 300 minutes.

* dati relativi alle condizioni operative di riferimento (20°C e 0.101 MPa) riprodotte dall'attrezzatura / values refer to ideal working conditions (20°C and 0.101 MPa) simulated by the equipment

** inferiore alla soglia rilevabile dalla metodica / below the instrument sensitivity

Tab. 6: Sostanze Organiche Volatili. / Volatile Organic Compounds.

stanza di piccole dimensioni e senza rinnovo d'aria, non producono livelli rilevabili di nicotina nell'aria.

Glicole Propilenico Altro parametro inatteso è il glicole propilenico, che non è stato rilevato durante la prova con il fumo elettronico, pur costituendo il 50% del liquido³.

Questo curioso fenomeno è stato osservato anche in un altro studio simile [11]. Anche questo studio non ha rilevato nicotina nel vapore passivo di una stanza sperimentale (significativamente più piccola della stanza da noi utilizzata). Alcuni esperimenti suggeriscono che l'assorbimento del glicole propilenico per via inalatoria sia estremamente rapido [17] e questo potrebbe spiegare perché questa molecola pur così abbondante non è stata rilevata.

Glicerina e Acroleina Non è stata rilevata glicerina relativamente al fumo di sigaretta, mentre ne è stata rilevata una traccia con il fumo elettronico, pari a 72 μg , valore molto al di sotto della soglia di

Propylene Glycol Results on propylene glycol were also unexpected. During e-smoking tests, propylene glycol was not detected, although 50% of liquid³ consisted of propylene glycol.

This curious phenomenon has also been observed in a similar study [11]. Even in that case, nicotine was not detected in an experimental room of the passive vaping (which was significantly smaller than the room we used). Some studies suggest that propylene glycol absorption via inhalation is extremely rapid [17]. This could explain why this molecule has not been detected even though it was present in significant amounts in the liquid used.

Glycerine and Acrolein No glycerine was detected in air during cigarette smoking. On the other hand, 72 $\mu\text{g}/\text{m}^3$ were detected during e-smoking. This amount is much lower than the threshold safety

Parametro Parameter	Volume Campionato* Sampled Volume* [L]	Concentrazione Media* Mean Concentration* [$\mu\text{g}/\text{m}^3$]	
		Sigaretta Tradizionale Traditional Cigarette	Sigaretta Elettronica Electronic Cigarette
Naftalene / Naphthalene	600	2.78	< 0.02**
Acenaftilene / Acenaphthylene	600	< 0.02**	< 0.02**
Acenaftene / Acenaphthene	600	0.19	< 0.03**
Fluorene / Fluorene	600	0.47	< 0.06**
Fenantrene / Phenanthrene	600	0.37	< 0.08**
Antracene / Anthracene	600	< 0.04**	< 0.04**
Fluorantene / Fluoranthene	600	0.13	< 0.02**
Pirene / Pyrene	600	< 0.01**	< 0.01**
Benzo(a)antracene / Benzo(a)anthracene	600	< 0.16**	< 0.16**
Crisene / Chrysene	600	5.46	< 0.14**
Benzo(b)fluorantene / Benzo(b)fluoranthene	600	< 0.33**	< 0.33**
Benzo(k)fluorantene / Benzo(k)fluoranthene	600	< 0.74**	< 0.74**
Benzo(a)pirene / Benzo(a)pyrene	600	< 0.62**	< 0.62**
Indeno(1,2,3-cd)pirene / Indeno(1,2,3-cd)pyrene	600	< 1.47**	< 1.47**
Dibenzo(a,h)antracene / Dibenzo(a,h)anthracene	600	< 1.47**	< 1.47**
Benzo(ghi)perilene / Benzo(g,h,i)perylene	600	< 1.60**	< 1.60**

Tempo di campionamento: 300 minuti. / Sampling time: 300 minutes.

* dati relativi alle condizioni operative di riferimento (20°C e 0.101 MPa) riprodotte dall'attrezzatura / values refer to ideal working conditions (20°C and 0.101 MPa) simulated by the equipment

** inferiore alla soglia rilevabile dalla metodica / below the instrument sensitivity

Tab. 7: Idrocarburi Policiclici Aromatici. / Polycyclic Aromatic Hydrocarbons.

azione (TWA-TLV 10 mg/m³) e ben al di sotto della soglia definita di rischio moderato o irrilevante [4].

Tuttavia, bisogna rilevare che l'acroleina, molecola che si forma dalla disidratazione ad elevate temperature della glicerina, era presente e ben rilevabile nell'aria della stanza, durante la prova dei fumatori (20 $\mu\text{g}/\text{m}^3$).

È noto infatti che la glicerina viene spesso aggiunta ai tabacchi come umettante e durante la combustione si trasforma in acroleina [3]. L'assenza di processi di combustione nel fumo elettronico, è di fondamentale importanza per comprendere come mai l'acroleina non sia stata rilevata nell'aria durante la prova.

L'acroleina è una sostanza notoriamente molto tossica e irritante, inoltre è attualmente sospetta per avere un ruolo nei processi di cancerogenesi [1].

SOV Dall'analisi delle sostanze organiche volatili, sono state evidenziate fondamentalmente componenti aromatiche, in particolare il longifolene, tipico dell'aroma di pino, era presente in entrambe le prove. È probabile che questo composto facesse parte dei prodotti detergenti o deodoranti impiegati per pulire la stanza prima dell'esperimento. In merito

limit (TWA-TLV 10 mg/m³) and much lower than the threshold for moderate risk [4].

However, it's important to note that acrolein, a molecule formed by dehydration of glycerine due to high temperatures, was present in the air of the room during cigarette smoking test (20 $\mu\text{g}/\text{m}^3$).

In fact, it is well known that glycerine is often added to moisten tobacco. During combustion glycerine is transformed into acrolein [3]. The fact that no combustion is involved when using e-cigarettes probably plays a fundamental role in the absence of acrolein from indoor air during their use.

As everyone knows, acrolein is a very toxic and irritating substance. Moreover it is currently suspected of having a fundamental role in the carcinogenic process [1].

VOCs During the analysis of volatile organic compounds, aromatic components were detected, in particular longifolene, typical of pine aroma, in both tests. One of the detergents used to clean the room before the test could have contained this compound. Regarding cigarette smoking, xylene and toluene were detected. These are two very common toxic

al fumo di sigaretta, si rilevano comunque tracce di xilene e toluene, due composti tossici, normalmente presenti nel fumo di sigaretta. Il limonene, terpene dell'olio essenziale di limone, è stato rilevato solo durante la prova con il fumo tradizionale ed in effetti questa molecola è stata riscontrata anche da altri studi come componente del fumo di sigaretta [11] (Tab. 6).

IPA Tra i composti più rilevanti, in termini di tossicità cronica del fumo di tabacco, ci sono certamente gli idrocarburi policiclici aromatici. Questi composti, prodotti durante il processo di combustione, sono noti per gli effetti cancerogeni e mutageni.

La prova ha identificato 6 dei 16 IPA ricercati, durante la sessione con il fumo tradizionale, mentre non è stato rilevato nulla con il fumo elettronico (Tab. 7).

COT [15] L'analisi del carbonio organico totale, non ci dà informazioni specifiche sulla tossicità. È un modo per valutare globalmente la quantità di materia organica immessa nell'aria, senza distinguere tra sostanze tossiche e non tossiche. Tuttavia questo parametro ci fornisce una visione globale del grado di contaminazione dell'aria, durante tutta la durata dell'esperimento.

Nel grafico è possibile osservare l'andamento dei livelli di COT nell'aria durante le 5 h di campionamento.

Dal grafico è stato sottratto il valore di fondo presente all'inizio del campionamento (1 mg/m^3).

Due aspetti sono interessanti a mio parere. In primo luogo i livelli massimi con il fumo di sigaretta sono oltre 9 volte più alti che con il fumo elettronico, in secondo luogo, il fumo impiega appena 11 minuti, a raggiungere il valore massimo raggiunto dalla sigaretta elettronica (0.73 mg/m^3), nel tempo di 5 h (Fig. 8).

Conclusioni

L'esperimento su descritto ha evidenziato, limitatamente ai parametri osservati, che il fumo elettronico non comporta l'immissione nell'aria di un ambiente chiuso, di sostanze tossiche o cancerogene in quantità rilevabili. Ulteriori studi sono necessari, per approfondire e meglio definire tutti gli aspetti coinvolti, ma questa valutazione preliminare suggerisce che l'impatto del fumo elettronico passivo, se confrontato con quello del fumo di sigaretta, è talmente ridotto da essere appena rilevabile e non presenta le caratteristiche di tossicità e di cancerogenicità rilevate nel fumo di sigaretta. L'assenza di combustione e la mancanza di fumo secondario (*sidestream smoke*), noto per i suoi effetti tossici [2, 6], sono probabilmen-

compounds in cigarette smoking. Limonene which is an oil lemon terpene, was detected only during the traditional smoking test. In fact this molecule was found as a component in cigarette smoke even in other studies [11] (Tab. 6).

PHAs Polycyclic aromatic hydrocarbons are, without doubt, among the most important compounds in terms of chronic toxicity caused by tobacco smoking. These substances, which are produced during the combustion process, are well known for their carcinogenic and mutagenic effects.

During the traditional cigarette smoking session, 6 out of 16 PAHs were identified. Nothing was identified during the e-cigarette session (Tab. 7).

TOC [15] The total organic carbon analysis does not give us specific information about toxicity. It is a measure of the overall amount of organic matter released in the air. There is no distinction between toxic and non-toxic substances. However this parameter gives us a global view of the degree of contamination of air, throughout the whole experiment.

The chart shows the TOC level trends in the air during the 5 h sampling.

The chart does not contain the original value of air at the beginning of the sample (1 mg/m^3).

In my opinion there are two interesting aspects which should be underlined. Firstly, the maximum levels during cigarette smoking sessions are 9 times higher than the e-smoking session. Secondly, cigarette smoking takes just 11 minutes to reach a value similar to the maximum value measured for the e-cigarette (0.73 mg/m^3), in 5 h (Fig. 8).

Conclusions

The above experiment, within the limits of the observed parameters, has underlined that e-smoking does not produce detectable amounts of toxic and carcinogenic substances in the air of an enclosed space. Further studies are needed to better understand all the involved aspects. However this preliminary assessment indicates that passive vaping impact, when compared to the traditional cigarette smoking, is so low that it is just detectable, and it does not have the toxic and carcinogenic characteristics of cigarette smoking. The absence of combustion and the lack of sidestream smoking, with its known toxic effects [2, 6] are probably the main reasons for the differences observed in air pollution characteristics

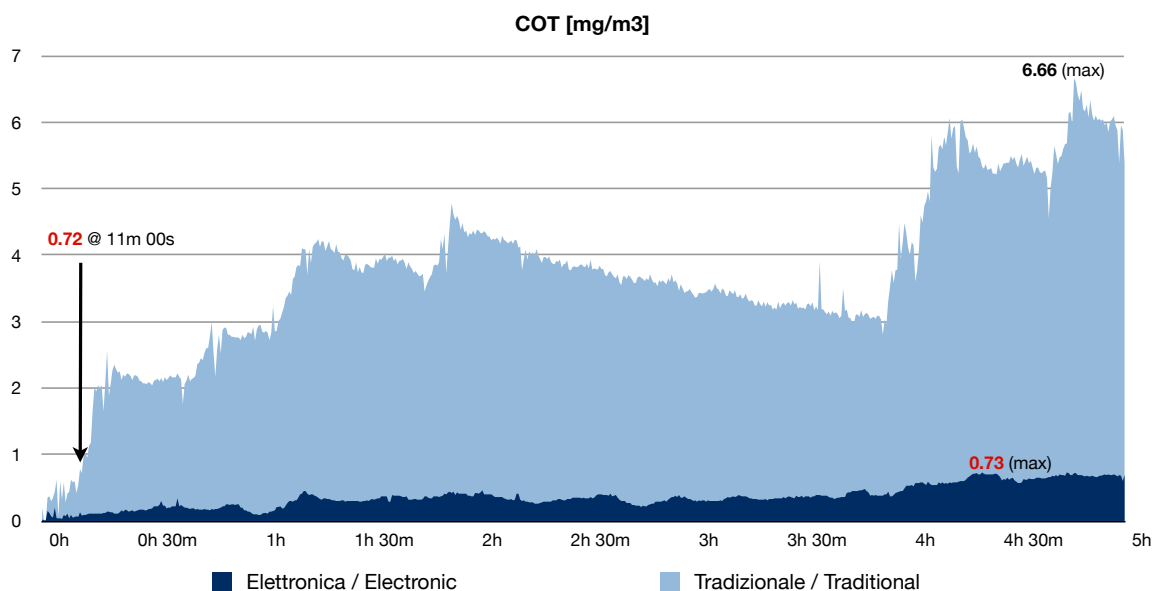


Fig. 8: Carbonio Organico Totale. / Total Organic Carbon.

te alla base delle differenze osservate, in termini di inquinamento dell'aria, tra fumo di tabacco e fumo elettronico.

Come considerazione finale, basandosi sui risultati ottenuti e sui dati dell'ARPA in materia di inquinamento urbano, potrebbe essere meno salutare, respirare l'aria di una grande città nell'ora di punta, piuttosto che sostare in una stanza con qualcuno che usa una sigaretta elettronica.

between e-cigarettes and tobacco smoking.

On the base of the obtained results and on ARPA data about urban pollution, we can conclude by saying that could be more unhealthy to breath air in big cities compared to staying in the same room with someone who is vaping.

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Comparison of the effects of e-cigarette vapor and cigarette smoke on indoor air quality.

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Author information

Abstract

CONTEXT: Electronic cigarettes (e-cigarettes) have earned considerable attention recently as an alternative to smoking tobacco, but uncertainties about their impact on health and indoor air quality have resulted in proposals for bans on indoor e-cigarette use.

OBJECTIVE: To assess potential health impacts relating to the use of e-cigarettes, a series of studies were conducted using e-cigarettes and standard tobacco cigarettes.

METHODS AND MATERIALS: Four different high nicotine e-liquids were vaporized in two sets of experiments by generic 2-piece e-cigarettes to collect emissions and assess indoor air concentrations of common tobacco smoke by products. Tobacco cigarette smoke tests were conducted for comparison.

RESULTS: Comparisons of pollutant concentrations were made between e-cigarette vapor and tobacco smoke samples. Pollutants included VOCs, carbonyls, PAHs, nicotine, TSNAs, and glycols. From these results, risk analyses were conducted based on dilution into a 40 m³ room and standard toxicological data. Non-cancer risk analysis revealed "No Significant Risk" of harm to human health for vapor samples from e-liquids (A-D). In contrast, for tobacco smoke most findings markedly exceeded risk limits indicating a condition of "Significant Risk" of harm to human health. With regard to cancer risk analysis, no vapor sample from e-liquids A-D exceeded the risk limit for either children or adults. The tobacco smoke sample approached the risk limits for adult exposure.

CONCLUSIONS: For all byproducts measured, electronic cigarettes produce very small exposures relative to tobacco cigarettes. The study indicates no apparent risk to human health from e-cigarette emissions based on the compounds analyzed.

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E-cigarettes: harmless inhaled or exhaled No second hand smoke

CHEMICALS IN SMOKE and E-cigarette MIST		
Leading chemicals only	Cigarette SMOKE	E-cigarette MIST
Nicotine per puff	YES 0.1 mg/puff	YES 0.01 mg/puff
Propylene glycol	NO 0 mg/puff	YES 0.7 mg/puff
Carbon monoxide	YES	NONE
Acrolein	YES	NONE
Hydrogen cyanide	YES	NONE
CARCINOGENS	1,3-Butadiene and 20+ others:	Trace amounts of a few only:
Acetaldehyde	YES	TRACE
Acrylonitrile	YES	NONE
Arsenic	YES	NONE
Benzalaphapylene	YES	NONE
Benzene	YES	NONE
Cadmium	YES	NONE
NNN, NNK (nitrosamines)	YES	TRACE

Second hand cigarette smoke is a mixture of mainstream and sidestream smoke. It contains the same toxicants as mainstream smoke, but at reduced levels. It is responsible for about 8% of the deaths caused by direct smoking.

Second hand mist from an e-cigarette is not smoke at all, and does not contain any substance known to cause death, short or long term, in the quantities found. It becomes invisible within a few seconds, and is not detectable by smell.

Exhaled breath after e-cigarette use has been tested for CO only. No increase in CO was found.

The e-cigarette does not create side-stream smoke. Exhaled breath after e-smoking contains even less nicotine per puff, as much of the nicotine inhaled is absorbed. Similarly, propylene glycol is largely absorbed and little is exhaled.

No harm found in e-cigarette mist

Nicotine is not harmful in the quantities mentioned.¹

Propylene glycol is harmless – it is used in making theatrical fog and as an ingredient in soaps, personal lubricants and intravenous medicines.

1. Murray RP, Bailey WC, Daniels K. et al. Safety of nicotine polacrilex gum used by 3,094 participants in the Lung Health Study. LHS Research Group. Chest 1996; 102: 438-45.

Some smokers need satisfying replacement products to help them quit smoking

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Journal of General Internal Medicine

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E-Cigarette Versus Nicotine Inhaler: Comparing the Perceptions and Experiences of Inhaled Nicotine Devices

ABSTRACT

BACKGROUND

Novel nicotine delivery products, such as electronic cigarettes (e-cigarettes), have dramatically grown in popularity despite limited data on safety and benefit. In contrast, the similar U.S. Food and Drug Administration (FDA)-approved nicotine inhaler is rarely utilized by smokers. Understanding this paradox could be helpful to determine the potential for e-cigarettes as an alternative to tobacco smoking.

OBJECTIVE

To compare the e-cigarette with the nicotine inhaler in terms of perceived benefits, harms, appeal, and role in assisting with smoking cessation.

DESIGN

A cross-over trial was conducted from 2012 to 2013

PARTICIPANTS/INTERVENTIONS

Forty-one current smokers age 18 and older used the e-cigarette and nicotine inhaler each for 3 days, in random order, with a washout period in between. Thirty-eight participants provided data on product use, perceptions, and experiences.

MAIN MEASURES

The Modified Cigarette Evaluation Questionnaire (mCEQ) measured satisfaction, reward, and aversion. Subjects were also asked about each product's helpfulness, similarity to cigarettes, acceptability, image, and effectiveness in quitting smoking. Cigarette use was also recorded during the product-use periods.

KEY RESULTS

The e-cigarette had a higher total satisfaction score (13.9 vs. 6.8 [$p < 0.001$]; range for responses 3–21) and higher reward score (15.8 vs. 8.7 [$p < 0.001$]; range for responses 5–35) than the inhaler. The e-cigarette received higher ratings for helpfulness, acceptability, and “coolness.” More subjects would use the e-cigarette to make a quit attempt (76 %) than the inhaler (24 %) ($p < 0.001$). Eighteen percent (7/38) of subjects abstained from smoking during the 3-day periods using the e-cigarette vs. 10 % (4/38) using the inhaler ($p = 0.18$).

CONCLUSION

The e-cigarette was more acceptable, provided more satisfaction, and had higher perceived benefit than the inhaler during this trial. E-cigarettes have the potential to be important nicotine delivery products owing to their high acceptance and perceived benefit, but more data are needed to evaluate their actual efficacy and safety. Providers should be aware of these issues, as patients will increasingly inquire about them.



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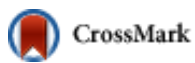
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EU Classification of nicotine mixtures under CLP Regulation 1272/2008 (as amended and corrected)

Bibra Proposal

30 June 2014

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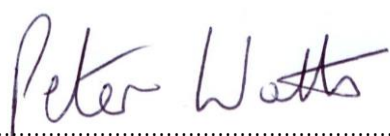
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EU classification of nicotine mixtures under CLP Regulation 1272/2008 (as amended and corrected)

Bibra Proposal

INTRODUCTION

Bibra was asked for independent advice on the appropriate EU classification of mixtures containing nicotine, for acute toxicity by the oral and dermal exposure routes. The client asked that the classification be carried out according to current EU legislation as laid down in EU Regulation 1272/2008, as amended. In particular, the client asked about the concentration-related category transitions for nicotine mixtures (where the other components were not acutely toxic).

KEY LEGISLATIVE REFERENCES

The overarching EU regulation for classification of substances and mixtures is EU Regulation 1272/2008¹. Tables 3.1 and 3.2 of Annex VI of 1272/2008 set out the official EU classifications for numerous substances. This Regulation has been amended by five Adaptations to Technical Progress (Regulations EC 790/2009², EU 286/2011³, EU 618/2012⁴, EU 487/2013⁵ and EU 944/2013⁶). A correction to Annex VI has also been published (Regulation EU 758/2013⁷). A consolidated version available on the ECHA website⁸ takes into account 790/2009 and 286/2011, but not the third, fourth and fifth adaptations, or 758/2013.

¹ Regulation 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation 1907/2006. Official Journal of the European Union L353, 1-1355 <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:353:0001:1355:en:PDF>.

² Commission Regulation (EC) 790/2009 of 10 August 2009 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:235:0001:0439:en:PDF>

³ Commission Regulation (EU) No 286/2011 of 10 March 2011 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (Text with EEA relevance). <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:083:0001:0053:en:PDF>

⁴ Commission Regulation (EU) No 618/2012 of 10 July 2012 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (Text with EEA relevance). <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:179:0003:0010:EN:PDF>

⁵ Commission Regulation (EU) No 487/2013 of 8 May 2013 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (Text with EEA relevance). <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:149:0001:0059:EN:PDF>

⁶ Commission Regulation (EU) No 944/2013 of 2 October 2013 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (Text with EEA relevance). <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:261:0005:0022:EN:PDF#>

⁷ Commission Regulation (EU) No 758/2013 of 7 August 2013 correcting Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (Text with EEA relevance). <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:216:0001:0058:EN:PDF>

⁸ Consolidated version: Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance) as amended by Regulations EC 790/2009 and EU 286/2011. <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2008R1272:20110419:EN:PDF>

HARMONISED ACUTE TOXICITY CLASSIFICATION OF NICOTINE (SUBSTANCE)

Acute oral toxicity

EU experts on classification have reviewed the acute oral toxicity data on nicotine. Although the specific data that were reviewed are unknown to bibra, the experts agreed a classification as: Toxic if swallowed (T; R25). This implies a rat acute oral LD50 of between 25 and 200 mg/kg bw.

Under 1272/2008, this 67/548/EEC classification has been translated to its modern equivalent, which is: Toxic if swallowed. Acute Toxicity Category 3 (H301). This classification implies a rat acute oral LD50 value of between 50 and 300 mg/kg bw (i.e. slightly modified from 67/548/EEC criteria). Generically, this Category is assigned a “converted acute toxicity point estimate” (ATE) of 100 mg/kg bw (for use in the calculation of the ATE for classification of a mixture based on its components).

Acute dermal toxicity

EU experts on classification have reviewed the acute dermal toxicity data on nicotine. Although the specific data that were reviewed are unknown to bibra, the experts agreed a classification as: Very toxic in contact with skin (T+; R27). This implies a rat or rabbit acute dermal LD50 of <50 mg/kg bw (24-hr contact time).

Under 1272/2008, this 67/548/EEC classification has been translated to its modern equivalent, which is: Fatal in contact with skin. Acute Toxicity Category 1 (H310). This classification implies a rat acute dermal LD50 value of 0-50 mg/kg bw (i.e. unchanged from 67/548/EEC criteria). Generically, this Category is assigned a “converted acute toxicity point estimate” (ATE) of 0.5 mg/kg bw (for used in the calculation of the ATE for classification of a mixture based on its components).

ACUTE ORAL AND DERMAL TOXICITY VALUES FOR NICOTINE

Summary of acute oral lethal values

In classification for acute toxicity, laboratory animal data (notably rat LD50s) are generally critical. For nicotine, reported rat oral LD50 values range from 50-188 mg/kg bw, with most between 50-83 mg/kg bw (DECOS, 2004; Gaines, 1960; Lazutka et al. 1969; Sine, 1993; Trochimowicz et al. 1994; Vernot et al. 1977; Yam et al. 1991). Mice may be slightly more sensitive, with most reported values lying between 16-60 mg/kg bw (DECOS, 2004; Trochimowicz et al. 1994; Vernot et al. 1977). A lower LD50 value (3.3 mg/kg bw) was reported in an early Eastern European study (Lazutka et al. 1969) of uncertain reliability.

[Reviews have reported estimated mean lethal acute oral doses in children and adults of about 10 mg (about 0.5 mg/kg bw) and about 30-60 mg (about 0.4-0.9 mg/kg bw), respectively (Arena, 1974; Gosselin, 1988; Lazutka et al. 1969). However, the scientific validity of these figures is unclear, and they do not seem to have played any role in the nicotine-classification deliberations of the EU expert group on harmonised classification.]

Summary of acute dermal lethal values

In rats, acute dermal LD50 values of 140-285 mg/kg bw have been reported (Gaines, 1960; Trochimowicz et al. 1994), with rabbits (LD50 50 mg/kg bw) seemingly more sensitive (Trochimowicz

et al. 1994). In cats, doses of about 66-100 mg/kg bw caused clinical toxicity (vomiting, CNS effects and deaths (Travell, 1960).

Tabulated acute oral lethal studies

Species, Sex, Number	Brief study description (if available)	LD50	Reference
Mouse, strain, sex and number not specified	LD50 study using nicotine base	3.3 mg/kg bw	Lazutka et al. 1969
Mouse, CF-1, male, number not specified	LD50 study using nicotine sulphate	16 mg/kg bw	Vernot et al. 1977
Mouse, strain, sex and number not specified	LD50 study	24 mg/kg bw	DECOS, 2004 (cited as Ray91); Trochimowicz et al. 1994
Mouse, strain, sex and number not specified	LD50 study	50-60 mg/kg bw	Trochimowicz et al. 1994
Rat, strain, sex and number not specified	LD50 study	50 mg/kg bw	Sine, 1993
Rat, strain, sex and number not specified	LD50 study	50-60 mg/kg bw	Trochimowicz et al. 1994
Rat, strain, sex and number not specified	LD50 study using nicotine base	53 mg/kg bw	Lazutka et al. 1969
Rat, Sprague-Dawley, male and female	LD50 estimated by fixed-dose procedure or the up-and-down method. In the fixed-dose procedure, groups of 5 males and 5 females were treated with one of four predetermined dose levels. In the up-and-down method, females were dosed, one at a time, starting with an estimate of the LD50 and adjusting the dose until 4 rats were treated. In both protocols, rats were observed for 14 days	70-71 mg/kg bw	Yam et al. 1991
Rat, Sprague-	LD50 study using nicotine	75 mg/kg bw	Vernot et al. 1977

Species, Sex, Number	Brief study description (if available)	LD50	Reference
Dawley, male, number not specified	sulphate		
Rat, Sherman, adult, female, 80/group	LD50 study using nicotine sulphate, rats observed for 4 days only	83 mg/kg bw	Gaines, 1960
Rat, strain, sex and number not specified	LD50 study	188 mg/kg bw	DECOS, 2004 (cited as Ray91).

Tabulated acute dermal lethal studies

Species, Sex, Number	Brief study description (if available)	LD50	Reference
Rat, strain, sex and number not specified	LD50 study	140 mg/kg bw	Trochimowicz et al. 1994
Rat, Sherman, adult, female, 70/group	LD50 study on nicotine sulphate [Note: rats were only observed for 5 days]	285 mg/kg bw	Gaines, 1960
Rat, Sprague-Dawley, 5 male and 5 female	A mixture of 18% nicotine and 82% of an ion-exchange resin applied at 2 g/kg bw to the covered skin for 24 hr, followed by rinsing with water OECD Guideline study No. 402	>360 mg/kg bw [no deaths were seen]	Guerriero et al. 2001
Rabbit, strain, sex and number not specified	LD50 study	50 mg/kg bw	Trochimowicz et al. 1994
Rabbit, strain, sex and number not specified	LD50 study	140 mg/kg bw	UK PSD, 2008
Cat, 21/group, sex not specified	Application of 200 mg nicotine or nicotine sulphate (providing approximately 66-100 mg nicotine/kg bw) to the uncovered skin.	The nicotine base produced overt CNS toxicity, vomiting, and 17/21 cats died in 21-195	Travell, 1960

Species, Sex, Number	Brief study description (if available)	LD50	Reference
		min. The sulphate caused milder effects and all 21 cats survived.	
Cat, 5 treated with free nicotine and 3 treated with nicotine sulphate, sex not specified	2-10 ml "Nico-Fume Liquid" (containing 40% free nicotine) or 10 ml "Black Leaf 40" (containing 40% nicotine sulphate) was applied under cover to the clipped skin. In the free nicotine experiment, the skin of one cat was washed after 3 hours. [Travell (1960) stated that the free nicotine doses causing death were 280-1500 mg/kg bw, and the nicotine sulphate dose was about 1100 mg/kg bw.]	Nicotine caused CNS effects and vomiting, loss of consciousness and death. No effects were reported with the sulphate.	Faulkner, 1933

SELECTION OF KEY LD50 VALUES FOR MIXTURE CLASSIFICATION

When multiple options are available for a rather simple and crude endpoint such as median lethality, selection of the most appropriate value for use in classification can be challenging.

According to Regulation 1272/2008 "The preferred test species for evaluation of acute toxicity by the oral and inhalation routes is the rat, while the rat or rabbit are preferred for evaluation of acute dermal toxicity". The original harmonised expert classification (under 67/548/EEC) for acute oral toxicity (Toxic if swallowed; T; R25) implies that the committee selected an acute oral LD50 of between 25 and 200 mg/kg bw as being key to classification. This indicates that the experts either dismissed or were unaware of three of the mouse studies. Under 1272/2008, the earlier 67/548/EEC classification has been translated to its modern equivalent (Toxic if swallowed; Acute Toxicity Category 3. H301), which is associated with an acute oral LD50 between 50-300 mg/kg bw. Without a detailed assessment of each LD50, it is not entirely clear which reports should be set aside. Nevertheless, the fact that all of the rat LD50 figures are 50 mg/kg bw or above supports the experts' choice of Category 3.

For the dermal classification, there seems to be a good case for the selection of the rabbit dermal LD50 of 50 mg/kg bw and a precautionary choice of assigning to the more toxic class (Category 1) when a value falls on the class boundary.

Rat oral LD50: >50 mg/kg bw.

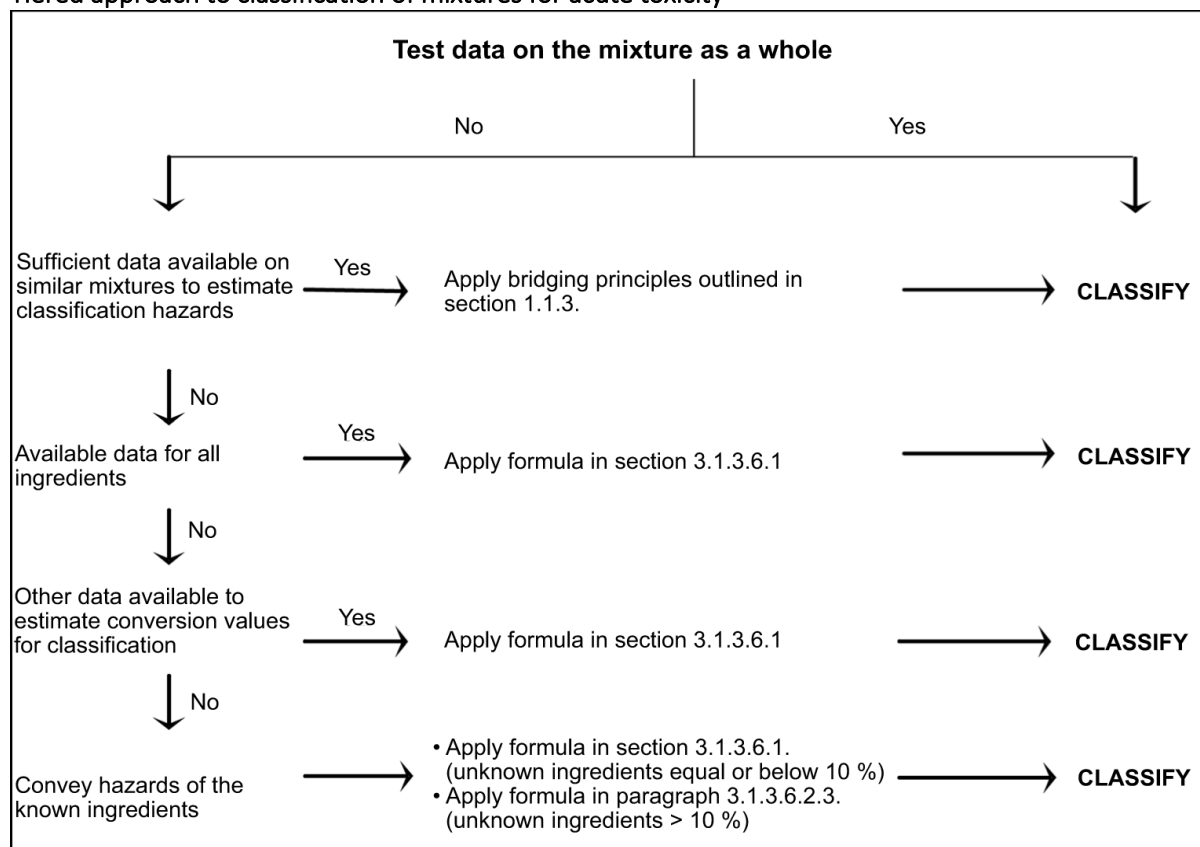
Rabbit dermal LD50: 50 mg/kg bw.

CLASSIFICATION OF NICOTINE MIXTURES

Mixtures should be classified in line with EC 1272/2008 (as amended). Guidance is given in section 3.1.3. **Criteria for classification of mixtures as acutely toxic.** This states that “For mixtures, it is necessary to obtain or derive information that allows the criteria to be applied to the mixture for the purpose of classification.” Such information would include LD50 or ATE figures, for example. The approach to classification for acute toxicity is tiered, and is dependent upon the amount of information available for the mixture itself and for its ingredients.

A flow chart (Figure 3.1.1 in 1272/2008) outlines the process to be followed.

Tiered approach to classification of mixtures for acute toxicity



In this instance, “Test data on the mixture as a whole” are not available, nor are there “Sufficient data available on similar mixtures”. However, there are “Available data for all ingredients”, allowing classification by applying the formula in section 3.1.3.6.1.

Section 3.1.3.6. **Classification of mixtures based on ingredients of the mixture (Additivity formula)** provides guidance on such classification.

“3.1.3.6.1. Data available for all ingredients

In order to ensure that classification of the mixture is accurate, and that the calculation need only be performed once for all systems, sectors, and categories, the acute toxicity estimate (ATE) of ingredients shall be considered as follows:

- (a) include ingredients with a known acute toxicity, which fall into any of the acute toxicity categories shown in Table 3.1.1;
- (b) ignore ingredients that are presumed not acutely toxic (e.g., water, sugar);
- (c) ignore ingredients if the oral limit test does not show acute toxicity at 2000 mg/kg bodyweight.

Ingredients that fall within the scope of this paragraph are considered to be ingredients with a known acute toxicity estimate (ATE).

The ATE of the mixture is determined by calculation from the ATE values for all relevant ingredients according to the following formula for Oral, Dermal or Inhalation Toxicity:

$$(100/ATE_{mix}) = \sum n (C_i/ATE_i)$$

where:

C_i = concentration of ingredient i (% w/w or % v/v)

i = the individual ingredient from 1 to n

n = the number of ingredients

ATE_i = Acute Toxicity Estimate of ingredient i.”

In the current exercise, bibra was told to assume that the non-nicotine ingredients of the mixtures are not acutely toxic, and nicotine is the only ingredient with a known acute toxicity.

Acute oral classification

The boundary range for Categories 3 and 4 are 50-300 and 500-2000 mg/kg bw, respectively. This means that mixtures containing nicotine can be classified as follows:

Nicotine concentration (%)	Estimated oral LD50 (mg/kg bw)	CLP Category
100	>50	3
16.6-100	50-300	3
2.5-<16.6	300-2000	4
<2.5	>2000	Not classified

Acute dermal classification

The boundary range for Categories 1, 2, 3 and 4 are <50, 50-200, 200-1000 and 1000-2000 mg/kg bw, respectively. This means that mixtures containing nicotine can be classified as follows:

Nicotine concentration (%)	Estimated dermal LD50 (mg/kg bw)	CLP Category
100	50	1
25-100	50-200	2
5-<25	200-1000	3
2.5-<5	>1000-2000	4
<2.5	>2000	Not classified

NOTE

This bibra proposal focuses on the classification of mixtures, accepting the literature LD50 figures and the existing classification views of the harmonised experts. It did not attempt to critically evaluate the reliability of the actual LD50 figures. It is possible that a critical evaluation of the existing LD50 literature might lead to a more confident identification of the best LD50 figures to use in substance and mixture classification.

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Details

Created on Friday, 13 June 2014 19:54

Latest Comments

Effects of e-cigarette use on exhaled nitric oxide

By Dr Farsalinos

A study was recently published in [Toxicology and Applied Pharmacology](#) examining the effects of using e-cigarettes and tobacco cigarettes on exhaled nitric oxide (FeNO). They found that similar **reductions** in FeNO are observed after e-cigarette and tobacco cigarette use. The authors concluded that in the aspect of FeNO, e-cigarettes are not safer than tobacco cigarettes, and mentioned that this finding is indicative that lung function is affected by e-cigarette use.

The conclusions of the authors are arbitrary and completely wrong. FeNO is a marker of inflammation to the lungs, most commonly used in asthmatics. However, inflammation is characterized by **high** levels of FeNO. Reductions in FeNO are observed in asthmatics after corticosteroid therapy, indicating that there is a response to the therapy and inflammation is **reduced**. Low levels are indicative of either no inflammation at all, or is a false negative finding of non-eosinophilic inflammation in patients with symptoms of respiratory disease. In any case, all participants in the study had normal FeNO levels, while a further reduction means absolutely nothing. By definition, it **does not** mean that there is a decline in lung function, because FeNO cannot be used as a marker of respiratory function; it just measures inflammation. Moreover, a significant problem in the statistical analysis should be mentioned. In a study evaluating different interventions in the same population, you do NOT use student t-tests but you perform repeated measures ANOVA. I would not expect the journal to accept such an analysis. Finally, it should be mentioned that while this study is inline with findings from [Vardavas et al.](#), it is contradictory to findings by [Schober et al.](#) and [Flouris et al.](#) Schober found elevation in FeNO levels after e-cigarette use. As we explained in a [letter to the editor](#), it is controversial to expect that both a reduction and an elevation of any biomarker mean the same thing!!

Of course, FeNO levels have nothing to do with NO production and effects on the endothelium of the arteries and on cardiovascular disease incidence, and, as mentioned above, do not indicate lung dysfunction. Anyone, making **such statements**, such as Stanton Glantz, is probably confused and is ignoring some basic facts. For the current study he mentions: "... the fact that exposure to e-cigarette aerosol reduces exhaled NO in the lungs may help explain why people who use e-cigarettes have a drop in lung function. (The fact that smoke reduces NO production in arteries is an important reason that smoking and passive smoking contribute to heart attacks)". Amazing statements for a study that **did not find any drop in lung function**, because they **did not measure lung function**. Moreover, they **did not assess NO production or effects on the endothelium of blood vessels** and thus the results are completely irrelevant to the cardiovascular system. Obviously, he is underestimating the intellectual abilities of regulators because he submitted his theories to the FDA as "scientific evidence".

In the past Glantz was once again **shouting about the adverse effects of e-cigarette use** when the Schober et al. study was published, which showed the **exact opposite** results compared to the current study (Schober showed elevated FeNO after e-cigarette use). In that case he mentioned: "They also found increased measures of inflammatory processes in the people using e-cigarettes, which could indicate lung irritation. (Increase levels of inflammation could also have effects on blood and blood vessels in

[Letter to New York Councilman concerning a proposal to ban flavored electronic cigarette liquids](#)

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ways that increase the risk of triggering a heart attack)”).

In reality the data are completely irrelevant to his arguments. **No study evaluated any cardiovascular effects and FeNO is not a marker of systemic inflammation.** Still, he jumps from the respiratory to the cardiovascular system and back. Finally, he needs to decide what he considers as problem arising from e-cigarette use? Elevated or reduced FeNO?

I must regretfully say that this is not science...



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Comments

#8 **Dr Farsalinos** 2014-06-14 11:47 0
 The site is not blocked (for an unknown reason) does anyone have access, perhaps the webmasket will figure out why this is happening...
 ... is just one specific server which (for an unknown reason) does not have access, perhaps the webmasket will figure out why this is happening...
 Quote

#7 **dave** 2014-06-14 21:29 0
 This site is blocked in Germany. Any reason for this?
 Quote

#6 **Margaret Hermon** 2014-06-14 16:04 +3
 Quoting Laurie Carlson:

If the lungs are supposed to be irritated or inflamed, then how did my severe asthma go AWAY, as documented by my doctors, once I quit smoking tobacco cigarettes and switched over to electronic cigarettes? The asthma still has NOT come back! It was BAD! I sat here and my lungs gurgled and gurgled while smoking tobacco cigarettes - that has gone COMPLETELY AWAY thanks to electronic cigarettes! Again, it is medically documented!

Same here - just had bad infection which has affected most of my bits, but no asthma attack. Stan seems to be suffering a great deal of confusion, a few mil of nicotine might help?
 Quote

#5 **Spazmelda** 2014-06-14 11:47 +4
 Fabulous example of illogic :D. Reduced FeNO is bad, and increased FeNO is bad, therefore ecigs are bad. Very convenient interpretation for the ANTZ. One must assume that no changes in FeNO would also somehow be interpreted as bad with enough diligence and twisted reasoning. ANTZ say, "Conflicting evidence, no problem. It's all BAD."
 Quote

#4 **Mick Wright** 2014-06-14 11:44 +3
 I'm not really sure that all of this in-depth analysis of chemistry is needed when there are so many vapers.
 Its all very well examining the effects of vapers in a confined and controlled environment. There are indeed things we do not know and need to find out. Usually this sort of experimentation is done in response to an emerging health concern that manifests in the general population. To find out whats happening.
 That's what is occurring with obesity...we know who the culprits are and experiments and studies are a response to the real world increase in obesity.
 The first question I'd ask Glantz is 'so what is the estimate you have for increased visits to hospitals of folks suffering from vaping induced lung conditions?'
 And he better get that right because it can be counted based on A&E admission reports.
 Quote

#3 **Laurie Carlson** 2014-06-14 10:42 +6
 If the lungs are supposed to be irritated or inflamed, then how did my severe asthma go AWAY, as documented by my doctors, once I quit smoking tobacco cigarettes and switched over to electronic cigarettes? The asthma still has NOT come back! It was BAD! I sat here and my lungs gurgled and gurgled while smoking tobacco cigarettes - that has gone COMPLETELY AWAY thanks to electronic cigarettes! Again, it is medically documented!
 Quote

#2 **Robert Innes** 2014-06-14 09:58 +4
 "Stanton Glantz, is probably confused.." We need accuracy with this type of statement. Take out 'probably.'
 Once again thank you so much for providing the explanations and details which at times, we so desperately need.
Quote

#1 **Michael** 2014-06-14 02:31 +2
 If this is the best you have against vapoing, maybe you should pick a new target to slander. You are really bad at this one.
Quote

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Details

Created on Monday, 05 May 2014 05:30

Formaldehyde release in e-cigarette vapor The New York Times story explained in detail

Dr Farsalinos

A study to be published in *Nicotine and Tobacco Research* was featured in the [New York Times](#) and has generated a lot of interest. The article mentioned that e-cigarette vapor can be the source of carcinogens, depending on the heating process.

The article is true and expected. We know that thermal degradation can lead to the release of toxic chemicals. And we know that formaldehyde, acetaldehyde and acrolein have been found in vapor. There is nothing new to it. However, this study found that levels may approach those present in tobacco cigarettes. Of course there are some inaccuracies in the NYT article, such as that nicotine gets overheated (which means nothing).

Herein, I present with more detail the results of this study. Researchers used an EGO Twist battery (variable voltage) and a top-coil clearomizer (with unknown resistance, thus unknown wattage delivery). At 3.2 and 4.0 volts, formaldehyde levels were 13-807 times lower compared to tobacco cigarettes!! At 4.8 volts, formaldehyde levels were increased by up to 200 times, and reached to levels similar to tobacco cigarettes.

The main criticism to this study is that in my opinion it is highly unlikely that a top-coil atomizer like the one used in this study would be used at 4.8 volts. At a resistance of 2.2 Ohms that would represent 10.4 watts of energy delivery to the atomizer. I tried 10 watts with an EVIC battery in a Vivi Nova top-coil atomizer (for a clinical study I performed few months ago), and many vapers were unable to use it due to the dry puff phenomenon. Unfortunately, the researchers did not measure and could not provide any information about the resistance of the atomizers, thus it is unknown how much energy was delivered to the atomizer. In my opinion, this is crucial. Moreover, it is very important to examine new-generation (rebuildable or bottom coil) atomizers at similar conditions, since it is more likely for vapers to use such advanced atomizers for high-wattage vaping. I am certain that, due to better liquid resupply to the resistance and wick, the results will be much more favorable.

Another important point is that, although formaldehyde levels can be similar to tobacco, several other toxic chemicals are completely absent from e-cigarette vapor. For example, acrolein was completely absent although they used liquids with glycerol as the main ingredient. In fact, glycerin-based liquids had much lower formaldehyde levels in vapor compared to PG or PG/VG liquids, suggesting that they are much safer to use. As a general remark, finding few chemicals at similar levels does not mean that the risk is equivalent to tobacco cigarettes. Of course, all this information was not presented in the NYT article.

Concerning the remarks about dripping, we should admit that dripping does not allow the user to see how much liquid is present in the atomizer. The same happens with cartomizers. We currently do not know whether the elevation in formaldehyde levels happens just at the time of dry puff phenomenon, or it happens earlier (before being detected by the vaper). Clearomizer-type atomizers (also called tank systems) seem to be the future in e-cigarette use, giving consumers the ability to know when they need to resupply the atomizer with liquid.

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Comments

1 2 3 4 5 6

#57 **Dr Farsalinos** 2014-08-12 17:15 +1
In reality, it was a 2.8sec puff duration. They activated the e-cigarette 1 second before drawing air from it. Thus, the total activation time was 2.8sec.

Quote

#56 **Tom Blackwell** 2014-08-12 16:58 +1
Never mind. I see it now: In the current study, all tests were performed with the following puffing conditions: puff duration 1.8 s, puff volume 70ml, and puff intervals 17 s 😊

Quote

#55 **Tom Blackwell** 2014-08-12 16:50 +2
Not only did they use a CE4 type clearo turned all the way up to 4.8 volts they also measured it in a 10 second draw!
Not only would it burn your mouth and taste so burnt and bad a human couldn't do it. The longest I could draw from any of my devices even at the lowest settings was 7 seconds and that was due to the airflow restriction of the tank.
I could barely inhale just air for 10 seconds.
So they were not using a real world scenario instead choosing one that would produce their desired results.

Quote

#54 **john r walker** 2014-08-08 07:07 0
I have just taken delivery of a battery control device ("batteries not included") that allows precise control of both Voltage and Wattage, and also does checks as to the exact resistance of the particular atomizer attached to it, have also added a cartomiser designed to create a lower atmospheric pressure in the chamber, i.e should produce a lower vapor point . So far it is giving very good results at quite low power.

Quote

#53 **tmmhmm** 2014-08-08 03:03 +3
So I guess when someone lights the wrong end of a cigarette (filter) by mistake they say "meh what the heck I'll keep smoking it?" LOL

It's almost the same as vaping dry:)

Quote

#52 **john r walker** 2014-07-30 05:37 0
Dr Farsalinos
The results for A6 and the control PG/VG liquid (C2) differ only in the level of butanal produced . All the other results for these two liquids are 'not detected' . Doesn't this suggest that A6 is also likely to be based on a PG/VG and nicotine mix- just as its maker says?

Quote

#51 **Dr Farsalinos** 2014-07-28 23:29 +1
You are right, it is unclear how they found PEG. Based on the way they mention it, it seems that it was through the label.

Quote

#50 **john r walker** 2014-07-28 23:18 +1
Actually the paper states that the liquids were grouped as : " Based on the labeling information, we grouped the products into VG based (only VG; A1–A3), VG:PG based (both VG and PG mixed in various ratios; A4–A6), and PG based (only PG; A7–A10)."

Quote

#49 **Dr Farsalinos** 2014-07-28 22:48 0
The paper mentions that they did perform chemical analysis.

Quote

#48 **john r walker** 2014-07-28 22:38 0
Dr Farsalinos
The studies chart <http://ntr.oxfordjournals.org/content/early/2014/05/14/ntr.ntu078/T1.expansion.html> for the 13 liquids tested states : "Ingredients (as listed on labels)".

Did the researchers do a chemical analysis of A6 ?

The make up of the liquid that performed so well in a fairly extreme test is of interest.

Quote

1 2 3 4 5 6

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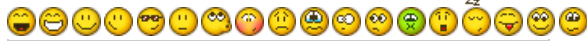
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Good Neighbor Operations Plan for the Outdoor Activity Area

-During our outreach, after talking to some neighbors we have decided to cut back the hours to 8PM for the outdoor activity area.

-The outdoor activity area is strictly for sampling flavors and devices.

-We will have 3 standing tables and there will be no more than 10 people in the outdoor activity area.

-The duration each user may spend in the outdoor activity area will be 5 to 15 minutes.

-We will have signage stating "Be respectful of our neighbors!"

-We will have trained employee to monitor the outdoor activity area.

-We will provide the owners and managers' contact information to our neighbors and we will take their complaints into consideration and come up with solutions.

High Percentage of Vacancy

-According to Invest In Neighborhoods San Francisco, Ocean Avenue Profile:

- “Ocean Ave from Ashton to Manor are mostly “dead blocks”; few businesses bring foot traffic. (That is 1900 block and 2000 block of Ocean Avenue)
- High Retail Leakage.
- Lack of public space to congregate.
- Residents complain about lack of diverse offerings; many don’t patronize shops and instead shop at West Portal, Stonestown.

-There are a total of 34 commercial storefronts on the 1900 block of Ocean Ave. 5 of them are vacant and 2 are use as storage. That’s 20.6% vacancy on the 1900 block of Ocean Ave.

-Supervisor Katy Tang introduced a legislation that if a storefront is vacant for more than 270 days must now pay a \$765 annual fee to The City.

Abstract

Introduction

Electronic cigarettes (e-cigarettes) are not currently approved or recommended by the Food and Drug Administration (FDA) or various medical organizations; yet, they appear to play a substantial role in tobacco users' cessation attempts. This study reports on a physician survey that measured beliefs, attitudes, and behavior related to e-cigarettes and smoking cessation. To our knowledge this is the first study to measure attitudes toward e-cigarettes among physicians treating adult smokers.

Methods

Using a direct marketing company, a random sample of 787 North Carolina physicians were contacted in 2013 through email, with 413 opening the email and 128 responding (response rate = 31%). Physicians' attitudes towards e-cigarettes were measured through a series of close-ended questions. Recommending e-cigarettes to patients served as the outcome variable for a logistic regression analysis.

Results

Two thirds (67%) of the surveyed physicians indicated e-cigarettes are a helpful aid for smoking cessation, and 35% recommended them to their patients. Physicians were more likely to recommend e-cigarettes when their patients asked about them or when the physician believed e-cigarettes were safer than smoking standard cigarettes.

Conclusions

Many North Carolina physicians are having conversations about e-cigarettes with their patients, and some are recommending them. Future FDA regulation of e-cigarettes may help provide evidence-based guidance to physicians about e-cigarettes and will help ensure that patients receive evidence-based recommendations about the safety and efficacy of e-cigarettes in tobacco cessation.

Figures

Physician Characteristic	%
Extremely confident in ability to prescribe optimal doses	
Agree	42.8%
Disagree	37.2%
Offer intensive tobacco treatment counseling	
Most/Sometimes	63.6%
Rarely/never	36.4%
Document counseling in clinic notes	
Most times	57.8%
Sometimes/rarely	42.4%
Specialty	
Psychiatry	21.1%
Other	78.9%
Age	
44 and younger	47.9%
45 and older	52.1%
Frequency patients ask about e-cigarettes*	
Frequently	20.3%
Sometimes	31.1%
Rarely	36.1%
Never	12.5%
Believe e-cigarettes lower risk of cancer	
Yes	64.8%
No	35.2%

*Variable treated as continuous.
doi:10.1371/journal.pone.0103462.t001

Significant Variables	OR	Sig.	Exp(B)
Provider Age (reference = younger)	1	.021	3.150
Belief that e-cigarettes lower the risk of cancer	1	.001	4.817
Frequency which patients ask about e-cigarettes	1	.001	2.468
Physicians who document tobacco treatment counseling	1	.022	3.316

doi:10.1371/journal.pone.0103462.t002

Citation: Kandra KL, Ranney LM, Lee JGL, Goldstein AO (2014) Physicians' Attitudes and Use of E-Cigarettes as Cessation Devices, North Carolina, 2013. PLoS ONE 9(7): e103462.

doi:10.1371/journal.pone.0103462

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Competing interests: The authors have declared that no competing interests exist.

Introduction

The 2008 Treating Tobacco Use and Dependence Clinical Practice Guideline recommends that clinicians ask all patients about tobacco use, offer strong cessation messages, and provide assistance to those patients who use tobacco [1]. Recommended treatments for tobacco cessation include counseling and/or medications such as Bupropion SR or nicotine replacement (e.g., nicotine patch, gum, or inhaler). The combination of behavioral counseling with pharmacotherapy is also strongly recommended [1]. These guidelines do not discuss the use of electronic cigarettes (e-cigarettes), as the guidelines were written before e-cigarettes were widely available in the U.S. Since then, however, e-cigarettes have become a cessation tool for some tobacco users' cessation attempts [2], despite their use not being approved or recommended by the FDA [3] or various medical organizations, including the American Lung Association [4], the American Medical Association [5]–[6], the American Thoracic Society [7], and the Center for Public Health and Tobacco Policy [8]. The purpose of the current study is to report on a physician survey that measured beliefs, attitudes, and behavior related to e-cigarettes as a tool for smoking cessation. To our knowledge, only one study thus far has sought to measure e-cigarettes from the perspective of physicians, and that study focused on adolescent providers [9]–[10]. This study is unique in that it measures e-cigarettes from the perspective of physicians who treat adult patients.

Methods

Ethics Statement

- a. This submission was reviewed by the UNC Biomedical IRB and Office of Human Research Ethics, which has determined that this submission does not constitute human subjects research as defined under federal regulations [45 CFR 46.102 (d or f) and 21 CFR 56.102(c)(e)(1)] and does not require IRB approval.
- b. This study was deemed as non-human subjects research, which is similar to an exemption. As a result, federal regulations for consent are not applicable and a waiver for participation was not required from participants.

Recruitment and Sample

A random sample of North Carolina (NC) physicians were recruited to participate. From July–August, 2013, Infocus Marketing, Inc., a direct marketing company with access to the American Medical Association mailing list, attempted to contact 156 family medicine physicians, 161 internal medicine physicians, 159 obstetricians/gynecologists, 160 psychiatrists, and 151 surgeons (total recruitment, 787 providers) through three different waves of emails. From these emails, which invited physicians to participate in a survey on attitudes and use of QuitlineNC services for patients who use tobacco, 14 addresses were invalid or emails returned, 413 were opened, and 128 responded (28 family medicine physicians, 24 internal medicine physicians, 21

obstetricians/gynecologists, 27 psychiatrists, and 28 surgeons) for an overall response rate of 31%. Physicians were offered a \$100 gift card as an incentive for participation, and every physician contacted had the opportunity to decline participation by unsubscribing from the survey. Physicians were assured their responses would remain anonymous.

Survey Measures

A series of close-ended questions measured physicians' attitudes towards e-cigarettes. Specifically, physicians were asked if they believe e-cigarettes are approved by the FDA for smoking cessation; if they believe e-cigarettes lower the risk of cancer for patients who use them instead of smoking cigarettes; if they believe e-cigarettes are a helpful aid for smoking cessation; and if they recommend use of e-cigarettes to their patients. Response options provided were *yes* and *no*. Physicians were also asked how often their tobacco-using patients ask about e-cigarettes, with response options given as *frequently*, *sometimes*, *rarely*, and *never*. In addition, the survey contained items measuring personal and professional demographics (e.g., gender, age, years in practice, specialty), as well as items measuring clinic behaviors and attitudes (e.g., how often they document counseling in clinic notes after offering tobacco use treatment to their patients and how confident they are in their ability to prescribe optimal doses of tobacco cessation medications). Physicians rated these items using a 4-point response scale with varying labels such as *most times* to *never* and *strongly agree* to *strongly disagree*.

Analysis

Data were analyzed using SPSS version 21. Missing data were excluded from analysis, as were physicians who are not actively involved in clinical practice ($n = 6$). A positive response to recommending e-cigarettes to patients served as the outcome variable for a backward stepwise logistic regression analysis. After conducting a series of bivariate analyses, response categories were collapsed into two categories to ensure an adequate sample size within each category, and the following variables served as predictors: *agreement* with being extremely confident in ability to prescribe optimal doses (*disagreement* served as reference group); those who offer intensive counseling to those who use tobacco *most/sometimes* (*rarely* served as reference group); those who document counseling in clinic notes *most times* (*sometimes/rarely* served as reference group); *psychiatry* specialty (*others* served as reference group); *45 and older* (*44 and younger* served as reference group); frequency of patients asking about e-cigarettes (left as continuous); and *agreement* that e-cigarettes lower the risk of cancer for patients who use them instead of smoking cigarettes (*no* served as reference group). All variables used in the analysis may be found in [Dataset S1](#). Nonstatistically significant predictors were removed from the model so that the final model included only those variables statistically significant at $p < .05$.

Results

Demographics

Of the $n = 122$ physicians who were active in clinical practice, 64.7% had 10 or more years in their field, 85.2% saw 26 or more patients in a typical week, and 56.6% lived in towns with a population greater than 100,000. In addition, a majority of physicians were male, white, and had never been smokers. Group settings accounted for 36.7% of the sample; however, many physicians practiced in a hospital or academic setting, 24.2% and 21.1%, respectively.

E-cigarettes in Clinical Practice

Over two-thirds (67.2%) of the physicians indicated that e-cigarettes are a helpful aid for smoking cessation, and 35.2% recommended them to their patients. A majority (64.8%) believed that e-cigarettes lower the risk of cancer for patients who use them instead of smoking cigarettes. E-cigarettes were also frequently part of the

clinical encounter, with 48.4% of physicians responding that patients ask about e-cigarettes frequently or sometimes. Only 20.5% of physicians indicated they are never asked about e-cigarettes. 13% of physicians incorrectly believed that e-cigarettes are already approved by the FDA for smoking cessation.

Predictors of Recommending E-cigarettes

[Table 1](#) presents the breakdown of variables included in the logistic regression model, and [Table 2](#) presents the statistically significant logistic regression coefficients and odds ratios for predictors that remained in the final model. Increased odds of recommending e-cigarettes to patients is associated with physicians who believed e-cigarettes lower the risk of cancer for patients who use them instead of smoking cigarettes, increased frequency of patient inquiry about e-cigarettes, older physicians, and those physicians who documented tobacco use counseling in their clinic notes.

Physician Characteristics	%
Extremely confident in ability to prescribe optimal doses	
Agree	42.8%
Disagree	37.2%
Offer intensive tobacco treatment counseling	
Most/Sometimes	63.6%
Rarely/never	36.4%
Document counseling in clinic notes	
Most times	57.6%
Sometimes/rarely	42.4%
Specialty	
Psychiatry	25.1%
Other	74.9%
Age	
44 and younger	47.9%
45 and older	52.1%
Frequency patients ask about e-cigarettes*	
Frequently	20.5%
Sometimes	31.1%
Rarely	36.1%
Never	12.3%
Believe e-cigarettes lower risk of cancer	
Yes	64.8%
No	35.2%

*variable treated as continuous.
doi:10.1371/journal.pone.0103462.t001

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Table 1. Variables Included in Logistic Regression, 2013, n = 122.

doi:10.1371/journal.pone.0103462.t001

Significant Variables	Odds	Sig.	Exp(B)
Provider Age (Reference = younger)	1	.021	3.150
Belief that e-cigarettes lower the risk of cancer	1	.001	4.817
Frequency which patients ask about e-cigarettes	1	.001	2.468
Physicians who document tobacco treatment counseling	1	.022	3.316

doi:10.1371/journal.pone.0103462.t002

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Table 2. Significant Predictors of Recommending E-cigarettes, 2013, n = 122.

doi:10.1371/journal.pone.0103462.t002

Conclusions

Principal findings

Previous reviews have found that e-cigarettes are viewed by the general public as effective strategies for quitting and reducing harm, [9] and research suggests some smokers use e-cigarettes for cessation purposes [11]. The question remains of whether physicians share those same attitudes regarding e-cigarettes.

To date, only one study of adolescent providers has sought to answer this question [9–10–12], and this research suggests that physicians who treat adolescents lack professional education when it comes to e-cigarettes and often learn about e-cigarettes directly from their patients [10]. In our study, approximately four out of five participating physicians reported being asked about e-cigarettes from their patients who used tobacco. Interest in e-cigarettes appears high, and, despite an absence of evidence regarding the long-term health impact of e-cigarettes [13], over one-third of physicians in this sample reported recommending their use for patients, and over two-thirds believed e-cigarettes are a helpful aid for smoking cessation. Although some evidence suggests e-cigarettes can be effective for cessation [2]–[14], they are not included in current guidelines that recommend combination nicotine replacement therapy or varenicline as first-line therapy [15]. Because current smokers who have tried e-cigarettes do not report an increased intention to quit smoking [16] and concerns exist over dual use of these products [17], physicians should remain cautious until more data is available about recommending e-cigarettes as tobacco cessation tools in clinical practice in favor of more effective modalities. Behavioral counseling about tobacco use cessation should also remain prominent in all quit attempts [1]. Furthermore, there is insufficient research on the relationship between e-cigarettes and nicotine dependence, including whether or not e-cigarettes could actually increase dependence [13]. To what extent e-cigarettes work more or less effectively than FDA approved pharmacotherapy remains unclear.

Our results also suggest that physicians who document counseling in their clinic notes after offering tobacco use treatment to their patients are more likely to recommend e-cigarettes. This relationship suggests that physicians may be interested in continuing the e-cigarette conversation with their patients in future appointments, as advising patients to quit smoking is the most often utilized intervention by physicians [18]. However, it is then imperative that physicians stay current with evidence-based research on e-cigarettes because discrepancies already exist among physicians when it comes to tobacco use treatment options [19]. Our results are no different in that older physicians were more likely to recommend e-cigarettes than younger physicians, and some physicians incorrectly believed they are already approved by the FDA for smoking cessation. Without widespread dissemination of clear, evidence-based research on e-cigarettes, it is likely these discrepancies will continue and patients could potentially be given inaccurate information [10].

Limitations

This research has several limitations. As results are specific to a small sample of NC physicians, they may not generalize to other populations. Also, the response rate is relatively low and there is the potential for nonresponse bias. It is possible that our sample includes physicians who are more positive towards e-cigarettes than other non-participating physicians. However, our sample was recruited for a survey on the North Carolina Quitline without any indication there would be questions related to attitudes or behaviors regarding e-cigarettes as cessation devices. Furthermore, 31% for physicians participating in an email survey can be considered quite good [20–21–22]. Finally, results are descriptive in nature. Causality and directionality should not be inferred. Given the preliminary nature of this survey, it is recommended that ongoing surveillance of e-cigarettes as a tobacco use treatment option continues with a much larger, diverse, random sample of physicians.

Conclusion

This research provides a first look at how e-cigarettes are being used as cessation devices among physicians who treat adult patients. Our results suggest that physicians see potential in these products as a cessation device and that some make recommendations for their use. As e-cigarettes become more mainstream, physicians may be called on to engage in conversations with their patients about the safety and efficacy of these products. It is essential that the FDA critically review the current evidence on e-cigarettes and provide clear guidance about e-cigarettes and tobacco cessation.

Supporting Information

Dataset_S1.xlsx

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Dataset S1.

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(XLSX)

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Author Contributions

Conceived and designed the experiments: AG LR. Performed the experiments: AG JL LR. Analyzed the data: KK AG. Contributed reagents/materials/analysis tools: AG KK. Wrote the paper: KK. Review and editing of manuscript: AG LR JL KK.

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Public Health
England

Electronic cigarettes

A report commissioned by Public Health
England

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1. The public health impact of tobacco smoking in the UK

1.1 Background: Mortality and morbidity from smoking in adults, children, and the fetus

Smoking is the largest avoidable cause of death and serious disability in the UK and most other developed countries, and a global health threat. There are about one billion smokers worldwide, of whom about half will die prematurely as a direct consequence of their smoking, unless they quit.^[1] In the UK around one in five adults, or about ten million people, are current smokers,^[2, 3] five million of whom are expected to die prematurely from smoking, losing a total of around 100 million years of life.^[4] Smoking currently accounts for around 100,000, or about one in six, deaths each year in the UK.^[5]

Smoking causes around 85% of the approximately 40,000 cases of (and deaths from) lung cancer in the UK each year,^[6] and contributes to the development of many other cancers, including oral cavity cancer, oesophageal and gastric cancer, kidney and bladder cancers, and pancreatic cancer.^[7] Smoking also accounts for about 85% of the 23,000 deaths from chronic obstructive pulmonary disease (COPD) each year in the UK, and about 25,000 of the more than 200,000 deaths from cardiovascular disease.^[5] Smoking also increases the risk of pneumonia, asthma exacerbation,^[7] and a wide range of other adverse health effects.^[8]

Exposure to second-hand smoke (also referred to as passive smoking) also causes significant harm. Among adults, passive smoking causes thousands of deaths from lung cancer, cardiovascular disease and COPD.^[9] Passive exposure of children increases the risk of sudden infant death syndrome, lower respiratory infections, asthma and wheezing illness, meningitis and middle ear disease.^[10] Smoking during pregnancy harms the fetus, increasing the risk of premature birth, low birth weight, fetal anomalies, and fetal mortality.^[10]

1.2 Contribution of smoking to social inequalities in health and poverty

Smoking is strongly associated with socioeconomic disadvantage, and in most high income countries the prevalence of smoking is considerably higher among more deprived people than in those from affluent backgrounds.^[11] In the UK, the unemployed are twice as likely to be smokers compared to employed people,^[12] and smoking is highly prevalent among the homeless,^[13] those in prison,^[14] and other marginalised or otherwise highly disadvantaged groups. Smoking is also more than twice as prevalent among people with mental disorders than in the general population, and has changed little over the past 20 years, in contrast to the progressive decline in smoking

prevalence in the general population.^[15] Smokers in disadvantaged groups have also typically started to smoke at a younger age, smoke more cigarettes per day, and take in more nicotine from each cigarette.^[16] Smoking thus strongly exacerbates health inequalities.^[17]

2. Electronic cigarettes

2.1 Short history and description of products on the market

Electronic cigarettes (also known as e-cigarettes or electronic nicotine delivery systems (ENDS)) were invented in China in 2003^[18] and designed to provide inhaled doses of vaporized nicotine.^[19] Electronic cigarettes were first introduced to Europe in about 2005 and become increasingly popular since. The products have evolved and improved considerably, such that while most early models resembled cigarettes in shape and size^[19] (sometimes referred to a 'cigalikes', figure 1), many later ENDS models are larger, at about the size of a conventional fountain pen, and are known (among other terms) as 'personal vapourisers', or PVs (figure 2).

Electronic cigarettes typically comprise a re-chargeable lithium ion battery, and a battery powered atomiser which produces vapour by heating a solution of nicotine, usually in propylene glycol or glycerine, held in a (often refillable) cartridge in the device (figure 1). Drawing air through the e-cigarette triggers the heater to create vapour which contains nicotine and is inhaled by a smoker the same way as smoke from conventional cigarettes. Producing nicotine vapour from a solution rather than by burning tobacco means that electronic cigarette vapour is free from almost all of the many toxic chemicals that accompany nicotine in cigarette smoke. Not all electronic cigarettes include nicotine; some simply produce vapour for inhalation, but these are not popular among users.^[20]

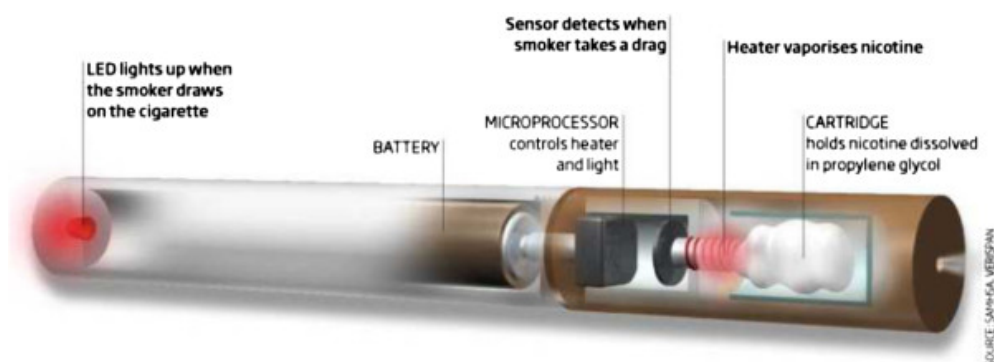


Figure 1: An electronic cigarette (reproduced from Polosa et al. A fresh look at tobacco harm reduction: the case of electronic cigarettes^[19])



Figure 2: an example of a personal vapouriser (from Wikipedia, <http://en.wikipedia.org/wiki/File:E-cigarette.jpg>)

2.2 Nicotine content, delivery and pharmacokinetics

Evidence on the content and emission of electronic cigarettes is limited. As nicotine is the addictive substance in tobacco cigarettes, nicotine delivery from electronic cigarettes is essential if these products are to be effective for smoking cessation or harm reduction. There are three key elements that influence nicotine delivery from e-cigarette vapour to human body: the nicotine content in the cartridge, which determines the amount of nicotine vapourised; the efficacy of vaporization, which affects levels of nicotine transferred from a cartridge into aerosol; and the bioavailability of nicotine, which determines the dose and speed of absorption of nicotine from the aerosol and subsequent transfer into the blood stream and hence to nicotine receptors in the brain.^[21] All of these characteristics vary across brands, manufacturers, and product designs.

Smoking a cigarette delivers nicotine throughout the lung and leads to absorption into both the systemic venous circulation from the oropharynx and large airways, and the pulmonary circulation from the small airways and alveoli. The latter route of absorption generates a rapid peak in systemic arterial nicotine levels and hence rapid delivery to the brain.^[22] No other nicotine product has yet been demonstrated to mimic the speed and high dose delivery characteristics of cigarettes. Since nicotine absorbed from the intestine is heavily metabolised on first pass through the liver, conventional nicotine replacement therapy (NRT) products rely on venous absorption from skin, nose or mouth, which avoid this hepatic metabolism but produce relatively low plasma levels, relatively slowly.^[23] It is not yet clear whether electronic cigarettes produce vapour that is sufficiently fine to reach the alveoli, but available pharmacokinetic data suggests that absorption is primarily from the upper airway, that is, slower than a cigarette, and achieving systemic venous blood levels of similar order of magnitude to a conventional NRT inhalator.^[24] Data on the arterial nicotine levels achieved by electronic cigarettes is not available.

It is also evident however that different electronic cigarette products are highly variable in the amount of nicotine they deliver in vapour,^[21, 25] and that the nicotine content indicated on a cartridge is not a reliable guide to likely nicotine delivery.^[25] Although there have been concerns that use of electronic cigarettes could lead to an overdose of nicotine, a study carried out using electronic cigarette brands available in the UK suggests that there is low risk of overdose of nicotine or even inhaling toxic doses of nicotine using electronic cigarettes.^[25] Newer generation PV devices may deliver higher doses of nicotine, but the absorption kinetics still indicate that absorption remains almost, if not completely, via the systemic rather than pulmonary vasculature.^[26]

2.3 Likely health effects relative to conventional cigarettes

The principal addictive component of tobacco smoke is nicotine. However, aside from minor and transient adverse effects at the point of absorption, nicotine is not a significant health hazard. Nicotine does not cause serious adverse health effects such as acute cardiac events, coronary heart disease or cerebrovascular disease,^[27, 28] and is not carcinogenic.^[29] The doses of nicotine delivered by electronic cigarettes are therefore extremely unlikely to cause significant short or long-term adverse events.

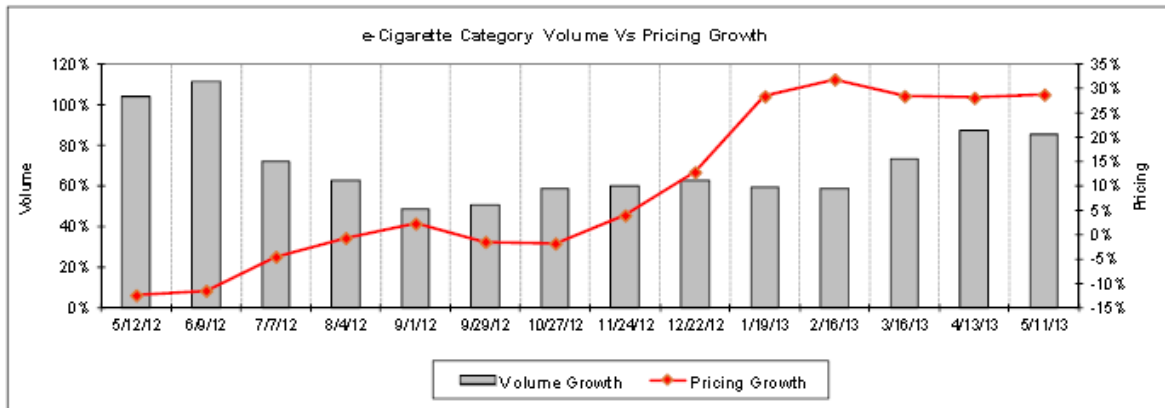
Cigarettes deliver nicotine in conjunction with a wide range of carcinogens and other toxins contained in tar, including nitrosamines, acetone, acetylene, DDT, lead, radioactive polonium, hydrogen cyanide, methanol, arsenic and cadmium,^[30] and vapour phase toxins such as carbon monoxide.^[7] In contrast, electronic cigarettes do not burn tobacco, so any toxins in vapour arise either from constituents and contaminants of the nicotine solution, and products of heating to generate vapour. The principal component other than nicotine is usually propylene glycol, which is not known to have adverse effects on the lung^[31] but has not to our knowledge been tested in models that approximate the repeated inhalation, sustained over many years, that electronic cigarettes involve. We are aware of two cases of lipoid pneumonia attributed to inhalation of electronic cigarette vapour, one in the peer-review literature^[32] the other a news report.^[33]

Despite some manufacturers' claims that electronic cigarettes are harmless there is also evidence that electronic cigarettes contain toxic substances, including small amounts of formaldehyde and acetaldehyde, which are carcinogenic to humans,^[34] and that in some cases vapour contains traces of carcinogenic nitrosamines, and some toxic metals such as cadmium, nickel and lead.^[34] Although levels of these substances are much lower than those in conventional cigarettes,^[34] regular exposure over many years is likely to present some degree of health hazard, though the magnitude of this effect is difficult to estimate.

2.4 Current trends in prevalence of electronic cigarette use

Worldwide use of electronic cigarettes has increased significantly over recent years, but varies markedly between countries. In a recent study carried out in four countries,

rates of ever use of electronic cigarettes were 15% in the US, 10% in the UK, 4% in Canada and 2% in Australia, typically with higher rates among younger age groups.^[35] In another representative study carried out in the US in 2010-11, 21% of adult smokers had ever used an electronic cigarette.^[36] Increasing use of electronic cigarettes in the US is also demonstrated clearly in data on trends in sales of electronic cigarettes which, in the US for example, demonstrated strong growth in volume and value of sales between 2012 and 2013 (figure 3).^[37]



Source: Nielsen C-Track Database and Wells Fargo Securities, LLC

Figure 3: Electronic cigarette market changes in the US (adapted from Wells Fargo Securities)

There is evidence that in the US, use of electronic cigarettes has become more popular among young people with ever use doubling between 2011 and 2012 from 3.3% to 6.8%, and current use increasing from 1.1% to 2.1%.^[38, 39] Most of this increase has occurred as a result of use by people who already use some form of tobacco product.^[38, 39] In a more recent analysis of 2011-12 data from young people in the US,^[40] reported widely (including by the British Medical Journal)^[41] to demonstrate gateway effects into smoking, use was again almost entirely restricted to young people who already smoked tobacco.^[40]

The most recent survey in the European Union (EU) demonstrates lower levels of use than in the US, with that in 2012, 7% of adults reporting in 2012 that they had tried an electronic cigarette, though most respondents reported awareness of the product.^[42] Data for the UK demonstrates trends in use similar to those in the US, with data from the Smoking Toolkit Study, a monthly survey of about 1800 adults including around 450 smokers, led by Professor Robert West at University College London.^[43] Data released in March 2014 demonstrates that electronic cigarette use, having increased rapidly over the past two years, has now stabilised at around 17%.^[44] *Action on Smoking and Health* (ASH) has estimated that currently about 1.3 million people in the UK use electronic cigarettes, and around 400,000 people have completely replaced smoking with electronic cigarettes.^[45] Electronic cigarettes are primarily used by current and former smokers, and only about 0.5% of never smokers in Great Britain have tried the product.^[46] Use of electronic cigarettes is equally common across age and socioeconomic groups.^[47]

3. Harm reduction

3.1 What is harm reduction, and how does it apply to tobacco use?

Harm reduction is a strategy used widely in health policy to reduce harm to an individual or society by modifying hazardous behaviours that are difficult, and in some cases impossible, to prevent. Examples include requiring drivers to wear seatbelts, promoting safer sexual practices, providing methadone to opiate addicts, and needle exchanges to reduce the risk of blood-borne infection in intravenous drug users.^[48]

Harm reduction policies have not to date been widely used in tobacco control, in which policies have to date tended to be centred on promoting complete cessation of all tobacco and nicotine use, with harm reduction limited to the introduction of cigarette filters, and (largely discredited) limits on machine-smoked tar yields. While this overall approach has achieved substantial success, with smoking prevalence having fallen among adults from 45% to 20% over the past four decades,^[49] the current 20% prevalence translates into about ten million smokers at immediate and sustained risk of premature death and disability. Conventional tobacco control approaches have by definition failed in these people, for whom harm reduction approaches, to minimise health harms until complete cessation can be achieved, are essential. The options for harm reduction in tobacco control include cutting down on smoking, use of modified cigarettes, smokeless tobacco products, nicotine replacement therapies, and more recently electronic cigarettes.

3.1.1 Cutting down on smoking

Cutting down on smoking, that is, reducing the number of cigarettes smoked each day, has been popular among smokers to reduce harm caused by cigarette smoking. However, smokers who cut down typically compensate by changing their smoking behaviour to extract higher doses of nicotine (and hence tar) from the cigarettes they smoke, by taking more and/or deeper puffs of smoke from each cigarette.^[50] This, and the fact that the exposure-response curves for harm are not all linear (for example, for cardiovascular disease risk increases dramatically with just one cigarette per day),^[4, 51] means that cutting down on the number of cigarettes smoked per day does not lead to proportionate reductions in harm to health, if indeed to any.^[52-55] There is benefit from cutting down on the number of cigarettes smoked, but this arises primarily from the fact that those who do so are more likely to make a quit attempt in the future.^[56]

3.1.2 Modified cigarettes

Modified cigarettes, sometimes referred to as potentially reduced exposure products (PREPS) have been promoted by the tobacco industry as an option to reduce risk. Low tar and low nicotine cigarettes, which promised enjoyment of smoking and lower risk to

health^[57] were an early example of this, though in practice the low tar yields were achieved by technologies such as filter ventilation which reduced machine-measured tar yields rather than 'real life' tar delivery, and were in any case undermined by compensatory smoking.^[50] Marketed as an alternative to quitting,^[57] low tar cigarettes proved to be counterproductive to public health.

In addition to conventional filters, which may have led to a modest reduction in cancer risk,^[58] other potential modifications include more effective (activated charcoal) filters, and heating rather than burning tobacco.^[59-61] To date however, non-combustion products have not proved commercially successful, and the extent to which minor reductions in toxin exposure translate into tangible reductions in health hazard to smokers remain far from certain.

3.1.3 Smokeless tobacco

Smokeless tobacco products, usually in the form of oral tobacco or nasal snuff, are widely available and used around the world. Although some are associated with significant health harms, including increased risks of nasal, oral or gastrointestinal cancer, none causes lung cancer or COPD and all are substantially less hazardous than smoked tobacco.^[62] Since smokers who switch from smoked to smokeless tobacco substantially reduce the hazard to their health from tobacco use, smokeless products have great potential as a harm reduction option for smokers. The least hazardous smokeless tobacco product in widespread use is Swedish snus, an oral product that has been used in Sweden for decades.^[62] However, with the exception of Sweden, supply of snus or similar products is prohibited throughout the European Union.

3.1.4 Nicotine replacement therapies (NRTs)

NRT comprises a group of medicinal nicotine products intended for use by smokers as a substitute for tobacco while attempting to quit smoking. Historically their use has been recommended in a reducing dose schedule over about three months from quitting smoking, but NRT products are also effective as a short- or long- term substitute for tobacco, that is, as a harm reduction option. UK medicines regulators have approved NRT for harm reduction indications including cutting down on smoking through dual use (which often leads to complete smoking cessation)^[63] and as a temporary or long-term abstinence from smoking, and in 2013 the National Institute for Health Care Excellence (NICE) issued guidance recommending use of NRT as a harm reduction substitute for smokers who are not ready or able to quit all tobacco and nicotine use.^[27, 64] However, NRT products have been designed to deliver low doses of nicotine, and most products to do so relatively slowly, in relation to absorption from cigarettes.^[23] This, and the fact that the products can be expensive relative to cigarettes at the point of sale, provide few if any of the behavioural characteristics of cigarettes that contribute to addiction,^[7] lack social acceptability as an alternative to smoking, and medicalise the act of trying to quit smoking, limits their attractiveness to smokers.

3.1.5 Electronic cigarettes

Electronic cigarettes offer nicotine delivery in a format that mimics smoking, have a socially acceptable non-medical image which enables users to retain their smoker identity but without the risk of smoke, are relatively inexpensive (start-up costs can be high, but running costs much lower than smoking), and despite (to date) nicotine delivery that is low relative to cigarettes,^[24] have proved popular with the current minority of smokers who use them. Consumer support for the product is evident from the user sites that a brief internet search on electronic cigarettes or vaping generates. To our knowledge, no users of NRT have ever felt sufficiently passionate about the product to establish a user website. Unlike NRT therefore, and particularly if nicotine delivery can be improved to mimic that of cigarettes more closely, these products have the potential mass appeal to challenge the primacy of smoked tobacco as the product of choice for nicotine users.

3.2 Evidence on effectiveness of harm reduction approaches

The experience of the availability of snus in Sweden provides a unique natural experiment in the impact of a socially accepted, non-medical, affordable and easily accessible reduced harm product on the prevalence of tobacco smoking.^[62] Snus is an oral moist tobacco which contains relatively low levels of tobacco specific nitrosamines^[65] and has a risk profile that includes possible increases in risk of oesophageal and pancreatic cancer,^[66] and of fatal (but not non-fatal) myocardial infarction,^[67, 68] but not COPD or lung cancer.^[62]

Although over recent decades the prevalence of any tobacco use has changed little in Sweden,^[65] the prevalence of smoking in Sweden, which has fallen from 30% in the 1980s^[69] to 13% today,^[42] is now the lowest in Europe. This in part reflects the effect of existing smokers switching to snus, and partly the effect of new tobacco users initiating snus use but not smoking.^[62, 65, 70, 71] One result is that Sweden now has an extremely low and decreasing lung cancer mortality rate.^[72] Similar trends and effects on smoking prevalence have been observed in Norway, where use of snus is a much more recent phenomenon, and both snus use has risen and smoking prevalence fallen markedly since the year 2000 (figure 4):

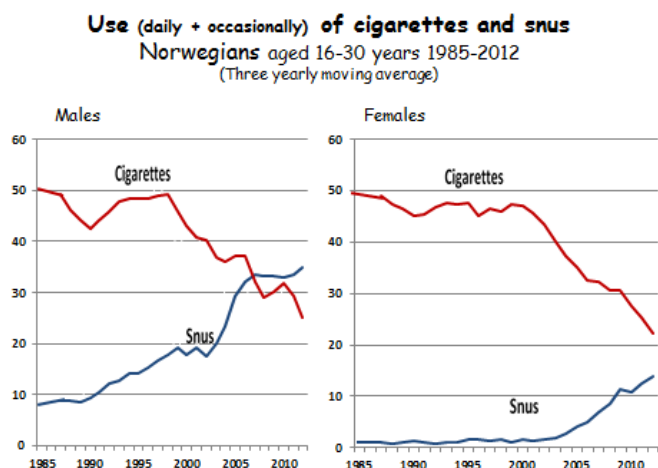


Figure 4: Trends in use of cigarettes and snus in Norwegian adults 1985-2012 (data presented to the Society for Research on Nicotine Conference 2013, figure provided by lead author)^[73]

Although controversial, the Swedish natural experiment demonstrates that despite dual use and primary uptake of the reduced-harm product by young people, availability of reduced-harm alternatives for tobacco smokers can have a beneficial effect. While snus is not likely to become a legal or indeed politically viable option in the UK, this data proves the concept that harm reduction strategies can contribute to significant reductions in smoking prevalence.^[62]

3.3 Where does harm reduction fit into UK policy and practice

Although historically in the UK, NRT was licensed for smoking cessation only, over recent years licencing regulations have become more relaxed, and in 2009 the UK Medicines and Healthcare products Regulatory Agency (MHRA) approved an extension to include harm reduction as an indication for the *Nicorette* inhalator, and suggested extending this indication to other nicotine containing products.^[74] In recent NICE guidelines, which cover licensed nicotine-containing products, long term use of medicinal nicotine has been recommended to help with quitting smoking, cutting down on smoking, or temporary abstinence.^[64] Harm reduction was also promoted in tobacco control white papers produced by both the previous Labour administration^[75] and the current coalition government.^[76] Many of these changes were encouraged in a report by the Royal College of Physicians, published in 2007.^[7] Harm reduction was also endorsed by Action on Smoking and Health in 2008 report endorsed by over 60 national organisations.^[77] In these respects UK tobacco policy leads the world. No other country, to our knowledge, has embraced the concept of harm reduction so strongly.

3.4 How do electronic cigarettes fit into a harm reduction strategy

Electronic cigarettes emerged on the UK market at around the time of the 2007 Royal College of Physicians report, which advocated making alternative sources of medicinal nicotine available to smokers as a competitive and non-medical alternative to tobacco. The rapid uptake of electronic cigarettes since then, despite uncertainties over their

purity and performance, demonstrates that, as has been the case with Swedish snus, many smokers welcome the availability of choice in nicotine products, and if provided with products that are attractive, affordable and easily available, will use them either in conjunction with, or in the longer term instead of, tobacco cigarettes. Electronic cigarettes also appeal to smokers by mimicking the sensation and appearance of smoking a cigarette, and by their market positioning as lifestyle rather than medical products. Electronic cigarettes, and the various new generation nicotine devices in development, clearly have potential to reduce the prevalence of smoking in the UK. The challenges are to harness that potential, maximise the benefits, and minimise risks.

4. Potential hazards of electronic cigarettes

As use of electronic cigarettes is a relatively recent phenomenon and evidence to date is scarce, there are still some major concerns about these products: those related to product itself, those about relation between use of electronic cigarettes and smoking, and concerns about renormalization and regulation of electronic cigarettes.

4.1 Hazards from the product itself

Potential hazards of electronic cigarettes relate primarily to the purity of nicotine emissions, and the effects of long-term exposure to vapour. Evidence on these is summarised in section 2.3 above, but relate primarily to the effects of substances other than nicotine in the vapour. Overall however the hazards associated with use of products currently on the market is likely to be extremely low, and certainly much lower than smoking. They could be reduced further still by applying appropriate product standards.

Electronic cigarettes do not produce smoke so the well-documented effects of passive exposure of others to cigarette smoke^[9, 10] are clearly not relevant. Exposure of non-smokers to electronic cigarette vapour poses a concern, though laboratory work suggests that electronic cigarette use in an enclosed space exposes others to nicotine at levels about one tenth generated by a cigarette, but little else^[78]. The health risks of passive exposure to electronic cigarette vapour are therefore likely to be extremely low.

4.2 Potential hazards, unintended consequences, harms to public health

Electronic cigarettes have caused controversy among public health professionals due to three main reasons: concerns about the relation between smoking and use of electronic cigarettes; regulations on advertising and promotion of electronic cigarettes; and involvement of the tobacco industry.

4.2.1 The relation with smoking

There have been some suggestions that among non-smokers, electronic cigarettes might be used as a gateway to smoking and promote smoking uptake and nicotine addiction, particularly among children and young people. However, to date there is no data supporting this claim. Experimentation with electronic cigarettes among non-smoking children in the UK is currently rare, and only about 1% of 16 to 18-year-old never smokers have experimented to electronic cigarettes and few if any progress to sustained use.^[47] Furthermore, experimentation with electronic cigarettes should be considered in the context of current levels of experimentation with tobacco cigarettes, which in Great Britain currently generates a prevalence of smoking of 15% among 16 to

19-year olds, and 29% in 20 to 24-year olds.^[79] Experimentation with electronic cigarettes is most likely to occur predominantly in the same group that currently experiment with tobacco, as indeed is suggested by recent US data.^[40] It is therefore relatively unlikely that availability and use of electronic cigarettes causes or will cause significant additional numbers of young people to become smokers than do at present. It has been suggested that there is a risk of sustained dual use among smokers who might otherwise have quit smoking completely, representing missed opportunities to achieve complete cessation. This concern clearly applies equally to NRT, which is licensed for what is in effect dual use and recommended on the grounds that dual use is likely to increase quit attempts. The concern is therefore inconsistent; if dual use is good as a pathway to quitting, that surely applies to dual use involving either NRT or electronic cigarettes.

Some argue that use of electronic cigarettes, which to a degree resembles cigarette smoking, in places where smoking is currently prohibited might re-normalize smoking and undermine tobacco control efforts.^[80] However, although similar in appearance, even cigalike products are easily distinguishable, both in appearance and smell, from tobacco cigarettes. Therefore, use of electronic cigarettes in smoke free places is more likely to lead to normalisation of nicotine devices than to smoking, and hence potential benefit as a support to existing well smoke-free policies.

4.2.2 Advertising and promotion

A potential greater concern over the similarity in appearance between the use of electronic and tobacco cigarettes relates to advertising, sponsorship, celebrity endorsement and portrayals in film and other media. In this area there is considerable scope for promotion of nicotine use to young people, representing a significant concern. Advertising will be controlled in future by developments in regulation of these products (see below), and the Committee of Advertising Practice is currently consulting on restricting the advertising of electronic cigarettes. Marketing of electronic cigarettes is covered in further detail in the parallel paper to this one, produced by Professor Linda Bauld.

4.2.3 Involvement of the tobacco industry

Although originally developed and marketed independently from the tobacco industry, all of the four transnational tobacco companies now own at least one electronic cigarette product, or has competitor products in development. In addition to sharing the commercial gains from electronic cigarettes, the tobacco industry is no doubt eager to exploit opportunities for advertising and promotion that might increase either electronic or tobacco cigarette use, and also, by becoming involved in the production of alternatives to smoking, circumvent current restrictions on engagement in policy imposed by the Framework Convention on Tobacco Control (FCTC).^[81] Given the ethical record of tobacco industry activity in promoting and defending smoked tobacco, this is an obvious and significant potential threat, but also one that needs to be

addressed across the board as all nicotine suppliers are driven primarily by commercial rather than public health interests. While those commercial and public health interests largely coincide in the promotion and sale of electronic cigarettes to smokers, they do not in the non-smoking population. This is a key argument for regulation to prevent abuse of the electronic cigarette market.

5. Potential benefits of electronic cigarettes

The potential benefits of electronic cigarettes lie in their role as a reduced-hazard competitor for cigarettes.

5.1 Who uses electronic cigarettes and why?

The great majority of the more than one million users of electronic cigarettes in the UK are current or former smokers.^[46] Most users use them to either replace cigarettes in places where smoking is prohibited or discouraged, to cut down on smoking, to reduce harm from smoking, or to quit smoking.^[20] As the nicotine delivery kinetics of electronic cigarettes improves with technological developments, these products may prove to be more effective than conventional NRT as a tobacco substitute as their physical and behavioural characteristics replace many of the co-stimulatory factors that contribute to nicotine addiction.^[7] Availability in convenience stores, competitive pricing, non-medical image and social acceptability also probably contribute significantly to use. Prevalence of use is similar between genders and socio-economic groups, though higher in younger than in older smokers.^[20, 46]

According to the Smoking Toolkit Study, use of electronic cigarettes is much more common among heavier smokers and ex-smokers (figure 5), and more recent ex-smokers report current use of electronic cigarettes than conventional NRT (figure 5).

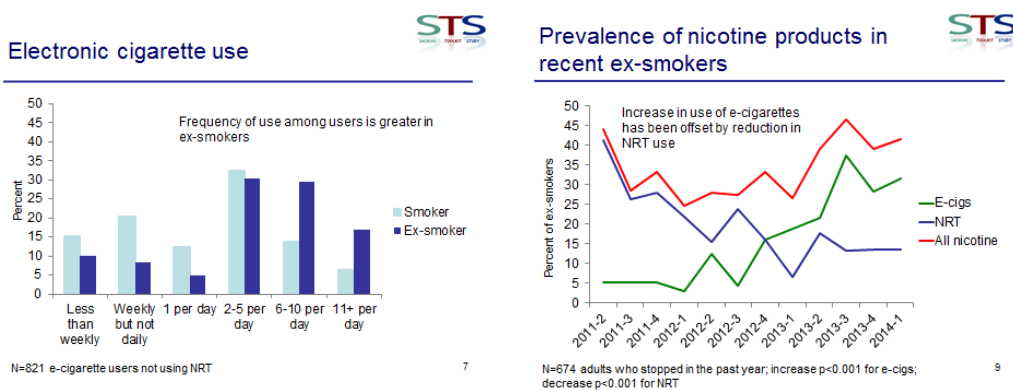


Figure 5: Use of electronic cigarettes by current and ex-smokers (left panel) and of nicotine products in recent ex-smokers (right panel; data from Smoking Toolkit Study[44])

The increase in electronic cigarette use over recent years appears to reflect in part, smokers using electronic cigarettes instead of NRT; and in part, users who would not otherwise have used NRT. This is particularly true of smokers attempting to quit, among whom electronic cigarettes are now the first choice. In this group, increasing

use of electronic cigarettes has been associated with reductions in numbers using NHS stop smoking support, or buying over-the-counter NRT, but there has also been an increase in the total number of smokers using any form of support to quit (figure 6). The net result appears to be an increase in the proportion of smokers who have quit within the past year (figure 6).

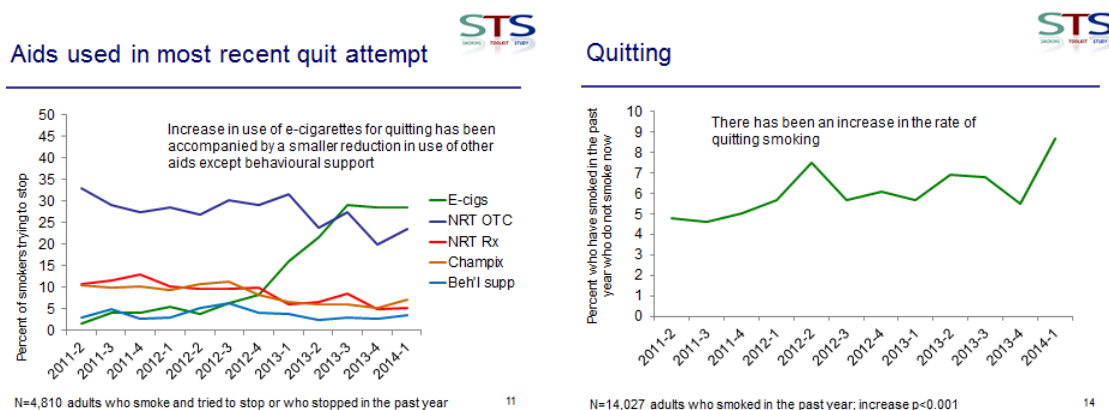


Figure 6: Aids used in most recent quit attempts (left panel) and proportion of smokers who have quit in the past year (right panel; data from Smoking Toolkit Study[44])

5.2 Effectiveness of electronic cigarettes as cessation aids

Evidence from clinical trials on the effectiveness of electronic cigarettes is limited, though results from observational and randomised trial data suggests that efficacy of first generation electronic cigarettes is similar to that of the transdermal NRT patches^[82] or the *Nicorette* NRT inhalator^[24]; findings that are consistent with the apparently low dose delivery and upper airway absorption of early generation products. Low nicotine delivery, or just the non-nicotine behavioural components of electronic cigarette use may explain why, in a trial comparing electronic cigarettes used to deliver either a constant nicotine dose, or a reducing dose, or no nicotine over 12 weeks demonstrated a decrease in tobacco consumption in all groups, but little difference between them.^[83] An observational study has also documented significant reductions in smoking among smokers with schizophrenia using electronic cigarettes.^[84] A recent study revealed that about 6% of former smokers who used electronic cigarettes daily relapsed to smoking after one month, and 6% after one year, and nearly a half of dual users stopped smoking after one year, indicating that electronic cigarette use might be effective in relapse prevention and smoking cessation.^[85] Dual users who used electronic cigarettes to cut down on smoking have lower levels of respiratory symptoms which is likely to be due to reduced smoking.^[20]

These studies indicate that electronic cigarettes are moderately effective as smoking cessation and harm reduction aids, but that a significant component of that effect is due to the behavioural rather than nicotine delivery characteristics of the devices. However, most of the available evidence relates to early generation devices of unknown but

almost certainly low nicotine delivery. More recent and future devices may prove much more effective.

5.3 Population-level impact of electronic cigarettes

The most effective way to quit smoking is to use a combination of pharmacotherapy and behavioural support, as for example provided in England by NHS Stop Smoking Services (SSS). However, while a majority of smokers report that they want to quit smoking, less than 10% access SSS each year.^[86] Most smokers attempt to quit without help ('cold turkey') or use over-the-counter NRT; and now electronic cigarettes.

The advantage of electronic cigarettes in this context is that, as shown in figure 6, they result in more smokers using some kind of medication or substitute for cigarettes to quit, and this appears to be increasing the proportion of smokers who quit. However the probability of quitting successfully without behavioural support, even with some form of nicotine replacement, is much lower than the quit rate among people who use SSS.^[87] Although this may reflect differences in motivation to engage fully with services, many of those who pass up on SSS to quit in other ways, and fail, represent missed opportunities.

Electronic cigarettes therefore increase smoking cessation to the extent that they draw in smokers who would not otherwise use a nicotine substitute in an attempt to quit, but reduce it to the extent that they take smokers away from SSS. The optimum solution for population health is to maximise both the use of electronic cigarettes among smokers, and the proportion of users who engage with SSS. This will require some changes to current SSS practice.

6. Regulation of electronic cigarettes in the UK

6.1 Current UK regulation

Electronic cigarettes are currently marketed in the UK under general product safety regulations which do not impose specific standards of purity or efficacy, and control advertising through voluntary codes of practice,^[88] which are now being reviewed,^[89] but deal with breaches reactively, in response to complaints, rather than proactively, through pre-screening. Proponents of this approach maintain that it minimises regulatory barriers and costs to product development and innovation, and that freedom to advertise maximises reach across the smoking population. Opponents hold that general product regulation does not ensure that products deliver nicotine reliably or without unnecessary and potentially hazardous components or contaminants, and allows inappropriate marketing, for example, to children or to non-smoking adults.

6.2 UK MHRA regulation

In 2013, after a consultation process that began in 2010, the UK MHRA announced that from 2016, it intended to regulate electronic cigarettes and other nicotine-containing products as medicines by function, and thus require manufacture to medicinal purity and delivery standards, and proactive controls on advertising.^[88] The proposed regulation, described as ‘right touch’, is intended to provide a relatively streamlined route to licensing, particularly by deeming any nicotine device that is proved to deliver nicotine to be effective as a smoking substitute or cessation aid, thus obviating the need for expensive clinical trials. Manufacturing to medicines standards does however represent a challenge and inevitably increases costs. On the positive side however, licensed NRT products currently enjoy a preferential 5% VAT rate, which to some extent offsets these additional costs, and will benefit from being prescribable on NHS prescriptions in the UK. Proponents of this approach welcome the quality and delivery standards imposed, and the advertising controls which should prevent marketing abuses before rather than after the event. Opponents argue that this level of regulation will stifle innovation and delay development of innovative products that could save lives.

These MHRA proposals were published before the revision of the EU Tobacco Products Directive in 2014 (see section 6.3), one consequence of which is to close off the option of deeming all nicotine products as medicines by function. MHRA regulation will therefore no longer be obligatory in the UK from 2016, but option of applying for a medicines licence remains open.

6.3 EU regulation

In March 2014 the European Parliament and Council moved to end marketing under general product safety regulations under the terms of the new Tobacco Product Directive (TPD).^[90] Under this directive, advertising of nicotine-containing devices that are not licensed as medicines will be prohibited, products will be required to carry health warnings, meet purity and emissions standards that are yet to be defined, provide data on nicotine uptake, be subject to restrictions on total nicotine content, and suppliers will be required to bear full responsibility for quality and safety when used 'under normal or reasonably foreseeable conditions'.^[90] Dates for enactment are yet to be specified, but legislation is expected to be required in member states by 2016, and full compliance by 2017. In practice, this means that from 2017 at the latest, suppliers will have to choose between the probably lower manufacturing costs but greater marketing restrictions imposed by the TPD, or to accept the higher manufacturing costs but other benefits of medicines licensing.

7. New developments

7.1 Technological developments

This is a rapidly developing field, and although this article has dealt predominantly with electronic cigarettes, there are many other novel nicotine devices in development likely to come to market in the relatively near future. British American Tobacco, for example, is bringing to market (via a wholly-owned subsidiary company, *Nicoventures*), a novel 'cigalike' device that is a nicotine metered dose inhaler, not an electronic cigarette.^[91] Philip Morris has also invested in a patented novel nicotine device, and other tobacco companies, the pharmaceutical industry and indeed electronic cigarette companies may elect to do the same. It is therefore likely that over the near term future, in addition to improvements and developments in the performance of electronic cigarette technology, novel devices that have similar or greater potential to appeal to smokers, and offer significantly greater purity and efficacy, and a lower hazard profile, will become available.

7.2 Licensing developments

It is now apparent that companies intending to market electronic cigarettes are now going to have to meet either medicines or TPD regulations, and probably from 2017 at the latest. Until the current draft of the TPD was circulated, applications to the MHRA in the public domain were few, but more manufacturers may now be considering opting for the clarity, albeit at a cost, of medicines regulation rather than the uncertainty and advertising restrictions of TPD regulation. The *Nicoventures* inhaler product is expected to be licensed by the MHRA, and marketed in the UK, within the year, and the same company has also applied for a medicines license for an electronic cigarette.^[91] Other tobacco companies may follow suit, while pharmaceutical companies, concerned by the loss of over-the-counter sales of NRT to electronic cigarettes, may also decide to enter this market. It is thus likely that by this time next year, health professionals will be able to prescribe, and patients will be asking them for, prescriptions of novel nicotine products. Some of those are likely to be produced by tobacco companies or wholly funded subsidiaries.

8. Research priorities

The world literature on harm reduction practice is extremely limited. Such data as is available on the content and emission characteristics of products currently on the UK market has been produced almost entirely by independent researchers, not by suppliers. Absorption characteristics are virtually unknown. However, this is data that can and should be required of manufacturers or suppliers, and will be as a result of medicines or TPD regulation, but for up to three years will not be required. While a clearly important area of research, it seems inappropriate to use scarce public research funding to provide this data. This responsibility should be placed, as soon as possible, on suppliers.

There is also questionable value in clinical trials of these products relative to NRT or placebo, if they are shown to deliver nicotine. There is a mass of evidence demonstrating that products that deliver nicotine help people stop smoking, which is why the MHRA, in its proposal for medicines licensing, does not require trial information. Requiring suppliers to demonstrate nicotine delivery and uptake will therefore obviate the need for placebo-controlled trials.

However, at a population level there is no experience of proactive introduction of a harm reduction strategy based on provision of alternative nicotine products anywhere in the world, and hence no direct evidence on the practical benefits, harms, opportunity costs or consequences of this approach. The key requirement of harm reduction research, in our view, is to monitor and where necessary identify opportunities to intervene to ensure that uptake and use follow patterns most likely to benefit public health; and act to prevent loopholes or practices that run counter to this objective. Priorities in this regard therefore include:

- frequent surveys to monitor trends in use of harm reduction products, to enable prompt corrective action where necessary
- monitoring of advertising, product placement, celebrity endorsement, and other direct or indirect marketing approaches, to prevent promotion likely to work against public health (particularly, marketing to children and other non-nicotine users)
- surveillance and reporting systems to identify potential long-term adverse effects of use, both of nicotine and of the carriers (such as propylene glycol) used in these devices
- methods of integrating electronic cigarette or other nicotine devices into health services, in general and particularly in mental health settings, where conventional approaches have failed
- studies of the economic impact of electronic cigarettes on health and wider economic and societal costs

9. Summary and conclusions

Smoking kills, and millions of smokers alive today will die prematurely from their smoking unless they quit. This burden falls predominantly on the most disadvantaged in society. Preventing this death and disability requires measures that help as many of today's smokers to quit as possible. The option of switching to electronic cigarettes as an alternative and much safer source of nicotine, as a personal lifestyle choice rather than medical service, has enormous potential to reach smokers currently refractory to existing approaches. The emergence of electronic cigarettes and the likely arrival of more effective nicotine-containing devices currently in development provides a radical alternative to tobacco, and evidence to date suggests that smokers are willing to use these products in substantial numbers. Electronic cigarettes, and other nicotine devices, therefore offer vast potential health benefits, but maximising those benefits while minimising harms and risks to society requires appropriate regulation, careful monitoring, and risk management. However the opportunity to harness this potential into public health policy, complementing existing comprehensive tobacco control policies, should not be missed.

Declaration of interests

John Britton is professor of epidemiology at the University of Nottingham and an honorary consultant in respiratory medicine at Nottingham City Hospital. He is director of the UK Centre for Tobacco and Alcohol Studies, chairs the tobacco advisory group of the Royal College of Physicians, a member of the board of trustees of Action on Smoking and Health, and chairs a Public Health Advisory Committee for the National Institute for Health and Care Excellence (NICE). He receives salary from the University of Nottingham and honoraria for NICE work, and has no financial or other conflicts of interest.

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Research paper

Levels of selected carcinogens and toxicants in vapour from electronic cigarettes

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Abstract

Significance Electronic cigarettes, also known as e-cigarettes, are devices designed to imitate regular cigarettes and deliver nicotine via inhalation without combusting tobacco. They are purported to deliver nicotine without other toxicants and to be a safer alternative to regular cigarettes. However, little toxicity testing has been performed to evaluate the chemical nature of vapour generated from e-cigarettes. The aim of this study was to screen e-cigarette vapours for content of four groups of potentially toxic and carcinogenic compounds: carbonyls, volatile organic compounds, nitrosamines and heavy metals.

Materials and methods Vapours were generated from 12 brands of e-cigarettes and the reference product, the medicinal nicotine inhaler, in controlled conditions using a modified smoking machine. The selected toxic compounds were extracted from vapours into a solid or liquid phase and analysed with chromatographic and spectroscopy methods.

Results We found that the e-cigarette vapours contained some toxic substances. The levels of the toxicants were 9–450 times lower than in cigarette smoke and were, in many cases, comparable with trace amounts found in the reference product.

Conclusions Our findings are consistent with the idea that substituting tobacco cigarettes with e-cigarettes may substantially reduce exposure to selected tobacco-specific toxicants. E-cigarettes as a harm reduction strategy among smokers unwilling to quit, warrants further study. (To view this abstract in Polish and German, please see the supplementary files online.)



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Electronic cigarettes: human health effects

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Safety evaluation and risk assessment of electronic cigarettes as tobacco cigarette substitutes: a systematic review

Therapeutic Advances in Drug Safety 2014;**5**:2 67-86

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New research shows electronic cigarettes better for quitting, than no aid; over the counter NRT worse than no aid

 Grzegorz Krol | 7 February 2014

New research presented by Jamie Brown and colleagues at the Society for Research on Nicotine and Tobacco conference, 20th Annual Meeting, held in Seattle on Saturday, February 8, 2014 shows that smokers wishing to quit who used electronic-cigarettes had best outcomes.

The study was conducted on a large representative sample of the English population, and was based on people who had smoked during the last 12 months. It looked at those who had made at least one quit attempt using only an electronic cigarette, used only over-the-counter NRT, or used no aid in their most recent quit attempt. The outcome assessed was abstinence from cigarettes up to the time of the survey.

Users of electronic cigarettes performed best – 19.9% had stopped smoking, better than the 15.1% success for those who used no aid. Surprisingly (perhaps for some public health experts) OTC NRT users came off worst, with only 10.0% abstinent.

Caution is needed: this is an abstract, and publication of the full paper will give further details. More details are needed about the length of abstinence from smoking. Those using NRT may be a different segment of the smoking population than those using electronic cigarettes: however the research team found that the difference persisted after adjusting for factors that might influence outcome such as smokers' levels of nicotine dependence.

The recent randomised controlled trial by [Chris Bullen](#) and colleagues showed that electronic cigarettes were equally as effective as NRT patches. It is difficult to extrapolate from RCTs to real world conditions. Hence the significance of the Jamie Brown study.

This study is complemented by growing evidence of the increasing *popularity* of e-cigarettes for switching from smoking. Robert West's [Smoking Toolkit](#) data shows that since 2013 electronic cigarette use has surpassed NRT; that almost 1 in 3 quit attempts involve the use of electronic cigarettes, that they are now the most commonly used resource for the last quit attempt (exceeding OTC NRT, varenicline, prescribed NRT, and behavioural support) and that there has been a decrease in use of other aids to smoking cessation.

The findings raise further questions about the effectiveness of OTC NRT. As recently reported, OTC NRT use in self-initiated quit attempts confers no advantage over stopping without any aid (Kotz, Brown, & West, 2013). At a population level, there is no measurable effect of OTC NRT on the overall prevalence of smoking.

Implications for public health experts and advisors

Gerry Stimson says: 'This study adds to the growing scientific evidence about the effectiveness of electronic

cigarettes and the seemingly lesser effectiveness of over the counter NRT. It could be said that it is no longer ethical to give advice to smokers that discourages use of electronic cigarettes and that advises smokers who wish to quit to use only medically licensed products such as gums, tablets and patches.'

This is the full abstract of the study:

Abstract from Society for Research on Nicotine and Tobacco conference, 20th Annual Meeting

PA18-4

REAL-WORLD EFFECTIVENESS OF E-CIGARETTES: A POPULATION STUDY

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Background: Electronic cigarettes (e-cigarettes) are rapidly increasing in popularity. Two randomised controlled trials have suggested that e-cigarettes can aid smoking cessation but there are many factors that could influence their real-world effectiveness. This study aimed to assess, using an established methodology, the effectiveness of e-cigarettes compared with nicotine replacement therapy (NRT) bought over-the-counter and with unaided quitting in the general population.

Methods: A large survey of a representative sample of the English population. The study included 5726 adults who had smoked within the previous 12 months and made at least one quit attempt during that period with either an e-cigarette only (n=391), NRT bought over-the-counter only (n=2031) or no aid in their most recent quit attempt (n=3304). The primary outcome measure was self-reported abstinence up to the time of the survey, adjusted for key potential confounders including nicotine dependence.

Results: E-cigarette users were more likely still to be abstinent than either those who used NRT bought over-the-counter (OR=2.23, 95%CI=1.67- 2.97, 19.9% vs. 10.0%) or no aid (OR=1.40, 95%CI=1.07-1.82, 19.9% vs. 15.1%). The adjusted odds of non-smoking in users of e-cigarettes were 1.66 (95%CI=1.17-2.36) times higher compared with users of NRT bought over-the-counter and 1.60 (95%CI=1.15-2.23) times higher compared with those using no aid.

Conclusion: Among smokers stopping without professional support, those who use e-cigarettes appear more likely to be able to remain abstinent than those who use a licensed NRT product bought over-the-counter or no aid to cessation. This difference persists after adjusting for a wide range of smoker characteristics such as nicotine dependence.

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funded by Cancer Research UK. We are grateful to Cancer Research UK, the Department of Health and Pfizer for funding this study. This study is partly funded by Pfizer under an investigator initiated award.

SRNT abstracts can be found here – 2014 Rapid Response Abstract Book

Bullen, C., Howe, C., Laugesen, M., McRobbie, H., Parag, V., Williman, J., & Walker, N. (2013). Electronic cigarettes for smoking cessation: a randomised controlled trial. *Lancet*, 382(9905), 1629–37. doi:10.1016/S0140-6736(13)61842-5

Kotz, D., Brown, J., & West, R. (2013). “Real-world” effectiveness of smoking cessation treatments: a population study. *Addiction* doi:10.1111/add.12429

10 Comments Nicotine Science and Policy

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Join the discussion...



Joe • 6 months ago

1 year ago today since I have been cigarette free. I like many others did patches, gum, pills. None of those worked. 3 days after I got my ecig I have been smoke free. 2 to 2.5 pack a day habit easily taken care of with ecig. I'm 53 yrs old and yes the flavors are a big part of helping me quit. Started at 36 mg and in one year down to 12mg and sometimes 8mg and zero. If anyone reading this is on the fence about ecigs then please believe this. These can save you or a loved ones life. I was extremely addicted to smoking. I can go 2 or 3 hours without ecig and when smoking no more than 20 min. Support ecigs even if your not a smoker and help save some people.

2 ^ | ▾ • Reply • Share ›



Michael Reynolds • 8 months ago

NRT didn't work for me. I had tried for many years, using patches, gum, inhalators, nasal spray, mouth spray, Champix, cold turkey and counselling alongside NRT.

I had a heart attack in March 2013. I was rushed to hospital for emergency angioplasty and had a stent fitted. I was told that if I didn't stop smoking I could be dead within a year. That should be enough to make you want to quit smoking completely. Once again, I was given patches and nasal spray, starting while I was still in hospital.

I soon ended up smoking again as the cravings and withdrawal symptoms were too much to cope with. I even smoked while wearing patches.

A month ago, I bought an e-cigarette after a friend told me how they had helped her to stop smoking.

The day I bought my e-cigarette was the last time I smoked a tobacco cigarette. I have had zero cravings or withdrawal symptoms.

My breathing has improved vastly in the short time I've been vaping. While I smoked, I could hardly walk and keep up with people as I got so out of breath. Now I'm walking normally and

[see more](#)

8 ^ | v • Reply • Share ›



keith stammers • 8 months ago

The forces against the electronic cigarettes are aligning , a motley group of unlikely allies, with questionable ethics and even more questionable motivations all with one aim in common - to fight off this young and vulnerable new technology that threatens to make them redundant. So who are this repugnant crew ? Big Pharma with its NRT and tobacco related disease drugs [worth over \$289 billion per year worldwide] , with their illegitimate father Big Tobacco still killing it's customers or driving them into arms of Big Pharma before they pass on , then you have the freeloader uncle, tobacco related harm groups and assorted bucket loads of charity's, that just love to live off misery of others [who else is going to pay for the new Mercedes if not those kind souls who think their pennies actually go to the victims?] The you have the abusive step- mother who lets it all happen as long as she gets hers, Government with it's tobacco taxes. "The customer be-dammed is their mantra", these people will fight till the death because if the poor old electronic cigarette wins they will have to seek honest employment and this is something they dread . So what of the poor smoker looking for a healthier alternative to tobacco? Who is looking out for them, other than themselves? NO ONE !

10 ^ | v • Reply • Share ›



Melody Chard ↗ keith stammers • 8 months ago

So true Keith! We are going to have to look out for ourselves....even if that means civil disobedience I think! I am prepared to go underground if that's what it takes! I am not going to let them snuff me out so they can make a buck of my suffering! I know there are plenty of us out here willing to start digging our tunnels. The "Powers that Be" can kiss my vaping ass!

6 ^ | v • Reply • Share ›



dodderer1 • 8 months ago

Combining this result with the "Real-world" study conclusion

"After adjusting for major confounding variables such as tobacco dependence, smokers in England who use a combination of behavioural support and pharmacotherapy in their quit attempts have almost three

times the odds of success than those who use neither pharmacotherapy nor

New research shows electronic cigarettes better for quitting, than no aid; over the counter NRT worse than no aid - Nicotine Science and Policy
 TIMES THE ODDS OF SUCCESS THAN THOSE WHO USE NEITHER PHARMACOTHERAPY NOR behavioural support. Smokers who buy nicotine replacement therapy over the counter with no behavioural support have similar odds of success in stopping as those who stop without any aid."

we conclude that NRT+behavioural support is more effective than anything - voila! Double the Smoking Cessation Services funding now.

I think the researchers' biases are the biggest confounding variable.

1 ^ | v • Reply • Share ›



castello → dodderer1 • 6 months ago

E-cigs work way better than any thing else! Quit wasting money on the smoking cessations services. They are feeding false info about e-cigs to the world!

1 ^ | v • Reply • Share ›



disqus_ovxuopQYu5 • 8 months ago

I do well on my vapor device or ecig to some. 35 years tobacco use I feel great being a non smoker for the past year. I am tired of the lies about this great invention it works several million people have switched to this over the world and we are fighting the right to have this alternative accepted and endorsed. If you smoke tobacco switch to ecigs and save your life. I will continue to use this device even if its illegal or banned everywhere. Because I know the science behind this device is positive despite the corruption of government and health groups. I don t want COPD or lung cancer or other cancers.

11 ^ | v • Reply • Share ›



Richard Thomas • 9 months ago

I've been saying that we are the most successful quit method out there. And soon will be more successful than all other methods combined. Critics use half truths and outright lies against us. So if my claim is not yet supported. Then oh well. Part of the success here is that the contents aren't limited by regulations. That is one thing that has screwed up other methods. Because all other FDA methods fail. I actually feel safer knowing Vaping is not approved.

10 ^ | v • Reply • Share ›



Melody Chard → Richard Thomas • 9 months ago

I agree that it has been a miracle for me and my hubby! I worry about the government getting its hands on e-cigs in any way, shape or form, but we know they are just itching to tax the living crap out of it somehow. I think it should not be sold to minors as far as regulation goes....but other than that, I want the government to stay away from something they didn't create for us, and we don't want to see them mess it up. If they regulate it as a medicine, that gives our e-juice to Big Pharma.....nightmare scenario for sure!!!! As a tobacco product....which it is not, would give the government the right to tax it out of existance. I know Big Pharma is losing money due to e-cigs and so is tobacco but I really don't care about them

They have made enough money off of us over the years. They don't care about helping the health of Canadians any more than Health Canada.....everyone wants their cash cows back, and they all seem to feed from the same trough. Its time for them to go on a diet I think!

14 ^ | v • Reply • Share ›



Melody Chard • 9 months ago

I smoked for 45 years and I was able to break those chains with e-cigs. I have been vaping for almost 5 years now, and it was the easiest transition I ever could have imagined. I could never return to stinky tobacco. I had tried every stop smoking aid known to man and Health Canada, and failed every attempt until I found e-cigs. I feel amazing, and my hubby has finally kicked his tobacco habit this year using e-cigs. They have been a gift in our lives. I use e-cigs as a safer alternative to tobacco, and like that I can reap the health benefits of low nicotine usage too. I have no plans to stop vaping. I think Public Health organizations that demonize e-cigs should hang their heads in shame. There is so much real, peer reviewed and published research out there now, they can no longer say it is dangerous and to stay away. In my opinion, they have lost all credibility with the masses. I personally know I no longer trust anything they say, and I am not alone!! They no longer have my support or respect. I give e-cigs a hi five!!!!

19 ^ | v • Reply • Share ›

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Statement from specialists in nicotine science and public health policy

Dr Margaret Chan
Director General
World Health Organisation
Geneva

CC: FCTC Secretariat, Parties to the FCTC, WHO Regional Offices

26 May 2014

Dear Dr Chan

Reducing the toll of death and disease from tobacco – tobacco harm reduction and the Framework Convention on Tobacco Control (FCTC)

We are writing in advance of important negotiations on tobacco policy later in the year at the FCTC Sixth Conference of the Parties. The work of WHO and the FCTC remains vital in reducing the intolerable toll of cancer, cardiovascular disease and respiratory illnesses caused by tobacco use. As WHO has stated, up to one billion preventable tobacco-related premature deaths are possible in the 21st Century. Such a toll of death, disease and misery demands that we are relentless in our search for all possible practical, ethical and lawful ways to reduce this burden.

It is with concern therefore that a critical strategy appears to have been overlooked or even purposefully marginalised in preparations for FCTC COP-6. We refer to 'tobacco harm reduction' - the idea that the 1.3 billion people who currently smoke could do much less harm to their health if they consumed nicotine in low-risk, non-combustible form.

We have known for years that people 'smoke for the nicotine, but die from the smoke': the vast majority of the death and disease attributable to tobacco arises from inhalation of tar particles and toxic gases drawn into the lungs. There are now rapid developments in nicotine-based products that can effectively substitute for cigarettes but with very low risks. These include for example, e-cigarettes and other vapour products, low-nitrosamine smokeless tobacco such as snus, and other low-risk non-combustible nicotine or tobacco products that may become viable alternatives to smoking in the future. Taken together, these tobacco harm reduction products could play a significant role in meeting the 2025 UN non-communicable disease (NCD) objectives by driving down smoking prevalence and cigarette consumption. Indeed, it is hard to imagine major reductions in tobacco-related NCDs without the contribution of tobacco harm reduction. Even though most of us would prefer people to quit smoking and using nicotine altogether, experience suggests that many smokers cannot or choose not to give up nicotine and will continue to smoke if there is no safer alternative available that is acceptable to them.

We respectfully suggest that the following principles should underpin the public health approach to tobacco harm reduction, with global leadership from WHO:

Statement from specialists in nicotine science and public health policy

1. *Tobacco harm reduction is part of the solution, not part of the problem.* It could make a significant contribution to reducing the global burden of non-communicable diseases caused by smoking, and do so much faster than conventional strategies. If regulators treat low-risk nicotine products as traditional tobacco products and seek to reduce their use without recognising their potential as low-risk alternatives to smoking, they are improperly defining them as part of the problem.
2. *Tobacco harm reduction policies should be evidence-based and proportionate to risk, and give due weight to the significant reductions in risk that are achieved when a smoker switches to a low risk nicotine product.* Regulation should be proportionate and balanced to exploit the considerable health opportunities, while managing residual risks. The architecture of the FCTC is not currently well suited to this purpose.
3. *On a precautionary basis, regulators should avoid support for measures that could have the perverse effect of prolonging cigarette consumption.* Policies that are excessively restrictive or burdensome on lower risk products can have the unintended consequence of protecting cigarettes from competition from less hazardous alternatives, and cause harm as a result. Every policy related to low risk, non-combustible nicotine products should be assessed for this risk.
4. *Targets and indicators for reduction of tobacco consumption should be aligned with the ultimate goal of reducing disease and premature death, not nicotine use per se, and therefore focus primarily on reducing smoking.* In designing targets for the non-communicable disease (NCD) framework or emerging Sustainable Development Goals it would be counterproductive and potentially harmful to include reduction of low-risk nicotine products, such as e-cigarettes, *within these targets*: instead these products should have an important role in *meeting the targets*.
5. *Tobacco harm reduction is strongly consistent with good public health policy and practice and it would be unethical and harmful to inhibit the option to switch to tobacco harm reduction products.* As the WHO's Ottawa Charter states: "*Health promotion is the process of enabling people to increase control over, and to improve, their health*". Tobacco harm reduction allows people to control the risk associated with taking nicotine and to reduce it down to very low or negligible levels.
6. *It is counterproductive to ban the advertising of e-cigarettes and other low risk alternatives to smoking.* The case for banning tobacco advertising rests on the great harm that smoking causes, but no such argument applies to e-cigarettes, for example, which are far more likely to reduce harm by reducing smoking. Controls on advertising to non-smokers, and particularly to young people are certainly justified, but a total ban would have many negative effects, including protection of the cigarette market and implicit support for tobacco companies. It is possible to target advertising at existing smokers where the benefits are potentially huge and the risks minimal. It is inappropriate to apply Article 13 of the FCTC (Tobacco advertising, promotion and sponsorship) to these products.

Statement from specialists in nicotine science and public health policy

7. *It is inappropriate to apply legislation designed to protect bystanders or workers from tobacco smoke to vapour products.* There is no evidence at present of material risk to health from vapour emitted from e-cigarettes. Decisions on whether it is permitted or banned in a particular space should rest with the owners or operators of public spaces, who can take a wide range of factors into account. Article 8 of the FCTC (Protection from exposure to tobacco smoke) should not be applied to these products at this time.
8. *The tax regime for nicotine products should reflect risk and be organised to create incentives for users to switch from smoking to low risk harm reduction products.* Excessive taxation of low risk products relative to combustible tobacco deters smokers from switching and will cause more smoking and harm than there otherwise would be.
9. *WHO and national governments should take a dispassionate view of scientific arguments, and not accept or promote flawed media or activist misinterpretations of data.* For example, much has been made of 'gateway effects', in which use of low-risk products would, it is claimed, lead to use of high-risk smoked products. We are unaware of any credible evidence that supports this conjecture. Indeed, similar arguments have been made about the use of smokeless tobacco in Scandinavia but the evidence is now clear that this product has made a significant contribution to reducing both smoking rates and tobacco-related disease, particularly among males.
10. *WHO and parties to the FCTC need credible objective scientific and policy assessments with an international perspective.* The WHO Study Group on Tobacco Product Regulation (TobReg) produced a series of high quality expert reports between 2005 and 2010. This committee should be constituted with world-class experts and tasked to provide further high-grade independent advice to the WHO and Parties on the issues raised above.

The potential for tobacco harm reduction products to reduce the burden of smoking related disease is very large, and these products could be among the most significant health innovations of the 21st Century – perhaps saving hundreds of millions of lives. The urge to control and suppress them as tobacco products should be resisted and instead regulation that is fit for purpose and designed to realise the potential should be championed by WHO. We are deeply concerned that the classification of these products as tobacco and their inclusion in the FCTC will do more harm than good, and obstruct efforts to meet the targets to reduce non-communicable disease we are all committed to. We hope that under your leadership, the WHO and FCTC will be in the vanguard of science-based, effective and ethical tobacco policy, embracing tobacco harm reduction.

We would be grateful for your considered reaction to these proposals, and we would like to request a meeting with you and relevant staff and a small delegation of signatories to this letter. This statement and any related information will be available on the Nicotine Science and Policy web site (<http://nicotinepolicy.net>) from 29 May 2014.

Yours sincerely,

Statement from specialists in nicotine science and public health policy

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August 11, 2014

Owners of empty storefronts forced to rent or pay city fees

By Joshua Sabatini

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JESSICA CHRISTIAN/SPECIAL TO THE S.F. EXAMINER

A "For Rent" sign sits in the window of an empty storefront at 1918 Taraval Street in the Sunset District.

San Francisco loves to hate its empty storefronts.

For years merchants and residents have complained about how empty storefronts are a bane, attracting crime, graffiti and hampering economic activity. In 2009, empty storefronts were such a plague that The City got a little creative by launching an Art in Storefronts pilot program to try and bring a little life to the shuttered spaces in the Mid-Market and Tenderloin neighborhoods.

While empty storefronts are much maligned, the fact is that they are private property, and landlords can choose to rent them or not -- only now if they don't rent, it'll cost them. A new city law requires owners of any storefront left vacant for more than 270 days to pay \$765

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annually and register with The City.

Supervisor Katy Tang, who introduced the legislation, which was approved by the Board of Supervisors, made her case for its need by pointing to city data showing there were more than 45 vacant ground floor commercial spaces in the Sunset District, with 24 on Taraval Street, which she represents. Also, she noted that there were 179 vacant storefronts counted recently in 25 commercial corridors citywide.

Judging by Tang's legislation, empty storefronts are sinister. "In addition to being eyesores, these vacant commercial storefronts have a detrimental impact on the economic viability of the commercial corridors in which they are located. Vacant storefronts often attract illegal activity, such as squatting, vandalism, and dumping," the legislation says. "Such activity not only repels would-be customers and patrons from commercial corridors, but also places an undue burden on city agencies."

The fee for empty storefronts builds on an existing requirement for owners of vacant buildings to pay a fee and register with the city, which began in 2009, but excluded buildings with residences above commercial space.

The list of vacant buildings "with the building boom still going, has actually fallen from 500 during the recession of a couple of years ago to about 240 today," Department of Building Inspection spokesman William Strawn said in June.

Storefront owners who are actively acquiring permits or trying to proactively lease space, such as by having hired a real estate agent or listing the property for lease, can receive an exemption.

The Small Business Commission has discussed the need for something like Tang's proposal for at least four years. "This legislation will patch a critical gap in the existing vacant building registration ordinance," Small Business Commission director Regina Dick-Endrizzo said in a letter to the board.

Some who are working to revitalize commercial corridors see the registry as valuable assistance.

"An up-to-date registry of property owners and those responsible for maintaining vacant buildings will ensure that we know whom to contact to address problems and to facilitate negotiations with potential interested tenants," said Angela Minkin, chair of the Excelsior Action Group Advisory Board.

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Real-world effectiveness of e-cigarettes when used to aid smoking cessation: a cross-sectional population study

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ABSTRACT

Background and Aims Electronic cigarettes (e-cigarettes) are rapidly increasing in popularity. Two randomized controlled trials have suggested that e-cigarettes can aid smoking cessation, but there are many factors that could influence their real-world effectiveness. This study aimed to assess, using an established methodology, the effectiveness of e-cigarettes when used to aid smoking cessation compared with nicotine replacement therapy (NRT) bought over-the-counter and with unaided quitting in the general population. **Design and Setting** A large cross-sectional survey of a representative sample of the English population. **Participants** The study included 5863 adults who had smoked within the previous 12 months and made at least one quit attempt during that period with either an e-cigarette only ($n = 464$), NRT bought over-the-counter only ($n = 1922$) or no aid in their most recent quit attempt ($n = 3477$). **Measurements** The primary outcome was self-reported abstinence up to the time of the survey, adjusted for key potential confounders including nicotine dependence. **Findings** E-cigarette users were more likely to report abstinence than either those who used NRT bought over-the-counter [odds ratio (OR) = 2.23, 95% confidence interval (CI) = 1.70–2.93, 20.0 versus 10.1%] or no aid (OR = 1.38, 95% CI = 1.08–1.76, 20.0 versus 15.4%). The adjusted odds of non-smoking in users of e-cigarettes were 1.63 (95% CI = 1.17–2.27) times higher compared with users of NRT bought over-the-counter and 1.61 (95% CI = 1.19–2.18) times higher compared with those using no aid. **Conclusions** Among smokers who have attempted to stop without professional support, those who use e-cigarettes are more likely to report continued abstinence than those who used a licensed NRT product bought over-the-counter or no aid to cessation. This difference persists after adjusting for a range of smoker characteristics such as nicotine dependence.

Keywords Cessation, cross-sectional population survey, e-cigarettes, electronic cigarettes, nicotine replacement therapy, NRT, quitting, smoking.

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INTRODUCTION

Smoking is one of the leading risk factors for premature death and disability and is estimated to kill 6 million people world-wide each year [1]. The mortality and morbidity associated with cigarette smoking arises primarily from the inhalation of toxins other than nicotine contained within the smoke. Electronic cigarettes (e-cigarettes) provide nicotine via a vapour that is drawn into the mouth, upper airways and possibly lungs [2, 3].

These devices use a battery-powered heating element activated by suction or manually to heat a nicotine solution and transform it into vapour. By providing a vapour containing nicotine without tobacco combustion, e-cigarettes appear able to reduce craving and withdrawal associated with abstinence in smokers [2, 4, 5], while toxicity testing suggests that they are much safer to the user than ordinary cigarettes [3].

E-cigarettes are increasing rapidly in popularity: prevalence of ever-use among smokers in the United

States appears to have increased from approximately 2% in 2010 to more than 30% in 2012, and the rate of increase appears to be similar in the United Kingdom [6–9]. Although there are concerns about their wider public health impact relating to the renormalization of smoking and promotion of smoking in young people, crucially two randomized controlled trials have suggested that e-cigarettes may aid smoking cessation [10,11]. However, there are many factors that influence real-world effectiveness, including the brand of e-cigarette, the way they are used and who chooses to use them [12]. Therefore, it is a challenge to establish probable contribution to public health through randomized efficacy trials alone. Moreover, this kind of evidence will take many years to emerge, and in the meantime the products are developing rapidly and countries require evidence on effectiveness to inform decisions on how to regulate them [13–19]. As a result, there is an urgent need to be able to make an informed judgement on the real-world effectiveness of currently popular brands as chosen by the millions of smokers across the world who are using them in an attempt to stop smoking [6–9].

Several studies have attempted to examine the relationship between the use of e-cigarettes and smoking status in the real world by surveying regular e-cigarette users [20–27]. These studies—including one using a longitudinal design [27]—have found that users consistently report that e-cigarettes helped them to quit or reduce their smoking. However, because the samples were self-selected, the results have to be interpreted with caution. In more general samples the evidence is less positive. One national study of callers to a quitline, which assessed the cross-sectional association of e-cigarette use and current smoking status at a routine follow-up evaluation of the quitline service, found that e-cigarette users compared with never users were less likely to be abstinent [28]. In a longitudinal study of a general population sample, e-cigarette users at baseline were no more likely to have quit permanently at a 12-month follow-up despite having reduced their cigarette consumption [29]. However, neither of these studies adjusted for important potential confounding variables and both evaluated the association between quitting and the use of e-cigarettes for any purpose, not specifically as an aid to quitting. It is crucial to distinguish between the issue of whether use of e-cigarettes in a quit attempt improves the chances of success of that attempt from the issue of whether the use of e-cigarettes, for whatever purpose, such as aiding smoking reduction or recreation, promotes or suppresses attempts to stop. In determining the overall effect on public health both considerations are important, but they require different methodologies to address them.

An ongoing national surveillance programme (the Smoking Toolkit Study) has been tracking the use of

e-cigarettes as a reported aid to cessation among the general population in England since July 2009 [30]. This programme has established a method of assessing real-world effectiveness of aids to cessation by comparing the success rates of smokers trying to quit with different methods and adjusting statistically for a wide range of factors that could bias the results, such as nicotine dependence [31]. The method has been able to detect effects of behavioural support and prescription medications to aid cessation and found a higher rate of success when using varenicline than prescription nicotine replacement therapy (NRT) [32,33], supporting findings from randomized controlled trials and clinical observation studies [34–37]. This method cannot achieve the same level of internal validity as a randomized controlled trial, but clearly has greater external validity, so both are important in determining the potential public health contribution of devices hypothesized to aid cessation, such as e-cigarettes.

Given that smokers already have access to licensed NRT products, it is important to know whether e-cigarettes are more effective in aiding quitting. This comparison is particularly important for two reasons. First, buying a licensed NRT product from a shop, with no professional support, is the most common way of using it in England, and secondly, previous research has found that this usage was not associated with greater success rates than quitting unaided in the real-world [33]. It is therefore important to know whether e-cigarettes can increase abstinence compared to NRT bought over-the-counter.

The current study addressed the question of how effective e-cigarettes are compared with NRT bought over-the-counter and unaided quitting in the general population of smokers who are attempting to stop.

METHODS

Study design

The design was cross-sectional household surveys of representative samples of the population of adults in England conducted monthly between July 2009 and February 2014. To examine the comparative real-world effectiveness of e-cigarettes, the study compared the self-reported abstinence rates of smokers in the general population trying to stop who used e-cigarettes only (i.e. without also using face-to-face behavioural support or any medically licensed pharmacological cessation aid) with those who used NRT bought over-the-counter only or who made an unaided attempt, while adjusting for a wide range of key potential confounders. The surveys are part of the ongoing Smoking Toolkit Study, which is designed to provide information about smoking

prevalence and behaviour in England [30]. Each month a new sample of approximately 1800 adults aged ≥ 16 years are selected using a form of random location sampling, and complete a face-to-face computer-assisted survey with a trained interviewer. The full methods have been described in detail and shown to result in a sample that is nationally representative in its socio-demographic composition and proportion of smokers [30]. Approval was granted by the ethics committee of University College London, UK.

Study population

For the current study, we used aggregated data from respondents to the survey in the period from July 2009 (the first wave to track use of e-cigarettes to aid cessation) to February 2014 (the latest wave of the survey for which data were available), who smoked either cigarettes (including hand-rolled) or any other tobacco product (e.g. pipe or cigar) daily or occasionally at the time of the survey or during the preceding 12 months. We included those who had made at least one quit attempt in the preceding 12 months, assessed by asking: 'How many serious attempts to stop smoking have you made in the last 12 months? By serious attempt I mean you decided that you would try to make sure you never smoked again. Please include any attempt that you are currently making and please include any successful attempt made within the last year'. We included respondents who used either e-cigarettes or NRT bought over-the-counter during their most recent quit attempt, and an unaided group defined as those who had not used any of the following: e-cigarettes; NRT bought over-the-counter; a prescription stop-smoking medication; or face-to-face behavioural support. We excluded those who used either e-cigarettes or NRT bought over-the-counter in combination with one another, a prescription stop-smoking medication or face-to-face behavioural support.

Measurement of effect: quitting method

The use of different quitting methods were assessed for the most recent attempt by asking: 'Which, if any, of the following did you try to help you stop smoking during the most recent serious quit attempt?' and included: (i) e-cigarettes; (ii) NRT bought over-the-counter; (iii) no aid (i.e. had not used any of e-cigarettes, NRT bought over-the-counter, a prescription stop-smoking medication or face-to-face behavioural support).

Measurement of outcome: self-reported non-smoking

Our primary outcome was self-reported non-smoking up to the time of the survey. Respondents were asked: 'How long did your most recent serious quit attempt last before

you went back to smoking?'. Those responding 'I am still not smoking' were defined as non-smokers. Previous research has shown that self-reported abstinence in surveys of this kind is not subject to the kind of biases observed in clinical trials where there is social pressure to claim abstinence [38].

Measurement of potential confounders

We measured variables potentially associated with the different quitting methods and that may also have an effect on the outcome. These potential confounders were chosen a priori. The most important factor was nicotine dependence, for which we used two questions. First, time spent with urges to smoke was assessed by asking all respondents: 'How much of the time have you felt the urge to smoke in the past 24 hours? Not at all (coded 0), a little of the time (i), some of the time (ii), a lot of the time (iii), almost all of the time (iv), all of the time (v)'. Secondly, strength of urges to smoke was measured by asking: 'In general, how strong have the urges to smoke been? Slight (i), moderate (ii), strong (iii), very strong (iv), extremely strong (v)'. This question was coded '0' for smokers who responded 'not at all' to the previous question. In this population these two ratings have been found to be a better measure of dependence (i.e. more closely associated with relapse following a quit attempt) than other measures [32,33,39]. The demographic characteristics assessed were age, sex and social grade (dichotomized into two categories: ABC1, which includes managerial, professional and intermediate occupations; and C2DE, which includes small employers and own-account workers, lower supervisory and technical occupations, and semi-routine and routine occupations, never workers and long-term unemployed). We also assessed the number of quit attempts in the last year prior to the most recent attempt, time since the most recent quit attempt was initiated (either more or less than 6 months ago), whether smokers had tried to quit abruptly or gradually and the year of the survey.

Analysis

Bivariate associations between the use of different quitting methods and potentially confounding socio-demographic and smoking history variables were assessed with χ^2 tests and one-way analyses of variance (ANOVA)s for categorical and continuous variables, respectively. Significant omnibus results were investigated further by *post-hoc* Sidak-adjusted χ^2 tests and *t*-tests.

Our measure of dependence (strength of urges to smoke) assumed that the score relative to other smokers would remain the same from pre- to post-quitting [32,33]. If a method of quitting reduced the strength of

urges to smoke more than another method, this would tend to underestimate the effectiveness of that intervention because the smokers using this method would appear to be less dependent. To test for this bias, we used an analysis of covariance (ANCOVA) to examine whether the difference in strength of urges to smoke in smokers versus non-smokers depended upon the method of quitting, adjusting for the time since the quit attempt started.

In the analysis of the associations between quitting method and abstinence, we used a logistic regression model in which we regressed the outcome measure (self-reported non-smoking compared with smoking) on the effect measure (use of e-cigarettes compared with either NRT bought over-the-counter or no aid). The primary analysis was an adjusted model that included the potential confounders listed above and two interaction terms: (i) between time since last quit attempt and time spent with urges, and (ii) between time since last quit attempt and strength of urges to smoke. These interaction terms were used to reflect the fact that urges to smoke following a quit attempt are influenced by whether an individual is currently abstinent and the duration of abstinence [32,33]. In addition to the model from the primary analysis ('fully adjusted model'; model 4), we constructed a simple model including only the effect measure ('unadjusted model'; model 1), a model that included the effect measure, year of the survey and all potential confounders except for the two measures of tobacco dependence, and a model that included all variables from the previous model and the two measures of tobacco dependence but without their interaction terms ('partially adjusted models'; models 2 and 3, respectively) to assess the extent of confounding by dependence. As *post-hoc* sensitivity analyses, the models were re-examined using different potential confounders from the ones specified a priori and reported in previous publications using the same methodology [32,33]. First, the time since the initiation of the quit attempt was included using the following six categories: 'in the last week'; 'more than a week and up to a month'; 'more than 1 month and up to 2 months'; 'more than 2 months and up to 3 months'; 'more than 3 months and up to 6 months'; and 'more than 6 months and up to a year'. Secondly, an additional index of dependence—the heaviness of smoking index (HSI) [40]—was included. The HSI was assessed by asking current smokers to estimate current cigarettes per day and time to first cigarette (the two items comprising HSI) and by asking non-smokers to recall these behaviours prior to their quit attempt. Finally, in *post-hoc* subgroup analyses all models were repeated (i) among those reporting smoking one or more than one cigarette per day (CPD) to determine whether inclusion of very light smokers might have had an influence on the results; (ii) among those completing the survey between 2012–14

once e-cigarette usage had become prevalent; and (iii) in the two subsamples of respondents who had started their most recent quit attempt less or more than 6 months ago, in order to assess the interplay between long-term effectiveness and the occurrence of differential recall bias. All analyses were performed with complete cases.

RESULTS

A total of 6134 respondents reported a most recent quit attempt in the last 12 months that was either unaided ($n = 3477$) or supported by NRT bought over-the-counter ($n = 2095$), e-cigarettes ($n = 489$) or both ($n = 73$). Those using both were excluded as were those using a prescription stop-smoking medication or face-to-face behavioural support in combination with either NRT bought over-the-counter ($n = 173$) or e-cigarettes ($n = 25$). Thus, the study population consisted of 5863 smokers who had made an attempt to quit in the previous year, of whom 7.9% (464) had used e-cigarettes, 32.8% (1922) had used NRT bought over-the-counter and 59.3% (3477) had used no aid to cessation. Quitting method did not differ by sex or the number of quit attempts in the past year but was associated with age, social grade, time since the quit attempt started, CPD, smoking less than one CPD, the measures of dependence (time with and strength of urges and HSI) and whether the attempt had begun abruptly (see Table 1). The *post-hoc* comparisons showed that those who used either e-cigarettes or no aid were younger than those using NRT over-the-counter, and that those who used NRT over-the-counter or no aid were more likely to hold a lower social grade than those using e-cigarettes. As would be expected, given the recent advent of e-cigarettes, the quit attempts of e-cigarette users were less likely to have begun more than 6 months previously than those using NRT over-the-counter or no aid. Those using NRT bought over-the-counter smoked more cigarettes and scored higher than either of the other two groups on all measures of dependence. E-cigarette users smoked more cigarettes, and were more dependent by the strength of urges measure and HSI than those using no aid. Finally, those using no aid were more likely to have smoked less than one CPD and stopped abruptly than the other two groups.

Strengths of urges to smoke were higher in smokers than in non-smokers (see Table 2). However, the mean differences in strength of urges between smokers and non-smokers were similar across method of quitting: the interaction between smoking status (smokers versus non-smokers) and method of quitting in an ANCOVA of the strength of urges adjusted for the time since quit attempt started was not significant ($F_{(2, 5856)} = 1.50, P = 0.22$).

Non-smoking was reported among 20.0% (93 of 464) of those using e-cigarettes, 10.1% (194 of 1922) using

Table 1 Associations between characteristics of the sample and use of different quitting methods.

	<i>E-cigarettes</i> (<i>n</i> = 464)	<i>NRT over-the-counter</i> [§] (<i>n</i> = 1922)	<i>No aid</i> (<i>n</i> = 3477)	<i>P</i>
Mean (SD) age	39.0 (15.6) ^a	41.2 (15.3) ^{ab}	37.5 (16.2) ^b	***
% (<i>n</i>) Female	47.2 (219)	51.1 (982)	48.9 (1699)	NS
% Social grade C2DE	59.3 (275) ^{cd}	65.9 (1266) ^c	65.5 (2277) ^d	*
Mean (SD) cigarettes per day ^f	12.6 (8.0) ^{ef}	13.8 (8.5) ^{eg}	10.9 (8.1) ^{fg}	***
% (<i>n</i>) < 1 cigarettes per day ^f	0.7 (3) ^h	0.8 (15) ⁱ	2.8 (94) ^{hi}	***
% (<i>n</i>) Time since quit attempt started >26 weeks	23.7 (110) ^{jk}	36.4 (700) ^j	36.5 (1269) ^k	***
Mean (SD) quit attempts in the past year	1.6 (0.9)	1.6 (0.9)	1.5 (0.9)	NS
Mean (SD) time spent with urges to smoke (0–5)	1.9 (1.3) ^l	2.2 (1.3) ^{lm}	1.8 (1.3) ^m	***
Mean (SD) strength of urges to smoke (0–5)	2.0 (1.2) ^{no}	2.2 (1.1) ^{np}	1.8 (1.1) ^{op}	***
Mean (SD) heaviness of smoking index [†]	2.0 (1.5) ^{qr}	2.3 (1.5) ^{qs}	1.6 (1.5) ^{rs}	***
% (<i>n</i>) Abrupt attempt (no gradual cutting down first)	50.4 (234) ^t	52.5 (1010) ^u	59.0 (2051) ^{tu}	***

Different pairs of superscript letters indicate a significant difference ($P < 0.05$) between two groups after Sidak adjustment for multiple comparisons. * $P < 0.05$; *** $P < 0.001$; NS = not statistically significant ($P \geq 0.05$). [§]A subgroup of those using nicotine replacement therapy (NRT) over-the-counter provided information about the form of NRT ($n = 975$): 60.0% (585) used a patch, 21.0% (205) gum, 14.9% (145) an inhalator, 6.2% (60) lozenges, 1.2% (12) microtabs and 1.0% (10) nasal spray. NB: response options were not mutually exclusive and 11.1% (108) reported using more than one form. [†]Data were missing for 156 respondents (e-cigarettes: 22; NRT over-the-counter: 34; no aid: 100). [‡]Data were missing for 172 respondents (e-cigarettes: 23; NRT over-the-counter: 36; no aid: 113). SD = standard deviation.

Table 2 Differences between smokers and non-smokers in strength of urges to smoke by method of quitting.

<i>Method of quitting</i>	<i>n</i>	<i>Mean (SD) strength of urges to smoke in smokers</i>	<i>n</i>	<i>Mean (SD) strength of urges to smoke in non-smokers</i>	<i>Mean difference (95% CI) in strength of urges to smoke</i>
E-cigarettes	371	2.3 (1.1)	93	0.8 (1.1)	1.4 (1.2–1.7)
NRT over-the-counter	1728	2.3 (1.0)	194	1.2 (1.3)	1.2 (1.0–1.3)
No aid	2942	2.0 (1.0)	535	0.7 (1.1)	1.3 (1.2–1.4)

NB: the mean differences are calculated from exact rather than the rounded figures presented in columns 3 and 5 of this table. The mean difference in strength of urges to smoke was not different across the methods of quitting ($F_{(2, 5856)} = 1.50$, $P = 0.22$ for the interaction term between smoking status and method of quitting adjusted for the time since the quit attempt started). SD = standard deviation; CI = confidence interval; NRT = nicotine replacement therapy.

NRT over-the-counter and 15.4% (535 of 3477) using no aid. The unadjusted analyses indicated that e-cigarette users were more likely to be abstinent than either those using NRT bought over-the-counter [odds ratio (OR) = 2.23, 95% confidence interval (CI) = 1.70–2.93] or those who used no aid (OR = 1.38, 95% CI = 1.08–1.76; see model 1, Table 3). The primary analyses revealed that the fully adjusted odds of non-smoking in users of e-cigarettes were 1.63 (95% CI = 1.17–2.27) times higher compared with users of NRT bought over-the-counter and 1.61 (95% CI = 1.19–2.18) times higher compared with those using no aid (see model 4, Table 3). The relative magnitudes of the ORs from the fully adjusted model with the other three unadjusted and partially adjusted models illustrate the confounding effects of dependence (see Table 3).

In *post-hoc* sensitivity analyses, the associations between quitting method and non-smoking were re-examined using models including different potential confounders. In a model including the more fine-grained assessment of time since the initiation of the quit attempt

than the measure presented in Table 1, the adjusted odds of non-smoking in users of e-cigarettes were 1.58 (95% CI = 1.13–2.21) times higher compared with users of NRT bought over-the-counter and 1.55 (95% CI = 1.14–2.11) times higher compared with those using no aid. In another model that included another measure of dependence (HSI; missing data 3%, $n = 172$), the adjusted odds of non-smoking in users of e-cigarettes were 1.63 (95% CI = 1.15–2.32) times higher compared with users of NRT bought over-the-counter and 1.43 (95% CI = 1.03–1.98) times higher compared with those using no aid.

In *post-hoc* subgroup analyses, very light smokers were shown to have little influence on the pattern of results: in repeated analyses among those 5595 smokers reporting smoking one or more than one CPD the adjusted odds of non-smoking in users of e-cigarettes were higher compared with users of NRT bought over-the-counter (OR = 1.59, 95% CI = 1.13–2.26) and compared with those using no aid (OR = 1.63, 95% CI = 1.18–2.24). Similarly, the exclusion of respondents

Table 3 Associations between quitting method and abstinence.

	(1) <i>e</i> -Cigarettes	(2) NRT over-the-counter	(3) No aid	(1) versus (2)		(1) versus (3)	
				Model 1: OR (95% CI)	Model 2: OR (95% CI)	Model 1: OR (95% CI)	Model 2: OR (95% CI)
Full sample (<i>n</i> = 5863)							
% (<i>n</i>) Self-reported non-smoking	20.0 (93/464)	10.1 (194/1922)	15.4 (535/3477)	2.23 (1.70–2.93)***	1.88 (1.40–2.52)***	1.38 (1.08–1.76)*	1.21 (0.92–1.58)
				1.63 (1.17–2.28)**	1.63 (1.17–2.27)**	1.62 (1.19–2.19)**	1.61 (1.19–2.18)**
Subsample: quit attempt started ≤26 weeks (<i>n</i> = 3784)							
% (<i>n</i>) Self-reported non-smoking	20.3 (72/354)	11.0 (135/1222)	14.6 (323/2208)	2.06 (1.50–2.82)***	1.80 (1.27–2.55)***	1.49 (1.12–1.98)**	1.39 (1.01–1.90)*
				1.56 (1.06–2.29)*	–	1.88 (1.32–2.68)***	–
Subsample: quit attempt started >26 weeks (<i>n</i> = 2079)							
% (<i>n</i>) Self-reported non-smoking	19.1 (21/110)	8.4 (59/700)	16.7 (212/1269)	2.56 (1.49–4.42)***	1.98 (1.11–3.53)**	1.18 (0.72–1.94)	0.91 (0.54–1.55)
				1.64 (0.83–3.24)	–	1.10 (0.59–2.06)	–

Model 1 = unadjusted; model 2 = adjusted for age, sex, social grade, time since quit attempt started, quit attempts in the past year, abrupt versus gradual quitting and year of the survey; model 3 = adjusted for the variables from model 2 and time spent with urges to smoke and strength of urges to smoke; model 4 = adjusted for the variables from model 3 and the interaction terms time since last quit attempt started × time spent with urges and time since last quit attempt started × strength of urges to smoke. NB: for the two subsample analyses, model 4 is redundant, as there is no variation in the time since quit attempt. **P* < 0.05; ***P* < 0.01; ****P* < 0.001. OR = odds ratio; CI = confidence interval; NRT = nicotine replacement therapy.

during a time when e-cigarette usage was relatively rare (2009–11) had little effect on the results: among those 2306 smokers responding between 2012–14 the adjusted odds of non-smoking in users of e-cigarettes were higher compared with users of NRT bought over-the-counter (OR = 1.59, 95% CI = 1.05–2.42) and those using no aid (OR = 1.46, 95% CI = 1.04–2.05). In a final subgroup analysis the models were re-examined among those who started their quit attempt more or less than 6 months ago: there was only evidence among those who began their attempts less than 6 months ago of higher odds of non-smoking in users of e-cigarettes compared with users of NRT bought over-the-counter or those using no aid in the fully adjusted models (see Table 3).

DISCUSSION

Respondents who reported having used an e-cigarette in their most recent quit attempt were more likely to report still not smoking than those who used NRT bought over-the-counter or nothing. This difference remained after adjusting for time since the quit attempt started, year of the survey, age, gender, social grade, abrupt versus gradual quitting, prior quit attempts in the same year and a measure of nicotine dependence.

The unadjusted results have value in that they demonstrate self-reported abstinence is associated with quit-

ting method among those who use these methods to aid cessation in real-world conditions. However, this was not a randomized controlled trial and there were differences in the characteristics of those using different methods. For example, more dependent smokers tended to be more likely to use treatment, and smokers from lower social grades were less likely to use e-cigarettes. Although the adjustments go beyond what is typically undertaken in these types of real-world studies [28,29,41–44], it was not possible to assess all factors that may have been associated with the self-selection of treatment and we cannot rule out the possibility that an unmeasured confounding factor is responsible for the finding. For example, motivation to quit is likely to have been associated positively with the use of treatment. However, previous population studies have found that the strength of this motivation is not associated with success of quit attempts once started, so it is unlikely to explain our findings [45]. There are other variables which are typically related to abstinence that may also be related to the selection of treatment; for example, those using e-cigarettes may have been less likely to share their house with other smokers, had better mental health or greater social capital of a kind not measured by social grade. These possibilities mean the associations reported here must be interpreted with caution. Nevertheless, the data provide some evidence in forming a judgement as to whether the advent of e-cigarettes in the UK market is likely to be having a

positive or negative impact on public health, in a way that a randomized controlled trial is unable to do.

The finding that smokers who had used an e-cigarette in their most recent quit attempt were more likely to report abstinence than those who used NRT bought over-the-counter, and that the latter did not appear to give better results than not using any aid [33], contributes to the debate about how far medicine regulation can go in ensuring that products used for smoking cessation are or continue to be effective in the real world [14–17]. Randomized controlled trials are clearly important in identifying potential efficacy, but real-world effectiveness will depend upon a number of other contextual variables. The current study, together with previous randomized trials, suggests that e-cigarettes may prove to be both an efficacious and effective aid to smoking cessation [10,11]. In so far that this is true, e-cigarettes may substantially improve public health because of their widespread appeal [6–9] and the huge health gains associated with stopping smoking [46]. This has to be offset against any detrimental effects that may emerge, as the long-term effects on health have not yet been established. However, the existing evidence suggests the associated harm may be minimal: the products contain low levels of carcinogens and toxicants [3] and no serious adverse event has yet been reported in any of the numerous experimental studies. Regardless, the harm will certainly be less than smoking, and thus of greater importance is the possible long-term effect of e-cigarettes on cigarette smoking prevalence beyond helping some smokers to quit. For example, it has been suggested that e-cigarettes might re-normalize smoking, promote experimentation among young people who otherwise may not have tried smoking or lead to dual use together with traditional cigarettes, and thereby deter some smokers from stopping [47]. The current data do not address these issues. However, the rise in e-cigarette prevalence in England since 2010 has coincided with continued reduction in smoking prevalence [48].

If e-cigarette use is proving more effective than NRT bought over-the-counter, a number of factors may contribute to this [49]. A greater similarity between using e-cigarettes and smoking ordinary cigarettes in terms of the sensory experience could be one factor. Greater novelty is another. It is also possible that users of e-cigarettes use their products more frequently or for a longer period than those using NRT without professional support. These are all issues that need to be examined in future research.

This study was not designed to assess the comparative effectiveness of e-cigarettes and NRT or other medications obtained on prescription or behavioural support. The evidence still favours the combination of behavioural support and prescription medication as providing the

greatest chance of success [33,34,37], which is currently offered free at the point of access by the NHS stop smoking services in the United Kingdom.

A major strength of the current study is the use of a large, representative sample of the English population. Additionally, the study benefits from having begun to track the use of e-cigarettes as an aid to cessation at a time when e-cigarettes were only an emerging research issue. The importance of adjusting for nicotine dependence in real-world studies of smoking cessation is illustrated by the difference in the ORs between the models with and without this adjustment. The optimal method of adjusting for dependence would be to assess this in all participants prior to their quit attempt. However, in a wholly cross-sectional study, we believe the particular method used to adjust for dependence, established in two previous studies, is valid [32,33]. One of the most commonly used alternative measures of dependence—HIS—relies upon the number of cigarettes smoked and time to first cigarette of the day [40]. When smokers relapse they tend to do so with reduced consumption, which can lead to a false estimation of prior dependence in cross-sectional studies. This potential confound was avoided in the primary analysis by using a validated measure involving ratings of current urges to smoke and statistical adjustment of the urges for the time since the quit attempt was initiated [39]. The value of strength of urges as a measure of dependence in cross-sectional research would be limited if different methods of stopping were linked differentially to lower or higher levels of urges in abstinent compared with relapsed smokers. For example, a method of stopping that led to a relatively higher reduction in urges could underestimate the effectiveness of that method by making it seem that those using it were less dependent. However, we have not previously found evidence in this population data set that urges to smoke in smokers versus quitters differs as a function of method [33], and it was true again in this study. Regardless, the pattern of results remained the same in both a sensitivity analysis that also included HSI and in a subgroup analysis that excluded very light smokers. It is unlikely, therefore, that differential dependence between the users of different treatments has led to a substantial over- or underestimation of the relative effectiveness of e-cigarettes in the current study. Nevertheless, future studies may be able to draw stronger inferences by including a broader array of dependence measures or assessing dependence prior to a quit attempt.

The study had several limitations. First, abstinence was not verified biochemically. In randomized trials, this would represent a serious limitation because smokers receiving an active treatment often feel social pressure to report abstinence. However, in population surveys the

social pressure and the related rate of misreporting is low and it is generally considered acceptable to rely upon self-reported data [38]. A related issue is the assessment of abstinence by asking respondents whether they were 'still not smoking'. This definition classified as abstinent those who had one or more lapses but resumed not smoking. This limitation would be serious if the rate of lapsing was associated with method of quitting, and should be assessed in future studies. By contrast, advantages of this measure were the assessment of prolonged abstinence, as advocated in the Russell Standard, and a clear relationship to the quit attempt in question. An alternative approach, with a view to survival analysis, may have been to assess the length of abstinence since quit date among all respondents, including those who had relapsed by the time of the survey. However, this assessment would have added noise and potential bias with smokers needing to recall the time of relapse and having different interpretations of their return to smoking (i.e. first lapse, daily but reduced smoking, or smoking at pre-quit level). The strength of our approach is that smokers only needed to know whether they were currently still not smoking.

Secondly, there was a reliance upon recall data. The assessment of the most recent quit attempt involved recall of the previous 12 months and introduced scope for bias. The bias associated with recall of failed quit attempts would be expected to reduce the apparent effectiveness of reported aids to cessation because quit attempts using such aids would be more salient than those that were unaided [31]. Therefore, recall bias should militate against finding a benefit of e-cigarettes compared with no aid to cessation. Consistent with this explanation, the effect size for e-cigarettes compared with no aid appeared lower in smokers who started their quit attempt more than 6 months ago than in smokers who started their quit attempt less than 6 months ago. Although the power to detect the associations in these subgroups was limited, the explanation that the lack of effect in the more distant attempts was related to differential recall bias is also supported by the absolute rate of non-smoking being higher in those making unaided attempts more than 6 compared with less than 6 months ago. Alternatively, the finding may reflect a reduced long-term effectiveness of e-cigarettes. Future longitudinal studies of e-cigarettes as aids to cessation in the general population may differentiate these explanations and would represent a valuable improvement upon the current study.

Thirdly, NRT over-the-counter and e-cigarettes both represent heterogeneous categories. In particular, there is considerable variability in nicotine vaporization between different types of e-cigarette [50, 51]. Similarly, the simple definition of using one or the other aid to support an attempt is likely to have masked variability in how heavily, frequently and how long either NRT over-the-counter or

e-cigarettes were used by different smokers [12, 52–54]. It is also possible that there were differences between the groups in their experience of unanticipated side effects. It is precisely because of all these factors—type/brand of NRT over-the-counter or e-cigarette, intensity and frequency of usage and experience of unanticipated side effects—that it is important to examine real-world effectiveness. However, it also means that we cannot make more exact statements about relative effectiveness of different products and ways in which they may be used. Given this huge variability it may be many years before one could accumulate enough real-world data to address these questions. Finally, the prevalence of e-cigarettes has been increasing in England over the study period and this may affect real-world effectiveness. Although the evidence does not yet suggest an 'early adopters' effect—the current results persisted after adjusting for the year of survey and in a subgroup analysis limiting the data to a period when e-cigarette usage had become prevalent—these findings will need to be revisited to establish whether or not the apparent advantage of e-cigarettes is sustained.

In conclusion, among smokers trying to stop without any professional support, those who use e-cigarettes are more likely to report abstinence than those who use a licensed NRT product bought over-the-counter or no aid to cessation. This difference persists after adjusting for a range of smoker characteristics such as nicotine dependence.

Declaration of interests

All authors have completed the Unified Competing Interest form at http://www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare: JB's post is funded by a fellowship from the UK Society for the Study of Addiction; R.W. is funded by Cancer Research UK; Cancer Research UK, the Department of Health and Pfizer funded data collection for this study (including a Pfizer investigator initiated award), and that at the outset data collection for the Smoking Toolkit Study was also supported by GlaxoSmithKline and Johnson and Johnson; J.B., D.K. and E.B. have all received unrestricted research grants from Pfizer; R.W. undertakes research and consultancy and receives fees for speaking from companies that develop and manufacture smoking cessation medications (Pfizer, J&J, McNeil, GSK, Nabi, Novartis and Sanofi-Aventis); there are no other financial relationships with any organizations that might have an interest in the submitted work in the previous 3 years, particularly electronic cigarette companies, and there are no other relationships or activities that could appear to have influenced the submitted work. Funding was provided for the conduct of this research and preparation of the manuscript. The funders had no

final role in the study design; in the collection, analysis and interpretation of data; in the writing of the report; or in the decision to submit the paper for publication. All researchers listed as authors are independent from the funders and all final decisions about the research were taken by the investigators and were unrestricted.

Transparency declaration

J.B. affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained.

STROBE statement

All authors declare that study hypotheses arose before any inspection of the data and that all STROBE recommendations were followed.

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Secondhand Exposure to Vapors From Electronic Cigarettes

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Abstract

Introduction: Electronic cigarettes (commonly referred as e-cigarettes) are designed to generate inhalable nicotine aerosol (vapor). When an e-cigarette user takes a puff, the nicotine solution is heated and the vapor taken into lungs. Although no sidestream vapor is generated between puffs, some of the mainstream vapor is exhaled by e-cigarette user. The aim of the study was to evaluate the secondhand exposure to nicotine and other tobacco-related toxicants from e-cigarettes.

Materials and Methods: We measured selected airborne markers of secondhand exposure: nicotine, aerosol particles (PM_{2.5}), carbon monoxide, and volatile organic compounds (VOCs) in an exposure chamber. We generated e-cigarette vapor from 3 various brands of e-cigarette using a smoking machine and controlled exposure conditions. We also compared secondhand exposure with e-cigarette vapor and tobacco smoke generated by 5 dual users.

Results: The study showed that e-cigarettes are a source of secondhand exposure to nicotine but not to combustion toxicants. The air concentrations of nicotine emitted by various brands of e-cigarettes ranged from 0.82 to 6.23 µg/m³. The average concentration of nicotine resulting from smoking tobacco cigarettes was 10 times higher than from e-cigarettes (31.60±6.91 vs. 3.32±2.49 µg/m³, respectively; $p = .0081$).

Conclusions: Using an e-cigarette in indoor environments may involuntarily expose nonusers to nicotine but not to toxic tobacco-specific combustion products. More research is needed to evaluate health consequences of secondhand exposure to nicotine, especially among vulnerable populations, including children, pregnant women, and people with cardiovascular conditions.

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Smoking Kills, and So Might E-Cigarette Regulation

By Gilbert Ross, M.D.

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Smoking is a leading cause of death, and cessation treatments are largely ineffective, yet regulation threatens a promising new technology that might help smokers quit.



Anyone with a modicum of knowledge regarding public health will agree that the most important, devastating, and preventable issue facing America is the human toll of cigarettes. Yet our nation's main health regulator, the Food and Drug Administration (FDA), will issue regulations within the next few weeks that could harm our nation's 45 million smokers.

Smokers trying to quit have an extremely difficult time, yet a new technology which might ease their path — electronic cigarettes, or e-cigarettes — is facing relentless opposition from public health agencies such as the Centers for Disease Control, the FDA, and the American Cancer Society (which sponsors this week's Great American Smokeout to encourage quitting) — and their antipathy is certainly not based on science.

We do not yet know what the long-term health effects of e-cigarettes are, nor the benefits for smokers who switch or cut down on their daily quota of smokes via "vaping" (using e-cigarettes) since there is no smoke involved. But simple common sense would dictate that inhaling the fewer, less harmful ingredients of e-cigarettes as compared to inhaling the thousands of chemicals in the smoke from burnt tobacco, many of which have been shown to be carcinogenic, is highly likely to be healthier.

A tragic 450,000 Americans die from smoking each year. While the fraction of adult smokers has been in gradual decline since the groundbreaking 1964 surgeon general's report confirmed the

evidence of manifold smoking-related illnesses, the total number has not changed much and the decline in teen smoking initiation has stalled over the past few years. Although “cigarette smoke” is not listed as a cause of death per se, smokers whose lives are cut short die from a wide spectrum of illnesses, some chronic (cancers of many organs, COPD/chronic obstructive pulmonary disease), and some cruelly brief (heart attacks and strokes). If those who die prematurely from smoking were lumped together, they would constitute the third leading cause of death in America, after heart disease and cancer.

Most smokers understandably desire to quit. About half try each year, but a pitiful few — maybe 5 percent — succeed unaided or “cold turkey.” The addiction to smoking is extremely powerful, largely (but not solely) due to nicotine’s power. However, it is often believed by smokers, and even by some doctors, that it is the nicotine that is toxic and lethal. This is a dangerous myth. It has been proven that smokers smoke for the nicotine — but they die from the smoke. The FDA has approved various treatments to help smokers quit — NRT (nicotine replacement therapy) patches, gum, inhalers, and non-nicotine drugs such as bupropion and varenicline (Zyban and Chantix, respectively). The unfortunate fact is that adding one or more of these treatments to a smoker’s stated desire to quit increases his or her success rate — abstinence from cigarettes for one year — by about two- to three-fold, i.e. to 15 percent or less. These methods, which fail almost 9 times out of 10, provide an unacceptably low level of assistance in aiding escape from smoking’s deadly grip.

Over the course of the past few years, e-cigarettes (or “electronic nicotine delivery systems,” ENDS) have provided a ray of hope for an increasing number of desperate smokers. These devices use a battery to vaporize water and nicotine, which the user (“vaper”) inhales, along with vegetable glycerin and/or propylene glycol and flavoring. They often have a cigarette-like LED tip which glows red, or some other color if preferred, but without tobacco, without combustion, and without smoke. The ingredients noted are generally recognized as safe by regulatory agencies, and have been in common use for decades — although no long-term health studies have been done on their safety in combination with inhalational use.

Since 2007, when e-cigarettes were first imported from China, smokers have at first gradually, and more recently enthusiastically, become vapers. Solid data on long-term trends are only beginning to be accumulated, but the sales of e-cigarettes have doubled in each of the past few years, to the extent that a recent survey found that an astounding one-fifth of smokers had tried them — millions of people, in other words. How many have switched completely from deadly cigarettes? How many smokers also vape — “dual users”? None of this has been determined yet by randomized clinical trials. Although there are scant data even from observational studies, several small studies support the contention that vaping is likely to be more effective than NRT for smoking cessation, as well as for reducing the number of cigarettes smoked among those who have not yet quit.

The Upcoming FDA Decision

The Family Smoking Prevention and Tobacco Control Act, which granted the FDA oversight of tobacco in 2009, outlines a complex process for “modified risk tobacco products” (MRTPs) to be approved by the FDA. Such a product must undergo a lengthy and expensive trial process requiring demonstration that the product submitted reduces the harm of tobacco exposure not merely for the person using it, but for the population as a whole. Given the nefarious behavior of the tobacco industry over the 20th century, any proposal submitted to the FDA related to tobacco is going to have to strongly support any assertions with data.

Unfortunately, the Tobacco Control Act may become a detriment to public health if it is implemented to effectively ban e-cigarettes from the market. The Office of Management and Budget is currently deciding whether to designate e-cigarettes as a tobacco product to be regulated under the TCA, as a drug or medical device, requiring regulation from a different department of the FDA, or as neither such product. If e-cigarettes are designated as tobacco products requiring proof of modified risk, it is likely that the ramifications for millions of American vapers, and many more potential future ex-smokers, will be disastrous. E-cigarettes (at least those containing the nicotine smokers crave) would be exiled from the market while expensive, lengthy testing took place. Ironically, the industry's small businesses would suffer while Big Tobacco would profit, since it has also gotten into the e-cigarette market, and since larger companies would be the only ones who could afford to cut through the regulatory thicket. Meanwhile, some ex-smokers who have become vapers will find a way to secure their e-cigarette nicotine, via online or black market sources. Many, however, will revert to the deadly, toxic cigarettes from which they thought they had, at last, escaped.

There is, however, a better approach: the government could decline to classify e-cigarettes as tobacco products and allow their continued marketing, with the states establishing reasonable oversight — as many have already — for age limits, manufacturing standards, accurate ingredient listing, and warning labels. As a result, many lives will be saved from cigarette-related disease and death.

The World Health Organization predicts that the death toll from cigarettes could reach 1 billion this century, if current trends continue. The European Union only last month flouted the anti-e-cigarette campaigners and gave millions of European vapers a pass to keep on vaping. Given the current abysmal rate of successful quitting with the approved methods, the FDA should take the courageous, science-based, and compassionate course.

Effectively excluding e-cigarettes from the market via stringent regulation would have the effect of killing smokers and protecting cigarette and pharmaceutical markets. E-cigarettes, a far safer form of nicotine delivery, should not be submitted to tougher regulation than cigarettes.

Americans should not have to die from misguided regulation.

Gilbert Ross, MD, is medical and executive director of the American Council on Science and Health.

FURTHER READING: Ross also writes “The Deadly Crusade Against E-cigarettes.” Edward Tenner describes “Markets, Risk, and Fashion: The Hindenburg’s Smoking Lounge.” Roger Bates contributes “An Invaluable Insecticide” and “The Case for DDT.” Mark J. Perry shares “Unintended Consequences of Cigarette Taxes” and “Markets in Everything: Roll-Your-Own Cigarettes.”

Image by: Dianna Ingram / Bergman Group

Electronic Cigarettes As a Smoking-Cessation Tool

Results from an Online Survey

Michael B. Siegel, MD, MPH, Kerry L. Tanwar, BA, Kathleen S. Wood, MPH

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Background: Electronic cigarettes (e-cigarettes) are battery-powered devices that deliver nicotine without any combustion or smoke. These devices have generated much publicity among the smoking-cessation community and support from dedicated users; however, little is known about the efficacy of the device as a smoking-cessation tool.

Purpose: This study aimed to examine the effectiveness of e-cigarettes for smoking cessation using a survey of smokers who had tried e-cigarettes.

Methods: Using as a sampling frame a cohort of all first-time purchasers of a particular brand of e-cigarettes during a 2-week period, a cross-sectional, online survey was conducted in 2010 to describe e-cigarette use patterns and their effectiveness as a smoking-cessation tool. There were 222 respondents, with a survey response rate of 4.5%. The primary outcome variable was the point prevalence of smoking abstinence at 6 months after initial e-cigarette purchase.

Results: The primary finding was that the 6-month point prevalence of smoking abstinence among the e-cigarette users in the sample was 31.0% (95% CI=24.8%, 37.2%). A large percentage of respondents reported a reduction in the number of cigarettes they smoked (66.8%) and almost half reported abstinence from smoking for a period of time (48.8%). Those respondents using e-cigarettes more than 20 times per day had a quit rate of 70.0%. Of respondents who were not smoking at 6 months, 34.3% were not using e-cigarettes or any nicotine-containing products at the time.

Conclusions: Findings suggest that e-cigarettes may hold promise as a smoking-cessation method and that they are worthy of further study using more-rigorous research designs.

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Introduction

Electronic cigarettes (e-cigarettes) are battery-powered devices that deliver nicotine without any combustion or smoke. Use and awareness of e-cigarettes has dramatically increased over the past 3 years.¹⁻³ Ayers et al.,³ in this issue of the *American Journal of Preventive Medicine*, report that Internet searchers for e-cigarettes in the U.S. now exceed those for any other smoking alternative, nicotine replacement, or smoking-cessation product. Although e-cigarettes have generated much support from dedicated users, little is known about the efficacy of the device as a smoking-cessation tool.

Most smoking-cessation methods focus on one component of smoking: nicotine addiction. However, even with the assistance of medications that treat nicotine addiction, the success rate for quitting remains low. Based on a Cochrane review of seven studies⁴⁻⁹ that measured smoking cessation using nicotine replacement therapy (NRT), the average 6-month point prevalence of smoking abstinence is only 17.8%, and the 6-month point prevalence of smoking abstinence in the pooled data from these studies is only 11.9%.

Several studies^{10,11} have suggested that physical and behavioral stimuli—such as merely holding a cigarette—can reduce the craving to smoke, even in the absence of nicotine delivery. Given that both nicotine and smoking-related cues appear to influence cigarette craving, e-cigarettes may present a unique opportunity to promote smoking cessation. Two preliminary studies¹²⁻¹⁴ provide evidence that e-cigarette use suppresses the urge to smoke.

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Results from two recent surveys^{15,16} suggest that e-cigarettes may be effective in helping smokers quit. However, both of these surveys relied on convenience samples of e-cigarette users.

This paper reports the results of a survey conducted using a non-convenience sampling frame. Compared with previous studies, which used convenience samples, this survey is based on a sample of all first-time purchasers of a particular brand of e-cigarettes.

Methods

An anonymous Internet-based, cross-sectional survey was conducted among a cohort of first-time purchasers of e-cigarettes from a leading e-cigarette distributor to determine the effectiveness of e-cigarettes for smoking cessation.

Recruitment

A leading e-cigarette distributor (Blu) provided investigators with e-mail addresses of a consecutive sample of first-time Blu e-cigarette purchasers. This sample represented the first 5000 customers who purchased Blu e-cigarettes over a 2-week period beginning July 1, 2009, when Blu commenced its first, continuous operation. Subjects from this customer list were sent a recruitment e-mail. The e-mail invitation was sent to potential subjects in March 2010, that is, 7 months after their initial e-cigarette purchase.

Of the 5000 e-mail addresses to which the survey was sent, 4884 were valid. In total, 222 e-cigarette purchasers responded to the survey, resulting in a response rate of 4.5%. Of the 222 respondents, six were deleted because they did not meet the definition of a "smoker": having smoked 100 or more cigarettes in their lifetime. Therefore, the final sample consisted of 216 respondents, all of whom indicated that they had tried e-cigarettes.

Survey and Data Collection

Those who opted to participate in the study accessed the survey via a secure link in the recruitment e-mail. The current study was approved by the IRB at the Boston University Medical Center.

Data Analysis

The primary hypothesis tested in the present study was the effectiveness of e-cigarettes in smoking cessation, defined as the point prevalence of abstinence from cigarette smoking at 6 months after the first purchase of Blu e-cigarettes. For this estimate, 95% CIs were calculated using standard methods for the estimation of the variance of a proportion.¹⁷

Results

Participant Characteristics and Smoking History

There were more men (71.5%) than women (28.5%) in the study (Table 1). The majority of respondents had smoked for 6 or more years (81.1%), and nearly two

Table 1. Demographic information, smoking characteristics, and cessation/reduction of tobacco use after e-cigarette use

Variable	n (%)
DEMOGRAPHIC INFORMATION	
Gender	
Male	153 (71.5)
Female	61 (28.5)
Age (years)	
18–24	41 (19.1)
25–44	114 (53.0)
45–64	48 (22.3)
≥65	12 (5.6)
SMOKING CHARACTERISTICS	
Smoking history (years smoked)	
≤5	32 (14.7)
6–15	77 (35.5)
16–30	67 (30.9)
>30	41 (18.9)
Number of previous quit attempts	
0	17 (7.9)
1–2	59 (27.4)
3–5	90 (41.9)
>5	49 (22.8)
CESSATION/REDUCTION OF TOBACCO USE AFTER E-CIGARETTE USE	
Reported reducing nicotine use	
Yes	106 (49.3)
No	109 (50.7)
Reduced number of tobacco cigarettes per day after e-cigarette use	
Yes	143 (66.8)
No	71 (33.2)
Quit/abstained for a period of time	
Yes	104 (48.8)
No	109 (51.2)

thirds (64.7%) of participants reported having made three or more previous quit attempts.

Cessation or Reduction of Tobacco After E-Cigarette Use

More than two thirds of respondents (66.8%) reported having reduced the number of tobacco cigarettes they

smoked per day after trying e-cigarettes, and nearly half (49.3%) reduced their nicotine use (Table 1). Nearly half (48.8%) of respondents indicated that they quit smoking for a period of time after trying e-cigarettes.

E-Cigarette Use Patterns and 6-Month Smoking Status

Thirty-one percent (31.0%) of respondents were not smoking at the 6-month point (95% CI=24.8%, 37.2%; Table 2). Of those who were not smoking at 6 months, 56.7% were using e-cigarettes, 9.0% were using tobacco-free nicotine products, and 34.3% were completely nicotine-free.

Among subjects who were not using e-cigarettes at the time of the survey, only 26.8% were nonsmokers (Table 2). However, among current e-cigarette users, 34.5% were nonsmokers. Smoking abstinence rates generally increased with higher frequency of e-cigarette use, with more than two thirds (70.0%) of respondents using e-cigarettes more than 20 times per day being nonsmokers at 6 months.

Table 2. How e-cigarette use patterns relate to 6-month smoking status

Use pattern	% (95% CI) not smoking
Total: smoking status at 6-month point (n=216)	31.0 (24.8, 37.2)
Number of times used per day	
No current e-cigarette use (n=97)	26.8 (17.9, 35.7)
<5 (n=50)	28.0 (15.4, 40.6)
5–10 (n=31)	35.5 (18.4, 52.6)
11–15 (n=16)	31.3 (8.2, 54.3)
16–20 (n=12)	33.3 (6.3, 60.4)
>20 (n=10)	70.0 (41.2, 98.8)
Weekly pattern of e-cigarette use	
No current e-cigarette use (n=97)	26.8 (17.9, 35.7)
Only uses some days (n=71)	21.1 (11.5, 30.8)
Everyday use (n=48)	54.2 (39.9, 68.5)
Nicotine use of those who are not smoking at 6-month point (n=67) (n [%])	
Nicotine-free	23 (34.3)
Using tobacco-free nicotine products	6 (9.0)
Using only e-cigarettes	38 (56.7)

Discussion

The primary finding was a 6-month point prevalence of smoking abstinence among the e-cigarette users in the sample of 31.0%. This compares favorably to the average 6-month point prevalence of smoking abstinence of 17.8% in prior studies and to the 6-month point prevalence of smoking abstinence of 11.9% in the pooled data from these studies.^{4–9}

Of those respondents who were not smoking at the 6-month point, more than one third (34.3%) were also nicotine-free. This suggests that e-cigarettes can help decrease nicotine dependence, rather than maintain or increase nicotine addiction as some opponents have argued.¹

A large percentage of respondents reported a reduction in the number of cigarettes they smoked (66.8%) and almost half reported abstinence from smoking for a period of time (48.8%). These results are notable because smokers who reduce the amount of cigarettes smoked are more likely to quit smoking,¹⁸ and a reduction in the amount of cigarettes smoked can lower the individual's risk of smoking-related illnesses.¹⁹

There are a number of important limitations of this study. First, because of the low survey response rate, the sample is not representative of all smokers who have tried e-cigarettes. Further, because of lack of information on the survey non-respondents, the factors related to nonresponse could not be assessed. It is possible that smokers who had less success with e-cigarettes were also less likely to complete the survey. This would bias the results toward overestimating the 6-month abstinence rate. Second, self-reported abstinence was not verified using biochemical methods. It is possible that respondents over-reported smoking abstinence because of perceived social pressure. Third, only users of one brand of e-cigarettes were surveyed. Thus, these results cannot be generalized to the use of all e-cigarette brands.

Because of these study limitations, these findings must be viewed as suggestive, rather than definitive. Although the findings suggest that e-cigarettes may hold promise as a smoking-cessation method, further studies with more-rigorous research designs are warranted.

The distinct and unique advantage of e-cigarettes is that they allow individuals to utilize one device that can simultaneously address nicotine withdrawal, psychological factors, and behavioral cues that serve as barriers to smoking abstinence. The finding that most individuals who used e-cigarettes at least reduced the number of tobacco cigarettes they smoked suggests that if proven safe, e-cigarettes may be a potentially important tool for harm reduction, especially among smokers who have found currently available pharmaceutical smoking-cessation options to be ineffective. The present study suggests that

this alternative approach to smoking cessation is worthy of further investigation.

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Jacob Sullum Contributor

I cover the war on drugs from a conscientious objector's perspective.

Opinions expressed by Forbes Contributors are their own.

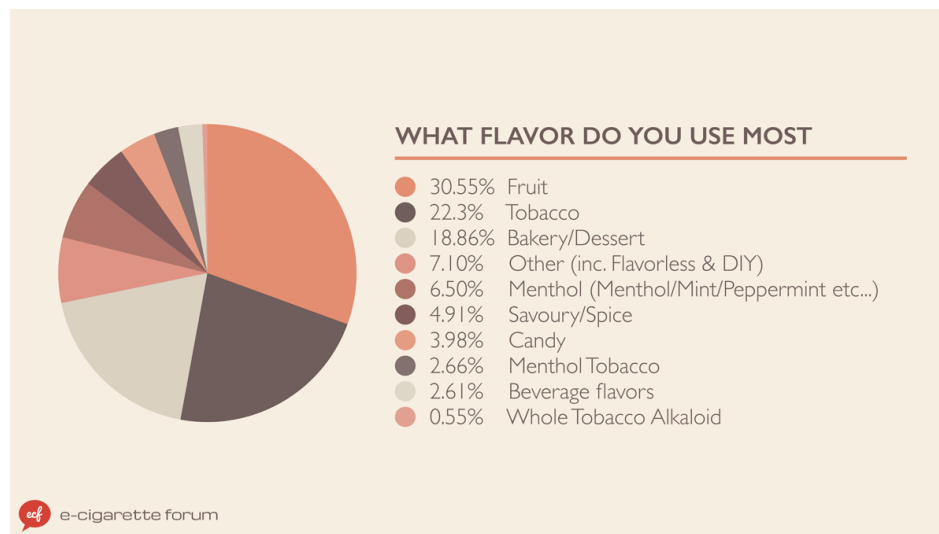
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Survey Shows Adults Who Use E-Cigarettes To Quit Smoking Prefer Supposedly Juvenile Flavors

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At a [Senate hearing](#) last month, Jay Rockefeller noted that electronic cigarette fluid is available in a wide variety of flavors—conclusive evidence, to his mind, that e-cigarette companies want to hook children on nicotine. “I am an adult,” the West Virginia Democrat said. “Would I be attracted to Cherry Crush, Chocolate Treat, Peachy Keen, Vanilla Dreams? No, I wouldn’t.”

Call it the Rockefeller Rule: If an e-cigarette flavor does not appeal to this particular 77-year-old senator, it could not possibly appeal to anyone older than 17. Rebutting that claim, Jason Healy, founder and president of Blu eCigs, cited a customer survey that found “the average age of a cherry smoker is in the high 40s.” [Survey results](#) released today by [E-Cigarette Forum](#), an online gathering spot for vaping enthusiasts, reinforce Healy’s point, showing that grownups prefer the flavors that Rockefeller insists are strictly for kids.



(Image: E-Cigarette Forum)

The survey, conducted in late June and early July, included more than 10,000 members of E-Cigarette Forum, 78 percent of whom live in the United States. Their ages ranged from 18 to “65 and over,” with 74 percent between 22 and 54. When they were asked which flavor they used most, 22 percent said tobacco, while an additional 3 percent said menthol tobacco. In other words, three-quarters of these adult vapers favor flavors other than tobacco, including fruit (31 percent), bakery/dessert (19 percent), and savory/spice (5 percent).

That make sense, because the proliferation of flavors—*The New York Times* [reports](#) that “more than 7,000 flavors are now available and, by one estimate, nearly 250 more are being introduced every month”—is especially evident among vapers who, like most of the participants in this survey, use devices with refillable tanks, rather than e-cigarettes that are either entirely disposable or take disposable cartridges. Refillable vaporizers, available mainly online or in specialized outlets, are less likely to interest teenagers than the cheaper “cigalikes” sold in supermarkets and convenience stores.



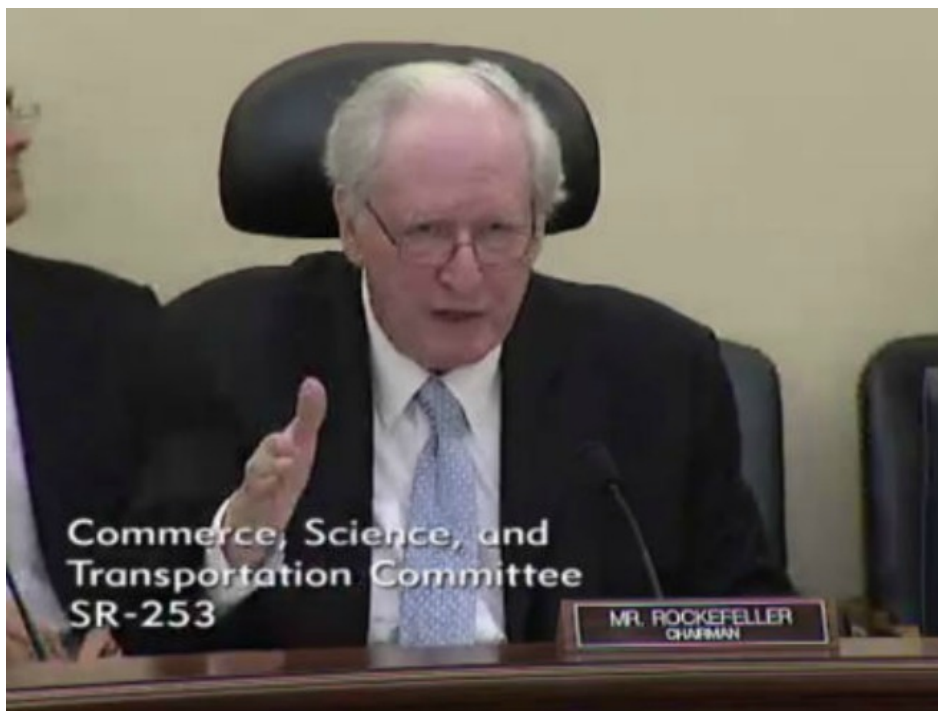
(Image: Vape Lounge)

The new survey also provides further evidence that e-cigarettes help smokers quit, a proposition that Rockefeller and other critics question. Eighty-nine percent of the respondents reported that they had smoked at least 10 cigarettes a day before they started vaping, and 88 percent said they were not currently smokers.

Those findings are similar to the results of [another survey](#) focusing on people who participate in online vaping forums, reported last April in the [International Journal of Environmental Research and Public Health](#). That study, which included more than 19,000 vapers from around the world, found that almost all of them (99.5 percent) were smokers when they started vaping. Four-fifths of them had stopped smoking completely, while the rest had reduced their cigarette consumption, on average, from 20 to four per day.

It should be emphasized that neither of these studies was designed to capture a representative sample of all vapers. Instead they focus on the most enthusiastic among them, whom you would expect to have had especially

satisfying experiences with e-cigarettes. The high success rates in these surveys therefore are unlikely to be seen among the broader group of smokers who [try to quit](#) with e-cigarettes, let alone among smokers who merely try the product out. But these surveys do indicate that e-cigarettes have helped many smokers quit.



"You're what's wrong with this country." (Image: Senate Commerce, Science, & Transportation Committee)

It borders on bizarre that critics like Rockefeller continue to question the existence of those former smokers, even while arguing that e-cigarettes should be restricted or banned based on the [entirely hypothetical risk](#) that vaping will lead to smoking among teenagers who otherwise never would have tried tobacco. But what do you expect from a politician who thinks a sample of one—himself—is perfectly adequate to reach sweeping conclusions about a product's intended use?

Notably, two-thirds of the ex-smokers in the E-Cigarette Forum survey said nontobacco flavors were important in helping them quit. Survey data [reported](#) in the *International Journal of Environmental Research and Public Health* last December likewise indicate that flavor variety is important in quitting. That study, which involved about 4,500 vapers, found that they tended to prefer tobacco-flavored fluid initially but later switched to other flavors. Most reported using more than one flavor on a daily basis and said the variety made the experience more interesting and enjoyable.

Nontobacco flavors may assist in quitting because learning to associate your nicotine fix with a new taste creates an additional barrier to backsliding: Returning to conventional cigarettes would mean getting used to the flavor of tobacco smoke again. Alternatively, the flavor of tobacco may trigger an urge to smoke.

More than nine out of 10 vapers in the E-Cigarette Forum survey said they worried that government regulations demanded by save-the-children alarmists like Rockefeller will remove products they use from the market. It's not hard to see why. "Why in heaven's name are you going ahead and marketing these things and selling these things?" Rockefeller asked Healy and another e-cigarette executive during last month's hearing. "I don't know how you go to sleep at night....You're what's wrong with this country."

Rockefeller's research methods begin and end with his own prejudices. The Food and Drug Administration, in deciding [how to regulate e-cigarettes](#), should aspire to higher standards.

This article is available online at: <http://onforb.es/1jUJLGK>

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TESTS FOR THE CHRONIC TOXICITY OF PROPYLEXE GLYCOL AND TRIETHYLENE GLYCOL ON MONKEYS AND RATS BY VAPOR INHALATION AND ORAL ADMINISTRATION

O. H. ROBERTSON, CLAYTON G. LOOSLI, THEODORE T. PUCK,
HENRY WISE, HENRY M. LEMON and WILLIAM LESTER, JR.

[+](#) Author Affiliations

Abstract

With a view to determining the safety of employing the vapors of propylene glycol and triethylene glycol in atmospheres inhabited by human beings, monkeys and rats were exposed continuously to high concentrations of these vapors for periods of 12 to 18 months. Equal numbers of control animals were maintained under physically similar conditions. Long term tests of the effects on ingesting triethylene glycol were also carried out. The doses administered represented 50 to 700 times the amount of glycol the animal could absorb by breathing air saturated with the glycol.

Comparative observations on the growth rates, blood counts, urine examinations, kidney function tests, fertility and general condition of the test and control groups, exhibited no essential differences between them with the exception that the rats in the glycol atmospheres exhibited consistently higher weight gains. Some drying of the skin of the monkeys' faces occurred after several months continuous exposure to a heavy fog of triethylene glycol. However, when the vapor concentration was maintained just below saturation by means of the glycostat this effect did not occur.

Examination at autopsy likewise failed to reveal any differences between the animals kept in glycolized air and those living in the ordinary room atmosphere. Extensive histological study of the lungs was made to ascertain whether the glycol had produced any generalized or local irritation. None was found. The kidneys, liver, spleen and bone marrow also were normal.

The results of these experiments in conjunction with the absence of any observed ill effects in patients exposed to both triethylene glycol and propylene glycol vapors for months at a time, provide assurance that air containing these vapors in amounts up to the saturation point is completely harmless.

Footnotes

Received June 4, 1947.

Articles citing this article

Electronic Cigarettes: A Policy Statement From the American Heart Association

Circulation October 14, 2014 130:1418-1436

[Full Text](#) [Full Text \(PDF\)](#)

Safety evaluation and risk assessment of electronic cigarettes as tobacco cigarette substitutes: a systematic review

Therapeutic Advances in Drug Safety April 1, 2014 5:67-86

[Abstract](#) [Full Text \(PDF\)](#)

Final Report on the Safety Assessment of Triethylene Glycol and PEG-4

International Journal of Toxicology March 1, 2006 25:121-138

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Ozone and Glycol Vapor Decontamination of Air in a Closed Room

JDR September 1, 1974 53:1132-1137

[Abstract](#) [Full Text \(PDF\)](#)



The Rest of the Story: Tobacco News Analysis and Commentary

...Providing the whole story behind tobacco news.

Thursday, October 31, 2013

First Study to Examine E-Cigarette Gateway Hypothesis Can Find Only One Nonsmoker Who Initiated with E-Cigs and Went on to Smoke

In the first [study](#) to examine the hypothesis that electronic cigarettes are a gateway for youth to become addicted to cigarettes, Dr. Ted Wagener from the University of Oklahoma Health Sciences Center reports being able to find only one young person who initiated nicotine use with e-cigarettes and then went on to smoke cigarettes, out of a sample of 1,300 college students.

The study has not yet been published, but it was presented Tuesday at the annual meeting of the American Association for Cancer Research in Washington, D.C.

According to Brenda Goodman's *HealthDay* [article](#) summarizing the study: "E-cigarettes don't appear to entice teens to try smoking tobacco, a new study says. ... Last month, the U.S. Centers for Disease Control and Prevention warned that "vaping," or inhaling the nicotine vapors from e-cigarettes, might be a dangerous new fad that could set teens up for smoking. In just one year, the number of kids in grades six through 12 who said they'd ever tried an e-cigarette more than doubled, rising from 3.3 percent to 6.8 percent. Among the 2.1 percent who said they were current e-cigarette users, more than three-quarters said they also smoked regular cigarettes. Given that overlap, many health experts worried that e-cigarettes might be acting like a gateway drug, sucking kids more deeply into nicotine addiction, and law officials urged the U.S. Food and Drug Administration to regulate e-cigarettes as tobacco products."

"The new study suggests that may not be the case. Researchers surveyed 1,300 college students about their tobacco and nicotine use. The average age of study participants was 19. "We asked what the first tobacco product they ever tried was and what their current tobacco use looked like," said researcher Theodore Wagener, an assistant professor of general and community pediatrics at the University of Oklahoma Health Sciences Center, in Oklahoma City. Overall, 43 students said their first nicotine product was an e-cigarette. Of that group, only one person said they went on to smoke regular cigarettes. And the vast majority

About Me

Michael Siegel

Dr. Siegel is a Professor in the Department of Community Health Sciences, Boston University School of Public Health. He has 25 years of experience in the field of tobacco control. He previously spent two years working at the Office on Smoking and Health at CDC, where he conducted research on secondhand smoke and cigarette advertising. He has published nearly 70 papers related to tobacco. He testified in the landmark Engle lawsuit against the tobacco companies, which resulted in an unprecedented \$145 billion verdict against the industry. He teaches social and behavioral sciences, mass communication and public health, and public health advocacy in the Masters of Public Health program.

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who started with e-cigarettes said they weren't currently using any nicotine or tobacco."

"It didn't seem as though it really proved to be a gateway to anything," said Wagener, who presented his findings at a meeting of the American Association for Cancer Research, in National Harbor, Md."

The Rest of the Story

This study provides preliminary evidence that electronic cigarettes are not currently serving as a major gateway to cigarette smoking. Of course, more studies of this nature, as well as longitudinal studies, are necessary to firmly answer this question. And importantly, this only reflects the current situation and things can change at any time. It is important that we remain vigilant and closely monitor youth electronic cigarette use over time.

I should also make it clear that in no way am I arguing that sales and marketing restrictions are not needed. In fact, I am hoping that the FDA will promulgate regulations that do strictly regulate the sale and marketing of electronic cigarettes to youth.

What this evidence does highlight is how unfortunate it was that CDC Director Dr. Thomas Frieden disseminated to the public a [conclusion](#) about this research question, telling the public that we already know the answer and that electronic cigarettes are a gateway to tobacco addiction. Dr. Frieden stated that: *"many kids are starting out with e-cigarettes and then going on to smoke conventional cigarettes."*

Unfortunately, this premature speculation (or conclusion, as the above statement does not seem to be speculative) led to widespread media dissemination to the public of the news that electronic cigarettes are a gateway to tobacco addiction. These articles are already having an effect on policy makers throughout the country.

In a *Forbes* magazine online [column](#) today, Jacob Sullum explains how many tobacco control advocates, including Dr. Frieden, "jumped all over CDC survey data indicating that the percentage of teenagers who have tried e-cigarettes doubled (from 3.3 percent to 6.8 percent) between 2011 and 2012." Sullum writes: "Many teens who start with e-cigarettes may be condemned to struggling with a lifelong addiction to nicotine and conventional cigarettes," CDC Director Tom Frieden [worried](#). But the survey data [the CDC data] provided no evidence that e-cigarettes are a gateway to the conventional kind, and a new study [the Wagener study] casts further doubt on that hypothesis."

The issue of whether electronic cigarettes serve as a gateway to youth tobacco addiction is a very serious one. It should not be taken lightly. If these products lead to increased cigarette smoking among youth then this harm would offset the benefits of enhanced smoking cessation and electronic cigarettes would no longer have net public health benefits. So this is a crucial research question.

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▶ [2008](#) (196)

▶ [2007](#) (250)

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▶ [2005](#) (281)

But I emphasize that it is a "question." It does a disservice to the public to draw pre-determined conclusions, as Dr. Frieden did in telling the public that we already have the answer: kids **are** starting out with e-cigarettes and going on to smoke conventional cigarettes.

Our public policies must be science-based. But when one draws pre-determined conclusions, rather than rely on the scientific evidence, this does not lead to evidence-based policies. My fear is that because of a strong pre-existing ideology against electronic cigarettes because they simulate the physical actions of smoking, tobacco control groups are drawing conclusions based on ideology rather than on science.

Posted by [Michael Siegel](#) at 9:14 AM 22 Comments

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22 Comments

The Rest of the Story

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H · a year ago

Good to see a follow up on yesterday's panel discussion with this recent study. It was unfair for Tim to question your commitment to public health and to suggest that you merely nit pick or drill down on isolated statements. I've never read your blog as an example of "gotcha politics/journalism" but rather a single minded focus on demanding accountability from both the industry and public health. That you give more attention to public health is a function of there being adequate criticism of the industry already and keeping one's own house in order.

Clearly, the words of the Director of the CDC hold a lot of weight with the public which is exactly why the CDC must be careful in its pronouncements. His carefully crafted statement echoed throughout most media channels for the past two months and it is the authoritative takeaway on e-cigs and youth that the public received.

Sure there may be some isolated sentence on your blog that could be stated better, but it was absurd to compare the Director's public comment to a professor's blog. As excellent as your writing and substance is, it doesn't have the same authority in the public's mind nor receive the same media coverage. (I'm sure you're aware of your relative status and recognize that this was not a put down.)

Hope to see an update once the study is released.

3 ^ | ▾ · Reply · Share >



[enemy_guest](#) · a year ago

"Our public policies must be science-based. But when one draws pre-determined conclusions, rather than rely on the scientific evidence, this does not lead to evidence-based policies. My fear is that because of a strong pre-existing ideology against electronic cigarettes

because they simulate the physical actions of smoking, tobacco control groups are drawing conclusions based on ideology rather than on science."

you believe in "science-based" policy on the e-cig thing a ma jig yet ideology based when it comes to your SHS scam ??? you can't have it both ways siegel....

3 ^ | v • Reply • Share >



Derek Yach • a year ago

Important early evidence suggesting that the theoretical fear of kids starting on e-cigs migrating to tobacco products may not be warranted. More studies in different settings and if longer duration will help.

^ | v • Reply • Share >



sheila → Derek Yach • a year ago

Make sure the patch and gum pushers, who did the SHS "studies" don't do the e cig "studies" or you are screwed.

12 ^ | v • Reply • Share >



Harry • a year ago

Here's a fine bit of nonsense:

"Raising the minimum sales age to 21 would reduce smoking among 14 to 17 year olds by two-thirds and cut rates by a little over half for 18 to 20 year olds, the health department said."

It's as though the easily-persuaded have been so brainwashed by lies that they'll now accept anything put out by an entity that goes under the title Health Department.

<http://in.reuters.com/article/...>

3 ^ | v • Reply • Share >



Sir_JayR → Harry • a year ago

So, 1/3 of the 14-17 year olds will still smoke.

The 18-20 year old young adults can go off and fight a war, and 40% of them use tobacco on the battlefield to increase vigilance and reduce combat stress and weight gain. Trying to police tobacco use in the sandbox would tie up too many scarce resources. But when these young warriors return home the NYC Tobacco Police would have them buy their smokes in New Jersey,

Welcome home,

7 ^ | v • Reply • Share >



Harry • a year ago

"The issue of whether electronic cigarettes serve as a gateway to youth tobacco addiction is a very serious one. It should not be taken lightly. If these products lead to increased cigarette smoking among youth then this harm would offset the benefits of enhanced smoking cessation and electronic cigarettes would no longer have net public health benefits. So this is a crucial research question."

You can't possibly know, doctor, whether there'd be a net offset in the direction you state. Or is that what you mean by "public policies must be science-based"?

5 ^ | v • Reply • Share >



Uma Kirk → Harry · a year ago

That one is an easy study. In a controlled lab setting, of course, hand 10 new never smoked an eGo Twist, with a Kanger T3 clearomizers or a Kanger ProTank2 and an assortment of Flavors to try @ 0-mg). Do the same with 10 always smoked, except with 12-16mg. At the end of day 2, hand each groupie a cigarette. Repeat at the end of one week.

Be handy with a mop & bucket first though...

1 ^ | v · Reply · Share >



epiphany · a year ago

It's really time to start denormalizing the anti-smokers at Tobacco Control. The first step is to use language appropriate to the various whopper lies they use. In pointing out a lie, it is necessary to use descriptive language of both the liar and the lie he tells. So, here, you refer to Frieden as an ideologue. That word carries with it an impression that he has a lofty mission that is for the good of us all. Clearly, Frieden does not have a lofty mission. He has a financial mission with ties to the drug companies who pay for his research and support his self-serving mission. So, start there by calling the so-called scientist what he is: a liar. There is no idealism in this movement, just greed and a lust for power. The continuing popularity of e cigs is not a threat to health. It is a threat to funding, nothing more and nothing less.

9 ^ | v · Reply · Share >



Sir_JayR → epiphany · a year ago

The better term is "confabulator".
Just like (Insular) stroke patients who confabulate (make up stories) to justify their new perceptions.

2 ^ | v · Reply · Share >



ladyraj · a year ago

Oh yes, the classic "gateway" argument. How does one defend against this nonsense association? By definition the association is made by pairing an initiating variable with a purported outcome variable. Using this logic I could proclaim that taking a bath is a gateway to drowning. lol

I can see it now....a child eats candy cigarettes and later in life that child begins using candy flavored e-cigs and eventually starts actually smoking cigarettes. Yep multiple gateways...they are everywhere, evidently!

6 ^ | v · Reply · Share >



Diane → ladyraj · a year ago

Marijuana was once the gateway drug to crack, cocaine and heroin. Makes me wonder what those in tobacco control is really smoking.

6 ^ | v · Reply · Share >



FXR · a year ago

Public Health is a gateway to the dark ages.

The science is settled !

7 ^ | v · Reply · Share >



Rehan Zaib · a year ago

eCig-Cigarette does not contain the over 4000 POISONOUS substances and harmful CHEMICALS found in real cigarettes that

cause heart attack and cancer, such as nicotine, tar, carbon monoxide, acetone, sulfuric acid & more.

You can ENJOY the eCig Cigarette in places where regular cigarettes are PROHIBITED, even in bed.

[Electronic Cigarettes](#)

2 ^ | v • Reply • Share ›



Rehan Zaib • a year ago

Electronic cigarettes are sparking lots of skepticism from public health types worried they may be a gateway to regular smoking.

But the cigarettes, which use water vapor to deliver nicotine into the lungs, may be as good as the patch when it comes to stop-smoking aids, a study finds.

[Electronic Cigarette Pakistan](#)

^ | v • Reply • Share ›



Sean Ben • 7 months ago

The smoke free safe smoking alternative device that don't contain the tar ash carcinogens and any such harmful ingredients in it like the normal cigs.

<http://www.atmostechnology.com>

^ | v • Reply • Share ›



thomas • 6 months ago

This blog post is really great; the standard stuff of the post is genuinely amazing.

<http://www.nitrovapes.com/prod...>

^ | v • Reply • Share ›



sameer bhatia • 5 months ago

Superb blog i really like it thanks for share and visit this site its so wonderful sites.

[electronic cigarette](#)

Thank you
Sameer Bhatia

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Albert einstien • 4 months ago

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Guest • 4 months ago

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Albert einstien • 4 months ago

<http://www.vividsmoke.com/ela-...>

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Daniel Kwok • 2 months ago

If you are being attentive to learn several strategies then you ought to browse this article, I am certain you'll get much additional from this article. [electronic cigarettes](#)

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Vapers Nightly News

Saturday, 19 January 2013

The Anti-Tobacco Activist's Foundation is a Lie

[1. The Anti-Tobacco Activists Know that their Ulterior Motives are Flawed, and so they take advantage of a Complex Debate](#)

Prof Stan Glantz and several of his colleagues submitted a public comment to the FDA docket regarding a "Report to Congress on Innovative Products and Treatments for Tobacco Dependence". Glantz and his colleagues made note of the fact that electronic cigarettes were successfully [ruled by The US Courts in 2010](#) to be excluded from FDA regulations, and regulated as "tobacco products" specifically because electronic cigarettes were not being marketed with therapeutic claims.

However, companies such as Sottera (owner of [NJOY](#)), and [SFATA](#) (an ecig trade association founded by [V2cigs](#)), are claiming that their products are "treatments for nicotine dependence". This was [criticised by TVECA](#), another ecig trade association that wishes to keep electronic cigarettes classified as tobacco products. Glantz argues that if electronic cigarette companies are marketing their products with therapeutic claims, the FDA should regulate electronic cigarettes as drug devices under the Food Drug and Cosmetic Act. Glantz also believes the FDA should restrict consumer advocate associations from making such claims, essentially aiming to stifle free political speech.

This is a very deceitful and insidious move by Glantz in attempt to restrict public access to knowledge about the usefulness of electronic cigarettes.

For decades, anti-tobacco activists and Governments have worked hard and spent a lot of money on social engineering, attempting to de-normalize the activity of tobacco smoking. Glantz's number one dilemma with electronic cigarettes, as has been argued by many anti-tobacco activists and the [World Health Organization](#), is that the mere appearance of electronic cigarette usage looks like tobacco smoking. Electronic cigarette usage, despite an overwhelming number of individual testimonies claiming that it has been beneficial in smoking cessation, is therefore perceived by the anti-tobacco activists to be a severe threat to their efforts to de-normalize tobacco smoking. Anti-tobacco activists, when arguing this point, often attempt to persuade public opinion by using emotional claims regarding the persuasion of children to use electronic cigarettes, at which they ultimately lead to their "gateway to tobacco smoking" fallacy.

This argument by anti-tobacco activists is nothing less than absurd. As Michael Ryan, co-director of E-Lites, pointed out in a [recent interview](#) whilst holding up a glass of water;

"if somebody sees me drinking a glass of water, does that mean they're going to go out and drink a glass of vodka because it looks like it?"

The reality is that electronic cigarette use does not normalize tobacco smoking. It normalizes electronic cigarette use.

Glantz understands that his main argument against electronic cigarettes is flawed, and hence has no real foundation to argue against electronic cigarette use. So instead, Glantz is taking advantage of the internal dispute within the electronic cigarette industry over whether electronic cigarettes should be classified as medical devices or tobacco products. He is seeking to use this unresolved debate to his advantage in hindering the spread of public knowledge of electronic cigarettes as a safe and effective alternative to tobacco smoking, and prevent further growth of the industry and public consumption.

If electronic cigarettes are classified as medical devices, then, as Glantz claims, they will have to undergo extensive longitudinal studies. It was [speculated by Prof Carl Phillips](#) that possibly;

"Glantz's real motive is that a longitudinal study would take much longer than clinical trials, and he just wants to stall"

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Glantz also makes the outrageous claim that due to the overwhelming individual submissions to the FDA by electronic cigarette users about their use of the devices for smoking cessation, the companies that sold them their products, and political associations that aided their use, are engaging in false advertisement - that the publication of personal testimonies on successful smoking cessation by electronic cigarettes is not free political speech - it is commercial speech which can be regulated.

Glantz has essentially argued that the electronic cigarette users who have submitted their personal testimonies to the FDA, are merely pawns of the electronic cigarette industry and consumer advocate associations, brainwashed into falsely believing that the products they use are of benefit to their health.

If electronic cigarettes are classified as tobacco products, then they could be subject to strict regulations, including the banning of nicotine liquids (loose juice) and on-line sales, which would have a devastating impact of the industry. Companies that primarily sell via retail stores and sell only pre-filled, non-refillable cartomizers wont be affected to the same extent. It should be noted that most of the companies that TVECA represent are companies that would not be affected by strict restrictions of the Tobacco regulations.

Either way, Glantz seeks to benefit by preserving his ideology that the only way to cease tobacco smoking is to use Nicotine Replacement Therapies (NRTs) or quit cold turkey - a very false and dangerous perception of the tobacco smoking epidemic.

2. There is no useful "Placebo" for Electronic Cigarettes

If one were to look closely at Glantz's reasoning that there is no scientific evidence that electronic cigarettes aid in smoking cessation, they would see that his grasp of science is indeed tenuous.

This week Glantz [came under heavy criticism](#) by two prominent pro-Tobacco Harm Reduction Public Health Professors, Micheal Siegel and Carl V Phillips, when he publicly announced that he believes that individual testimonies by electronic cigarette users are not evidence of electronic cigarettes as useful in smoking cessation. He has also begun censoring commentary from his university blog by individuals who contradict his arguments with their personal accounts on how electronic cigarettes have aided them in tobacco smoking cessation.

In his distorted reasoning Glantz references the "Placebo effect", indicating that since no studies have been conducted to test whether electronic cigarettes are more effective than the apparent 'placebo control' of the electronic cigarette, then there is no evidence yet that electronic cigarettes do work as smoking cessation aids.

Glantz then continued ;

"If and when there are high quality longitudinal studies showing that e-cigarettes as actually used actually help people quit smoking conventional cigarettes, I will modify my opinions on e-cigarettes as cessation aids"

This comment clearly demonstrates Glantz's lack of understanding about electronic cigarettes in aiding smoking cessation, and quite possibly science in general. Professors [Phillips](#) and [Siegel](#) wrote extensively on Glantz's referencing of a placebo control for testing electronic cigarette effectiveness.

Phillips wrote ;

"...while [clinical studies] are great for studying people's biology under fairly simple circumstances (e.g., for assessing most disease treatment options), they are generally quite poor for studying anything else, like behavior. Something like smoking cessation involves the effects of countless complicated real-world factors that are absent from an artificial clinical setting"

Phillips also makes note of what a placebo actually is, and explains the Hawthorn effect ;

"When a placebo is referred to without a research context, it generally refers to an actual treatment method, in which someone is cured of a disease by intentionally tricking them into believing they are receiving a treatment with known benefits..."

"...In clinical studies where some subjects are just given a sugar pill, there is perhaps some placebo effect. However, this is actually probably dwarfed by the "Hawthorne effect", the tendency of people to behave differently just because they know they are being studied, regardless of whether anything is being done to them."

Phillips also makes note that the Hawthorn effect would have most likely affected clinical studies of NRT products ;

"in the real clinical studies, extra cessation ... would mostly result from people who had been seriously thinking about quitting one of these days, and who — because they know that someone is watching them to see if it happens right now — go ahead and do it."

and noted that ;

"both placebo and Hawthorne effects are much more likely when the outcome of interest is decision-based rather than biological"

Phillip's also points out that Glantz was most likely confusing the placebo effect with the Hawthorn effect, and was claiming that electronic cigarette use in aid of smoking cessation was being subject to the same false positives as is thought to occur in NRT clinical trials.

Nevertheless, as Phillips mentions, that in NRT trials, people do become abstinent for a finite time at a much higher rate than smokers on average. But the effect is basically the same for those people on the NRT placebo.

And here lies the major difference between clinical testing of NRTs and Electronic cigarettes. Since NRTs are a chemical treatment, testing whether a particular drug being administered affects a particular behaviour, the subject being tested can be given a treatment that did not contain the substance (i.e a placebo).

With electronic cigarettes, you cannot administer a placebo control.

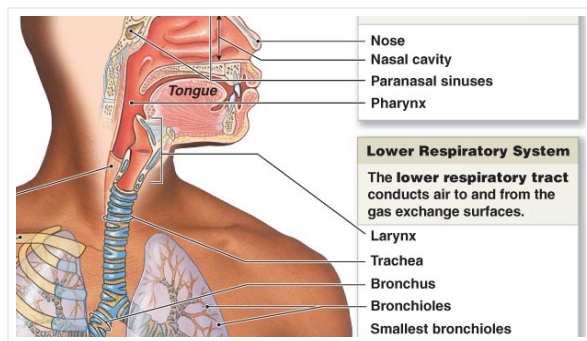
Electronic cigarette usage is far more complex than the administration of a drug. Electronic cigarette usage is behavioural and involves multiple factors such as the placing of a physical object in the mouth, the inhalation and exhalation of visible gas, the sensation of warm air in the mouth, the sensation of a throat hit, taste, smell, and obviously arm and hand movements. You cannot provide a fake alternative to test the effectiveness of this activity in smoking cessation.

In essence, the subjects cannot be *tricked* in the same manner that they can in an NRT trial.

3. Electronic cigarette use involves a number of factors, each as essential as each other

Of course, nicotine is a major aspect of electronic cigarette use, however, what most anti-tobacco/anti-ecig activists appear to be completely unaware of, is that apart from it's stimulative effects, nicotine contributes to another major and essential aspect of electronic cigarette use.

Part of the smoking simulation is what is called the "throat hit". It is the very brief sensation at the back of the throat as a person inhales the vapor or smoke. The science behind throat hit is still obscure. It may be caused by the sensation of the nicotine chemical reacting with the tissue lining of the Pharynx (back of the throat). Alternatively, it may be caused by the forcing of vaporised nicotine molecules into tighter spaces of the lower respiratory track (larynx and Trachea). In either case, the "throat hit" is an essential and critical aspect of a successful electronic cigarette product.



Nicotine is very much the main contributor to throat hit. An e-juice containing zero milligrams of nicotine will produce absolutely no throat hit. As a result, an electronic cigarette e-juice containing a zero nicotine could never be used as placebo control in a clinical setting.

There are, however, products on the market that have attempted to mimic the throat-hit provided by nicotine. These include FlavourArt's Flash, Totally Wicked' Diablo Loco, and Hangsen's Throat Hit E Liquid. It is suspected that these products use Capsaicin (chemical responsible for Chili spiciness) as their main component. Some electronic cigarette users have reported that Pure Grain alcohol can also be used to achieve a simulated nicotine-like throat hit.

Reviews of all these products however have [not been very positive](#), as they appear to be providing more of a [chemical burn sensation](#) rather than the very unique kind of throat hit that nicotine provides. They also affect the flavor of the vapor, with some users claiming they can taste the peppery-ness of the Capsaicin.

Hence, as of yet, no suitable placebo exists to test whether nicotine *has* to be an essential part of electronic cigarette use. If a suitable throat hit replacement were to be designed or discovered, the stimulant effects of nicotine consumed via electronic cigarettes could be tested in double blind placebo controlled experiments. As of now, since only nicotine can provide the desired throat hit that electronic cigarette users desire, nicotine is therefore essential to electronic cigarette use.

The topic of nicotine alone is beside the point of this particular discussion, and in any case, the anti-tobacco/anti-ecig activist's real problem with electronic cigarettes use is the *appearance* of it, rather than the *substance being consumed*.

What's actually being questioned here is the evidence for electronic cigarette usage as a whole, as being effective in smoking cessation. As noted previously, electronic cigarette use involves a number of factors. Each factor is as essential as each other to making what is essentially *electronic cigarette use*. Factors such as flavor, cloudiness of the vapor exhaled, temperature of the vapor, as well as nicotine concentration, all make up what is essentially electronic cigarette use.

Most importantly, each factor's involvement varies depending on the product and/or user self-set ups. Even the color of the electronic cigarette device can be considered an essential part of the use. In other words, **Personal Customization is vital for electronic cigarettes to work**, which is why it is critical that products such as liquids containing various levels of nicotine (aka "loose juice"), various flavorings, various refillable cartridge types, and various battery types must remain available to consumers.

4. What is Currently being Tested?

This post is not to make light of what clinical studies could provide. As one of [Phillips' responders](#) (Rory Morrison) wrote;

"just having lots of success stories is enough to assess that something works, but is not that useful in quantifying how well it works, or how well it works compared to something else, which method is the one for a commissioner...to recommend? the one with the most success stories? the one with the best-written ones? the most entertaining ones?"

Further, as [Siegel noted](#) ;

"Obviously, we also need clinical studies that document the cessation rates and the amount of smoking reduction achieved with electronic cigarettes. But to deny that the case reports are part of the overall scientific evidence is to ignore the science"

Indeed, a [clinical study](#) (pg16) funded by Health Research Council of New Zealand is being conducted on electronic cigarettes. In this study, 653 Participants are being tested, whereby 290 participants will use electronic cigarettes containing 16mg/ml cartridges, 290 participants will use 21mg nicotine Patches, and 73 will use electronic cigarettes with cartridges containing 0mg nicotine, all over a 12 week period. The participants will be using electronic cigarette devices and cartridges provided by PGM International Ltd, which means they are most certainly using the [Elusion 510](#) model.

Participants included in this study are smokers of 10 or more cigarettes per day, and who have been smoking for longer than one year. They are people over the age of 18 and who want to quit smoking. The primary test for smoking cessation of the participants will be by the measuring of carbon monoxide level exhaled, which is a [marker for evaluating smoking abstinence](#). However, as a secondary measurement, self reports of continuous abstinence at 1, 3 and 6 months after quit day will be recorded.

This secondary measurement of electronic cigarette usage is interesting. In criticism of Glantz's claim that personal testimonies of successful smoking cessation with electronic cigarettes are not scientific evidence, [Siegel writes](#) ;

"While case reports are obviously not the highest standard of scientific evidence, they are undeniably a valid form of scientific evidence. In the case of electronic cigarettes, the fact that millions of vapers are using these products with success is undoubtedly a valid piece of scientific evidence that these

products are useful as alternatives to smoking"

Is this study actually a good test for electronic cigarette efficacy in smoking cessation? It is probably not the kind of study that tests electronic cigarettes to their full potential as most electronic cigarette enthusiasts would explain. The key challenges listed in this study include frequent battery failure and participant withdrawal from the trial. Most electronic cigarette enthusiasts would suspect that these challenges are due to the quality design of PGM's Elusion e-cigarette device. It might be speculated that perhaps the withdrawal of participants from the trial could be due to insufficient knowledge about electronic cigarettes, media publications [falsely exaggerating the dangers of electronic cigarettes based on unpublished non-peer reviewed studies](#), and even a dislike of the electronic cigarette flavoring, battery charge time, and throat hit sensation - particularly in the sample of participants using the 0mg cartridges.

Understandably, in order keep all samples consistent for testing purposes, Personal Customization of the electronic cigarettes is not part of this study, so as mentioned above, essential aspects of electronic cigarette use are not being properly tested.

However, it is a start. This is the only electronic cigarette efficacy trial to be embarked upon to date. By early September 2012, more than 50% of participants had been randomized. Prior to this study, there had been one published [pilot study](#) showing that 54% of smokers were able to quit smoking or to cut down their smoking by more than half. This is contrary to Glantz's claim that "***such studies simply do not exist***".

5. The False Dichotomy

The whole topic of '*evidence for the efficacy of electronic cigarettes as a smoking cessation aid*' is clearly obscure. As noted in a [previous forum post](#), aside from studies that show the electronic cigarette vapor contains only minuscule amounts of toxins, and a few important [medical studies](#) on a small sample number of patients showing that electronic cigarettes are significantly safer than tobacco cigarettes, individual testimonies are perhaps the strongest evidence we have.

However, some may question the need for electronic cigarettes to be proven as smoking cessation aids in the first place. They may also ask why the devices and nicotine containing liquids can't simply be regulated as their own form of recreation product, just as caffeine or alcohol is.

There really is no need for electronic cigarettes and nicotine liquids to be classified as either a tobacco or medical product. This is a false dichotomy constructed by the anti-tobacco groups, and those who seek to profit by falsely labeling the behavior of tobacco smoking as a disease in and as itself.

As [Carl Phillips notes](#);

Smoking causes disease, of course, but it is obviously a consumer behavior, not a disease.

Pharmaceutical NRT producers, particularly, profit from this, both with the sale of their *cure* for this *disease*, as well as by politically hindering the growth of their market competitors; the electronic cigarette industry.

There is really no need for electronic cigarettes to be proved as smoking cessation product. Smoking cessation is actually a product of electronic cigarette usage. Only in the false conception that tobacco smoking is a disease, does the electronic cigarette's smoking cessation property become a *therapeutic device*, and therefore subject to regulations imposed on therapeutics.

Perhaps it's not the numerous absurd and trivial arguments spouted by the anti-tobacco/anti-ecig activists that we should be focusing on, but the underlying cultural propaganda on which they survive. Their entire approach to solving the tobacco smoking epidemic is founded on a misconception, a lie, and it is this foundation that should be attacked, rather than the trivial arrows they keep firing at us.

Posted by [Vapers Nightly News](#) at 15:31

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4 comments:



Michael J. McFadden 20 January 2013 10:33

"There really is no need for electronic cigarettes and nicotine liquids to be classified as either a tobacco or medical product. This is a false dichotomy constructed by the anti-tobacco groups, and those who seek to profit by falsely labeling the behavior of tobacco smoking as a disease in and as itself."

Excellent article overall, but I want to focus on the importance of this particular statement near its end. This emphasis on "labeling," and in particular, "negative" labeling, is just a manifestation of the entire complex of Antismoker psychopathology.

Products like nicotine gum and e-cigarette nicotine liquids should not be labeled in such ways any more than coffee and Coca-Cola should be similarly labeled because of their caffeine content. The drive for derogatory language and labeling stems from the need to support the negative imagery that supports the general world of antismoking psychology.

While it's clearly a very superficial summary of a much more complex subject, Stephanie Stahl's analysis of ASDS (AntiSmokers' Dysfunction Syndrome) is wonderfully done and well worth reading. See:

<http://wispofsmoke.net/recovery.html>

Aside from the psychological aspects of course there's also the practical end of things. Successfully labeling e-cigarettes as either "tobacco" or "medical" immediately puts them under a level of government control that will allow them to be heavily limited or taxed, thereby removing them from the reach of smokers who might like to switch to them or from people who might simply try them and enjoy them. For many Antismokers, the mere idea of people "looking" like they're doing something that resembles smoking sets off a wave of frantic concern, even if the activity is fairly or totally harmless and absent of annoying side effects for others. And the threat that their money streams could dry up as people avoid tobacco taxes in making such a switch is a profound threat for many of these so-called "activists" who depend on millions of dollars of grant money as well.

The motivations behind the antismoking movement are complex and multi-faceted in their basis, and need to be understood and appreciated by anyone working against them or in favor of substitutes such as e-cigarettes or snus. It would be simpler if it were a case of a unitary conspiracy with an easily targeted core (sort of like what Antismokers have tried to imagine with their rantings against "Big Tobacco" over the years) but it's not: it's a hydra-headed complex of many different people and groups with vastly different motivations ... "all" of which need to be addressed by those working to put it back into a reasonable box.

There's nothing inherently "wrong" with people "enjoying" cigarettes, e-cigarettes, or snus. There are pronouncedly concerning negative side-effects when they do so with cigarettes, far fewer such side-effects with snus, and quite possibly virtually "no" such negative side effects with e-cigarettes. People should have the freedom to make their own choices with regard to such enjoyments in life and the risks they entail without unreasonable government interference, and the current movement by the "establishment" regarding vaping is definitely one of setting the stage for such interference far into the future.

It needs to be stopped.

Michael J. McFadden
Author of "Dissecting Antismokers' Brains"

[Reply](#)



Vapers Nightly News 20 January 2013 19:17

Thank You for your comment MJM.

I think you are absolutely right about the so-called "activists" who depend on millions of dollars. It's blatant self-preservation. In fact, I think some of them see electronic cigarettes as a blessing to themselves, as they now have new fodder to play with and something new to write about in their grant applications.

I will say that, while I don't think electronic cigarettes and nicotine containing liquids should be classified as the tobacco or medical products, I do believe there should be some Governmental involvement, and that sales taxes are indeed required. Obviously, not to the same excessive tax levels as that placed on combustion tobacco products, but enough to regulate the industry and

uphold AEMSA's product standards (www.aemsa.org).

A small sales tax to pay for regulating against dodgy vendors is both beneficial and a small price to pay for legitimacy.

Lastly, a post on the ECF forum by Bill Godshall I believe is noteworthy in regards to the topic of labeling of smoking as "a disease".

Godshall writes ;

"...I also think a competent lawyer for an e-cigarette company can convince the federal courts that since "smoking" is not a disease or disorder, claiming that an e-cigarette can help someone quit smoking is not a "therapeutic claim". In fact, that's why the FDA has approved drugs for treating "tobacco dependence", not for treating "smoking". And I'm not aware of any e-cigarette company that has ever claimed their products treat "tobacco dependence". "

<http://www.e-cigarette-forum.com/forum/legislation-news/371175-stan-glantz-attacks-e-cigarette-industry-because-thousands-vapers-sent-comments-fda.html#post8362646>

[Reply](#)



Michael J. McFadden 23 January 2013 08:56

VNN, yes, I've always found the Antis' ability to avoid cognitive dissonance through doublethink to be fascinating. The question of "addiction" is particularly notable for this. Note how they'll claim, in quick succession, without ever noticing the internal contradictions:

- 1) Nicotine is the most addictive drug on the face of the earth.
- 2) Smokers should have no difficulty at all simply skipping their regular doses while in smoke-banned facilities. What's the big deal, right?
- 3) The "treatment" to give up this most addictive drug is for Big Pharma to sell smokers MORE of the addictive drug in its NRT products.

That final point brought me to this idea that I plan to make millions from!

===

A NEW form of gum therapy:

c*H*ick-o-lets!

Heroin gum for those seeking to kick the comparatively mild habit of heroin! Available in candy flavors at your local pharmacy, and no prescription or age-limits involved! Buy a bagful now! Perfect for stocking stuffers! And, as Jessica Simpson might say, it's "like having a party in my mouth!"

- MJM

[Reply](#)

jessica robert 13 February 2013 02:44

Yes it is correct that **Electronic Cigarettes INC** are a great achievement as compare to traditional cigarette and it is best for those people who are addicted in smoking.

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Key points:

- electronic cigarettes (e-cigarettes) are battery-powered devices that heat a liquid often containing nicotine and flavourings into an inhalable form – awareness and use of e-cigarettes among adult smokers and ex-smokers has risen rapidly in Scotland and the UK over recent years with negligible current use among adults who have never smoked
- because they are new products there is no direct evidence on the long-term safety of e-cigarettes themselves; analysis of the emissions from e-cigarettes finds many fewer potentially hazardous chemicals than in tobacco smoke, with those that exist typically in much lower quantities – most experts expect e-cigarettes to prove considerably less harmful to the user than tobacco smoking
- although e-cigarettes use does result in ‘second-hand vapour’ to some extent, these levels are likely to be very low and there is as yet no scientific consensus that such exposures pose a general risk to the health of bystanders
- e-cigarettes have been shown to deliver nicotine to the body effectively, though this varies by device type and configuration – current e-cigarettes seem to deliver nicotine more slowly than smoking tobacco
- there is little high-quality research on e-cigarette for stopping or as a substitute to smoking tobacco; one better quality randomised controlled trial from New Zealand found an e-cigarette with relatively poor nicotine delivery was about as effective as a medicinal nicotine patch, while a well-designed observational study from England found smokers who attempted to stop using an e-cigarette were more likely to be abstinent from smoking than those who quit using medicinal nicotine bought over-the-counter, or no aid
- the limited data on e-cigarette use among young people does not suggest a strong ‘gateway to smoking’ effect in the UK at present, but research on the issue is sparse and there is apparent disagreement and confusion over what a ‘gateway’ effect would look like were it to exist – researchers have recently highlighted the need for common standards and understanding in this area
- other issues to be addressed relating to e-cigarettes include adequate safety controls to prevent accidental injury, monitoring of trends in ‘dual use’ (e-cigarette use combined with continued smoking), regulation of marketing activity, and the involvement of the tobacco industry in the e-cigarette market
- Under new European regulations, by May 2016, e-cigarettes will be subject to either voluntary medicines regulation if they want to make claims to treat or prevent disease, or for products that do not seek to make therapeutic claims, a range of new controls on product quality, safety, and marketing.

What are e-cigarettes?

'Electronic cigarette' (e-cigarette) is the most commonly used term for a family of non-tobacco, non-medicinal, nicotine delivery devices that have become increasingly popular in recent years in Scotland and the rest of the UK. E-cigarettes come in a wide variety of different configurations, and are made and sold by many different manufacturers. Most e-cigarettes share common features of basic operation and have a battery (varying in size, type, capacity, and voltage) that is used to pass a current through a resistance coil (the atomiser) that is in contact with a fluid. The heat from the coil generates an aerosol from the fluid, without combustion, which is then able to be inhaled by the user (the aerosol is often referred to as 'vapour' hence the term 'vaping' is often used to describe e-cigarette use). The fluid used in most e-cigarettes normally consists of a carrier liquid of propylene glycol or glycerine (or a combination of the two), often nicotine (in a variety of concentrations), and frequently additives to enhance the palatability of the aerosol, such as flavourings¹.

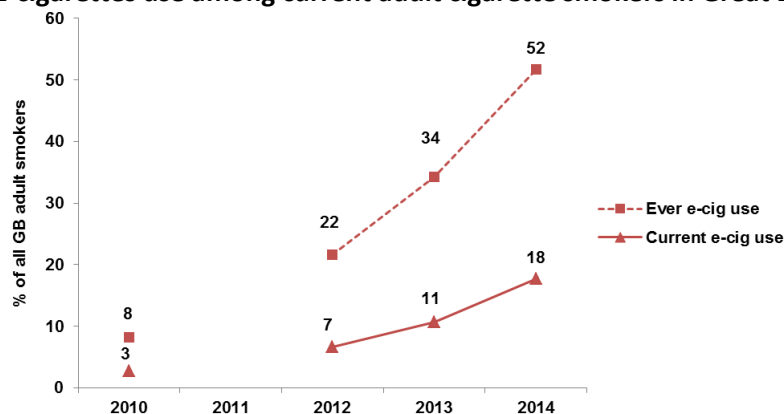
Physically, some types of e-cigarettes are made to resemble tobacco cigarettes with the 'filter' part of the e-cigarette being a cartridge containing the heating element and fluid (the 'cartomiser'), while the battery is typically made to look like the tobacco-containing part of a traditional cigarette. These are sometimes referred to in the UK as 'first generation' e-cigarettes or 'cigalikes'² and are either sold as disposable, or with replaceable pre-filled sealed cartridges. 'Second and third generation'² e-cigarettes typically do not resemble tobacco cigarettes and often have larger batteries and refillable liquid reservoirs (often called 'clearomisers' or 'tank' systems) or other more advanced features (such as variable voltage systems to alter the 'vaping' experience). In contrast to cigarette-like e-cigarettes where the whole cartridge normally needs to be replaced when it is empty, these e-cigarettes allow the user to refill the device with any of the different types of liquid (often referred to as 'e-liquid' or 'e-juice') themselves without replacing the reservoir each time, a practice users report as more economical.

E-cigarettes are relatively new products and the market changes rapidly, because of this terminology is also rapidly changing and different terms are often used colloquially or in marketing to refer to the same products, or substantively similar products. E.g. the different terms 'e-cigarettes', 'e-shisha', 'vape pens', 'personal vapourisers' 'shisha pens' can often refer to the same technology. Most e-cigarettes currently on the market are manufactured in China, imported to their target markets, and sold to the consumer via third party resellers³.

Who uses e-cigarettes in Scotland/Great Britain and what type of e-cigarette do they use?

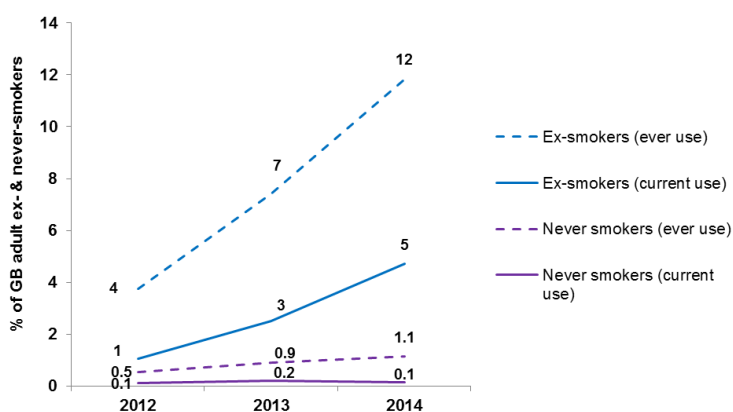
Adult awareness and use of e-cigarettes has increased rapidly in Scotland, as it has in the rest of the UK. In 2010 only 3% of adult (age 18+) smokers in Scotland reported using an e-cigarette, while by early 2014 this had risen to 17%⁴. The graphs below show patterns of e-cigarette use, by smoking status, among a large sample of adults in Great Britain⁵.

E-cigarettes use among current adult cigarette smokers in Great Britain (2010 -2014)



Unweighted base: GB adult smokers (2010, n=2297; 2012, n=2093; 2013, n=1895; 2014, n=1776)

E-cigarettes use among ex- and never smoking adults in Great Britain (2012 – 2014)

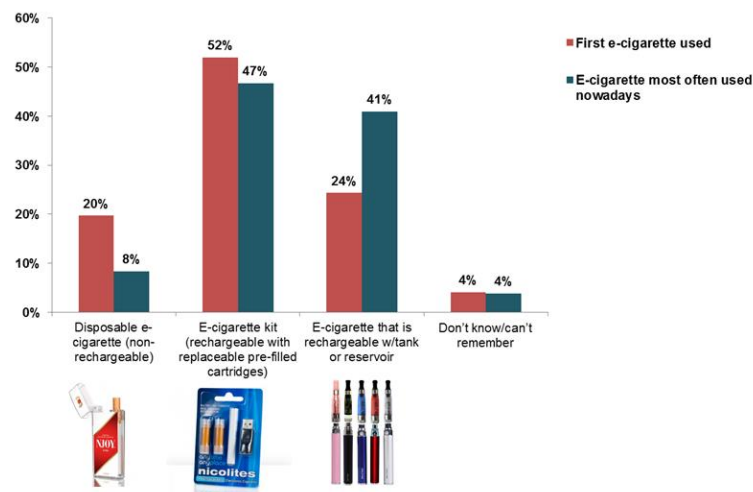


Unweighted base: GB adult ex-smokers (2012, n=4473; 2013, n=4303; 2014, n=4498), GB adult never smokers (2012, n=5886; 2013, n=5973; 2014, n=5995)

E-cig current use and experimentation among current and ex-smokers has increased rapidly over time, while current use among adult never tobacco cigarette smokers is, at present, negligible. This survey gives very similar estimates of e-cigarette use to the only other large general population survey of e-cigarette use among adults available at the present time⁶. The principal reasons e-cigarette users report for their use are as a stop-smoking aid, as an aid to prevent relapse to smoking, and to reduce smoking⁷. There are an estimated 2.1 million adult e-cigarette users in Great Britain in March 2014, approximately one-third being ex-smokers with the remaining two-thirds being current smokers⁷.

When looking at product choice among current e-cigarette users (both the type of e-cigarette they first used, and the type they are using now) in the graph below, most e-cigarette users started with a cigarette-like device (either disposable or rechargeable), but were more likely to report use of a rechargeable, refillable 'second generation' type device for the e-cigarette they are using now.

Type of e-cigarette first tried and type most often used now among current e-cigarette users in Great Britain (2014)



Unweighted base: GB adults who reported having tried e-cigarettes and still use them (n=498)

How hazardous are e-cigarettes to their users or bystanders?

E-cigarettes are new products, and as such there are no long term studies on the health effects of the products themselves. Because of this, judgements around the likely hazards of e-cigarettes are made from looking at chemical analysis and short-term studies on the products themselves and studies of long-term exposure to the chemicals present in e-cigarettes in other contexts.

Many e-cigarettes contain nicotine, the primary psychoactive dependence-inducing component of tobacco. Nicotine itself, in the doses smokers (or users of therapeutic nicotine replacement therapies – NRTs) are normally exposed to, is not considered especially harmful to health⁸. High quality controlled trials of short term treatment with therapeutic nicotine finds side-effects are common but normally mild and transient^{9,10}. Most trials only involve a short duration of NRT administration, with relatively short follow-up, however longer-term studies with extended duration of NRT use have not shown NRT to increase the risk of adverse cardiac outcomes¹¹ (when followed up for 5 years), nor cancer (when followed up for 12.5 years)¹².

Reviews of the many long-term studies of lower-toxicant smokeless tobacco products as used in some Scandinavian countries (that deliver nicotine, but also other chemicals such as tobacco-specific *N*-nitrosamines^{13,14,15}) find that use is not associated with cancer at most sites, or at sites where associations have been found, they are typically of lower magnitude than smoking^{16,17}. The use of these products may be associated with poorer cancer outcomes, once cancer has already been diagnosed¹⁸. Use of these products is not strongly associated with the incidence of cardiovascular disease^{19,20,21,22} though, as with cancer outcomes, it may be associated with greater likelihood of a fatal case^{19,20,22}.

Overall, nicotine delivered in forms other than via smoked tobacco does not have strong associations with disease, though there remains poor evidence in some groups (particularly during pregnancy, where there are potential developmental risks and a lack of good studies conducted in humans^{8,23,24}). Nicotine on its own is much less hazardous than smoking. Although public understanding of this in the UK appears to have improved over time, it remains poor as people tend to overestimate the risks posed by nicotine²⁵.

The carrier liquid used in many e-cigarettes is propylene glycol (PG). Toxicology reviews consider PG as presenting a low risk to human health²⁶, and its inclusion in other substances intended for human consumption (e.g. in food) has been approved by regulators for many years²⁷. Both PG and another commonly used carrier fluid vegetable glycerine (VG) are ingredients in an existing medical preparation of nicotine; the nicotine mouthspray²⁸. However, the type of exposure to PG/VG resulting from e-cigarettes use (long-duration high intensity inhalation of an aerosol generated by heat) does not have a precedent, and a review of the probable health effects of such exposure to PG/VG concludes that monitoring and surveillance of health outcomes is warranted²⁹.

Flavourings used in e-cigarettes to make use more palatable are often food additives³, that, while normally considered safe for oral consumption, may present health concerns when inhaled. A lab study of liquid cytotoxicity (being toxic to cells) of 35 e-liquids found that cytotoxicity was unrelated to nicotine content, but was correlated with the number and concentration of flavourings³⁰, suggesting this should be an area of continued investigation and monitoring.

As a result of the heating process, the constituents of the aerosol generated from e-cigarettes may be different from the constituents of the liquid. Because of this, the most informative analyses of the probable risk profile of e-cigarettes to the user are those that analyse the aerosol itself, as they examine levels of contaminants and other potentially harmful agents regardless of whether they come from a contamination of the liquid (or the use of a problematic flavourings), or arise as a by-product of heating. Several studies exist on this topic^{e.g. 31,32,33} including many unpublished lab reports, the results of which have been summarised in a recent systematic review²⁹.

These studies vary widely in methods, quality, and devices studied (and owing to the diversity and rapidly evolving nature of the e-cigarette market, cannot be taken to represent all devices). Substances tested for by these studies include polycyclic aromatic hydrocarbons (a family including several established carcinogens), volatile organic compounds (e.g. acrolein, acetaldehyde, formaldehyde) and metals (e.g. cadmium, lead). Overall, these studies tend to detect many fewer potentially hazardous chemicals than found in tobacco smoke with those that are found being at much lower quantities; however there is significant variation between devices³¹. Comparing the contaminants to commonly used standards for involuntary workplace exposures³⁴, the review²⁹ concludes that, based on studies to date, e-cigarette users are unlikely to be exposed to levels of contaminants that would warrant concern.

A recent study suggests that, when using higher voltage configurations e-cigarettes could be capable of producing similar levels of one carcinogen, formaldehyde, in comparable levels to those found in cigarette smoke³⁵. A commentary³⁶ on the research suggests that this is probably a result of the thermal breakdown of the carrier liquid that would be expected to occur at high temperatures, and notes that, when the devices are used at lower voltages, formaldehyde emissions are several magnitudes lower than tobacco smoke. These kind of analyses could have important implications for device design and safety.

Several studies^{e.g. 37,38,39} have attempted to examine likely exposure to bystanders from e-cigarette use (i.e. 'second-hand vapour'). These studies confirm that e-cigarette use results in emission and exposure to some toxins, as would be expected given the processes involved. Analyses of the emissions find pollutants are either at low concentrations compared to equivalent emissions from cigarette smoke, or below the limit of detection for

the measurement instruments used^{39,37}. In one study³⁷ nicotine in air was found at about one-tenth of the concentration present in second-hand tobacco smoke. Measurements of the concentration of respirable 'particulate matter' (often used as a marker of tobacco cigarette smoke^{e.g.40}) taken from these studies may not be directly comparable with the equivalent measurements of smoke generated by tobacco combustion. It is not clear if researchers working on the issue of 'second-hand vapour' have adequately calibrated measurement instruments to reflect differences in the physical properties of e-cigarette emissions (likely to be larger droplets in liquid state) when compared to the combustion generation carbon-based solid particles from traditional cigarettes⁴¹. While the small particles of second-hand smoke can linger for many hours in the air after a tobacco cigarette has been extinguished, it is likely the larger particles generated by e-cigarette use settle faster, which has implications for likely levels of bystander inhaled exposure⁴¹. Overall, there is not scientific consensus that second-hand exposure to e-cigarette emissions poses a general risk to the health of bystanders, though as with other forms of more common indoor air pollution it may cause irritation or other adverse reactions among some sensitive population sub-groups.

Do e-cigarettes help people quit smoking?

In order for e-cigarettes to be effective as an aid to help people stop smoking, or as a substitute for tobacco smoking, they should be able to deliver nicotine effectively. While an early study⁴² found the two brands tested did not deliver nicotine to their participants, subsequent studies^{43,44,45} have found e-cigarettes are capable of delivering nicotine (the early study involved first-time e-cigarette users and older technology, which is likely to explain its results). Comparison of different configuration of e-cigarettes in a recent evaluation⁴⁶ found that newer generation higher performance e-cigarettes were faster at delivering nicotine than older 'cigarette like' models, however both configurations of e-cigarettes were significantly slower at delivering nicotine than a conventional tobacco cigarette.

The evident commercial success of e-cigarettes has been driven by anecdotal reporting of many cases of successful smoking cessation and substitution among long-term tobacco smokers. This has also been found among surveys among (self-selecting) populations of dedicated e-cigarette users^{47,48} and a longitudinal study⁴⁹ has found low rates of relapse to smoking among this group (though this study has several weaknesses including very high loss to follow-up).

An issue common with these type of studies is their recruitment of participants from online e-cigarette enthusiast forums, where positive experiences with e-cigarettes will be over-represented. Several experimental studies enrolling participants from the general population (to overcome these issue of self-selection) have been conducted^{50,51,52,53,54}. These generally show favourable results for e-cigarettes in terms of cessation and cigarette reduction outcomes, however several of these studies are small, lack a control group, and are the product of only two research teams (one in Italy and another in New Zealand).

The most methodologically robust of these studies (from New Zealand⁵⁴) is a moderately sized randomised controlled trial that found approximate equivalency between the one brand of e-cigarette tested (an early model with relatively poor nicotine delivery⁵⁵) and a conventional NRT patch. While the primary analysis in this study was unable to conclude that e-cigarettes were superior to the NRT patch for cessation (in part due to the low overall cessation rates observed across all participants in the study), a secondary analysis of self-reported cessation suggested a marginally higher overall effect on cessation for e-cigarettes

compared to the NRT patch, with the time till relapse to smoking being twice as long in the e-cigarette group⁵⁵.

Outside of experimental studies that may impose artificial constraints on behaviour, the cessation effects of e-cigarettes have been examined in observational studies of e-cigarette use in the general population (i.e. examining outcomes in cessation between e-cigarette users and non-users in general health or tobacco control surveys)^{56,57,58,59}. These studies do not show strong associations between e-cigarette use and cessation from smoking. However, most of these studies were not designed with the intent of examining cessation outcomes, none adequately control for the many ways in which smokers who quit using a form of assistance differ from those who do not (e.g. differing nicotine dependence, a well-established issue in similar studies of medicinal NRT^{60,61}), or involve poor measurement of e-cigarette use (e.g. being unable to discriminate between the use of e-cigarettes in a concerted effort to stop/substitute for smoking and experimentation with no intent of sustained use). Recent research from a large general population survey England has made attempts to improve on the issues present in previous observational studies, and finds that smokers who attempted to stop using e-cigarettes were more likely to report abstinence from smoking compared to those who attempted to stop with NRT bought over-the-counter, or those who used no aid⁶².

Are e-cigarettes a gateway to smoking for young people?

A concern expressed around e-cigarettes is that they will act as an entry product to nicotine for children and young people – who would otherwise never have smoked – who would then go on to smoke tobacco due to their experiences with e-cigarettes. This is a difficult proposition to assess, and similar claims have been asserted, but also challenged, in relation to lower-risk smokeless tobacco^{63,64,65,66}. The difficulty arises because, although associations between starting one nicotine product use and subsequently going on to use another may be uncovered by research, the associations are not necessarily causal (i.e. it is the use of e-cigarettes that causes later smoking) and may be explained by shared risk factors that predispose individuals to engage in both behaviours⁶⁶.

Very limited data exists on e-cigarette use among young people in the UK, and no data currently exists for Scotland alone. One survey by ASH⁶⁷ of around 1,400 11 to 18 year olds in Great Britain in 2013 who were aware of e-cigarettes found that sustained use of e-cigarettes was rare, and, at the time of the survey, confined almost entirely to children who already have a history of use of tobacco cigarettes. However, because the sample was recruited via parents who were members of a commercial online survey panel, potential biases due to panel recruitment or accurate completion of the survey (e.g. if parents or householders were present while the survey was being completed by the young person) may exist. A convenience sample of 671 young people aged 13 to 18 in Wales that took part in an online survey for ASH Wales in late 2013/early 2014 found similar results⁶⁸.

A 2013 survey conducted with around 6,000 students aged 14 to 17 in Cheshire and Merseyside found around 13% of young people surveyed reported 'having accessed' e-cigarettes (this definition includes both 'having bought' and 'having tried' e-cigarette so gives no idea of intensity of usage) with most 'access' again concentrated in young people who have a history of smoking tobacco cigarettes. E-cigarette access was also strongly positively associated with another behavioural risk factor (alcohol consumption)⁶⁹. No data on e-cigarette use among young people in Scotland exists, though it will be reported in the large, nationally representative, SALSUS survey of 13 and 15 year olds which was conducted during 2013 and is due to report in November 2014⁷⁰.

Surveys from the United States conducted for the US Centres for Disease Control and Prevention (CDC)⁷¹ have shown an approximate doubling of both 'ever' and 'current' (within the last 30 days) use among middle and high school students between 2011 and 2012. CDC also report that, in 2012, around 7% of high school students who had ever used e-cigarettes reported never smoking conventional cigarettes. The same survey shows that tobacco cigarette smoking continued to decline during the 2011 and 2012 period⁷², and, as shown by a separate large survey of the US student population, has continued to decline throughout 2013⁷³, suggesting that, if a gateway effect does exist, it is not sizeable enough to change overall reductions in tobacco cigarette prevalence.

Recent cross-sectional surveys involving large datasets of e-cigarette use in Korean⁷⁴ and US⁷⁵ adolescents, found use was associated with cigarette smoking, attempts/intent to quit, but not with abstinence from conventional cigarettes. Because of the design and limitations of these studies, the findings are consistent with both the theory that e-cigarettes encourage tobacco cigarette use, and the opposing theory that e-cigarettes are being used as alternatives to smoking by the adolescent smokers that are most heavily addicted to nicotine or otherwise predisposed to engage in risky behaviours. Hence these findings are not enlightening as to whether gateway effects are happening in these populations.

Taken as a whole, the limited data available for the UK is not suggestive of a strong gateway effect at present as there appears to be limited sustained use among never smoking young people, though this should not be taken to conclude that such an effect could not exist (or even that it exists to some extent at present, but the current evidence is inadequate to detect it). Because the existence of 'gateway' effects is challenging to either confirm or deny and there is apparent disagreement on the issue, academics working in the area have recently made a call for clarity on the criteria needed for evidence to demonstrate either the existence or absence of a gateway effect, to set a standard upon which researchers could agree⁷⁶. Such an approach could facilitate a more balanced and evidence-led assessment of risks posed by a potential gateway effect to smoking, which could then be weighed against the potential benefits of e-cigarettes as a route away from smoking.

It is possible that the forthcoming 2013 SALSUS dataset in Scotland⁷⁰ – a large dataset containing rich information on other risk factors for smoking and substance use – could be used to help in setting this standard, by examining whether never smoking e-cigarette using young people possess many of the risk factors for tobacco smoking (i.e. to investigate whether, even if they did not currently smoke tobacco at the time they were trying e-cigarettes, they were nevertheless highly at risk for doing so).

Other issues

Accidental injury, quality control/product defects

The fatal adult human dose for nicotine was, until relatively recently, thought to be around 50 to 60mg⁷⁷. A current investigation into acute nicotine toxicity⁷⁸ suggests these values are too low by a substantial margin, and that the true value is likely to be instead in the region of 500 to 1,000mg. Even if these higher thresholds are accepted, the quantity of nicotine in a 10ml refill bottle of nicotine e-liquid at the higher strength end of currently available products still has the potential to be a hazard if ingested or otherwise absorbed, especially for children. In the US calls to poison centres involving e-cigarette liquid have increased in line with the increase in prevalence of e-cigarettes use⁷⁹. There is one suspected fatal case of poisoning from e-cigarette liquid in a child from Israel⁸⁰. This highlights the importance of proper packaging, labelling, and storage instructions for e-liquids.

As described previously, toxicant emissions from e-cigarettes appear to vary substantially by device configuration³¹. The quality of manufacture and materials used (e.g. in the quality of the wicking material used to supply liquid to the heating element, the composition of the metal heating element, purity of ingredients used in the liquid) are likely to impact on user exposure to undesirable toxicants, and there appears to be significant room for improvement in some devices⁸¹. As with other rechargeable battery-powered devices, safety during charging to avoid accidental fires and injury may be improved by the incorporation of adequate overcharge protection on the devices themselves, and the provision of clear instructions on charging by the manufacturer.

Dual use

'Dual use' – continued use of smoked tobacco alongside e-cigarettes – has been highlighted as a particular concern surrounding e-cigarettes. Because even low levels of continued smoking still confers substantial health risks, the magnitude of benefits that can be expected from reduced smoking alone (without cessation) are uncertain⁸². The introduction of e-cigarettes to the market could be problematic if it extended the duration of tobacco cigarette smoking in those who would otherwise have stopped entirely.

As this issue is related to the effectiveness of e-cigarettes as a cessation or substitute for tobacco smoking (because, if, on average, e-cigarettes cause more continued smoking than they prevent, this will start to become apparent in studies of e-cigarettes that examine cessation outcomes), the research already described in the section dealing with cessation applies to some extent to questions of dual use. Looking at other analogous products, in a systematic review of randomised controlled trials of medicinal NRT products among smokers who had no intention to quit smoking, dual use of NRT and smoking resulted in more, not less, abstinence from smoking at follow-up (approximately doubling quit rates⁸³). Continued monitoring of surveillance data and well-designed observational studies are necessary to determine if e-cigarettes are different in this regard from NRT.

At the population level, although the majority of e-cigarette use in Great Britain is dual use (approximately two-thirds of e-cigarette users being current smokers with the remainder being ex-smokers⁷), population level data from a large, regular survey in England⁶ shows that there has been a recent sharp decline in cigarette smoking prevalence, and an increase in quit attempts and success rates in quitting that correlate with the rise in popularity of e-cigarettes among smokers. While this cannot necessarily demonstrate that e-cigarettes are responsible for causing these outcomes, this data is inconsistent with a large effect of e-cigarette dual use in prolonging smoking.

Marketing and advertising

Concurrent with the growth of e-cigarette popularity has been a rapid growth in the general visibility of e-cigarette marketing through a variety of advertising channels^{84,85,86}. This has caused concern in that, even if the target of adverts are exclusively adult smokers, the relatively free rein that advertisers currently have regarding e-cigarettes means there are likely to be knock-on effects in generating interest in the product and e-cigarette brands among never smokers and young people. There is a well-established evidence base on the effects of tobacco advertising and promotion on adolescent smoking uptake⁸⁷, and given similarities in tone and technique of some e-cigarette advertising to tobacco cigarette advertising from previous decades, it is plausible widespread marketing of e-cigarettes will have the consequence (intended or unintended) of generating some degree of interest and trial in never smokers and young people. There are currently processes underway to attempt to bring more regulatory control to the marketing of e-cigarettes, see the section that follows on 'what regulations apply to e-cigarettes in the UK?'

The tobacco industry

The majority of the current e-cigarette market in the UK consists of a multitude of small and medium sized businesses and several larger companies that are independent of the tobacco industry. However, in recent years major international tobacco companies have either acquired existing e-cigarette companies, or brought new e-cigarette products to market themselves. This has provoked comment that tobacco industry motives in this field are unlikely to revolve around the sole goal of reducing health harms and saving lives⁸⁸. Analysis of tobacco industry documentation⁸⁹ has suggested that tobacco companies' involvement in harm reduction is an opportunistic tactical adaptation to the shifting policy environment on tobacco that it foresees will secure reputational benefits with policy makers and public health groups. These developments can be expected to raise new challenges around limiting tobacco industry involvement in, and interference with, public health policy.

What regulations apply to e-cigarettes in the UK?

In 2010, the UK Medicines Regulator, the Medicines and Healthcare products Regulatory Agency (MHRA) consulted on bringing all unlicensed nicotine products (including e-cigarettes) into their medicines regulatory framework⁹⁰. Following responses to the consultation, the MHRA conducted a period of scientific and market research and announced in June 2013 that it wanted to proceed with medicinal regulation, and that it expected all e-cigarettes in the UK would be regulated as medicines in line with the (at the time ongoing) negotiations on the European Tobacco Products Directive⁹¹ by 2016. In October 2013 during a key vote on the Directive at the European Parliament, mandatory medicinal regulation was rejected and an alternative system was proposed. European lawmakers agreed upon a 'two-track' system whereby e-cigarettes that make a therapeutic claim to treat or prevent disease (including smoking cessation claims) will be subject to regulation as medicines. All other e-cigarettes may remain on the market provided they meet certain requirements, including:

- a maximum nicotine concentration and volume for e-cigarette devices and refill containers, with requirements for child and tamper-proofing
- mandatory consumer warnings on e-cigarettes packaging with information on ingredients
- a requirement for manufacturers to notify countries before placing new products on the market, to provide details on the ingredients and emission of the products, and to provide data of sales volumes and profile of product consumers
- a ban on many forms of advertising (most forms of advertising that have a cross-border effect including television and radio advertising) – advertising that only has a local effect such as point of sale advertising or billboards will not be covered

These measures are expected to come into force in May 2016. The European Tobacco Products Directive will not set age of sale limits on e-cigarettes at the European level; this is a matter that individual countries must take forward and the Scottish Government has indicated its intent to legislate on this matter once it has identified the most appropriate means.

The MHRA continues to encourage manufacturers to voluntarily submit products for medicines regulation in the intervening period. E-cigarettes sold on the market at present must also be in compliance with existing regulations, such as general products safety legislation and the Chemicals (Hazard Information & Packaging for Supply) Regulations 2002

(CHIP) (which together require electronic cigarettes to function as intended, and be supplied with child-resistant packaging and toxic warning labels). Trading Standards has enforcement responsibility for ensuring compliance with existing regulations. The Committees of Advertising Practice, who write and maintain the codes that govern advertising in the UK have also recently (April 2014) consulted on how to modify advertising rules on e-cigarettes in the interim period before the European regulations come into force.

As e-cigarettes do not burn tobacco or another 'lit substance or mixture' they do not come under the legislation governing Scotland's smoke-free public places⁹². Individual public and private sector bodies in Scotland are responsible for creating and implementing their own policies on e-cigarette use.

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RESEARCH ARTICLE

Open Access

Acute effects of using an electronic nicotine-delivery device (electronic cigarette) on myocardial function: comparison with the effects of regular cigarettes

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Abstract

Background: Electronic cigarettes have been developed and marketed in recent years as smoking substitutes. However, no studies have evaluated their effects on the cardiovascular system. The purpose of this study was to examine the immediate effects of electronic cigarette use on left ventricular (LV) function, compared to the well-documented acute adverse effects of smoking.

Methods: Echocardiographic examinations were performed in 36 healthy heavy smokers (SM, age 36 ± 5 years) before and after smoking 1 cigarette and in 40 electronic cigarette users (ECIG, age 35 ± 5 years) before and after using the device with "medium-strength" nicotine concentration (11 mg/ml) for 7 minutes. Mitral flow diastolic velocities (E, A), their ratio (E/A), deceleration time (DT), isovolumetric relaxation time (IVRT) and corrected-to-heart rate IVRT (IVRTc) were measured. Mitral annulus systolic (Sm), and diastolic (Em, Am) velocities were estimated. Myocardial performance index was calculated from Doppler flow (MPI) and tissue Doppler (MPIt). Longitudinal deformation measurements of global strain (GS), systolic (SRs) and diastolic (SRe, SRa) strain rate were also performed.

Results: Baseline measurements were similar in both groups. In SM, IVRT and IVRTc were prolonged, Em and SRe were decreased, and both MPI and MPIt were elevated after smoking. In ECIG, no differences were observed after device use. Comparing after-use measurements, ECIG had higher Em ($P = 0.032$) and SRe ($P = 0.022$), and lower IVRTc ($P = 0.011$), MPI ($P = 0.001$) and MPIt ($P = 0.019$). The observed differences were significant even after adjusting for changes in heart rate and blood pressure.

Conclusions: Although acute smoking causes a delay in myocardial relaxation, electronic cigarette use has no immediate effects. Electronic cigarettes' role in tobacco harm reduction should be studied intensively in order to determine whether switching to electronic cigarette use may have long-term beneficial effects on smokers' health.

Trial registration: Current Controlled Trials ISRCTN16974547

Keywords: Electronic cigarette, Smoking, Myocardial function, Diastolic function, Tobacco harm reduction, Nicotine

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Background

Smoking is a major risk factor for cardiovascular disease [1,2]. Although several pharmaceutical products are available for smoking cessation, long term quit-rates are relatively low [3]. Therefore, tobacco harm reduction strategy and products have been developed, with the main goal to reduce the amount of harmful substances administered to the human body.

Electronic cigarettes have been introduced to the market in recent years as an alternative-to-smoking habit. They consist of a battery-part, a cartridge containing liquid and an electrical resistance that is heated by activation of the battery and evaporates the liquid. The liquid usually contains glycerol, propylene glycol, water, nicotine and a variety of flavours that the user can choose. By using this device, nicotine is delivered to the upper and lower respiratory tract without any combustion involved. Millions of people are using electronic cigarettes worldwide; however, lack of clinical research has raised global debate, controversy and serious public health concerns [4].

Several studies have shown that, even in healthy smokers, acute smoking inhalation has significant adverse effects on left ventricular (LV) myocardial function that can be detected by echocardiography [5-7]. No study has ever evaluated the effects of electronic cigarette use on cardiac function; thus, the purpose of the current study was to investigate the acute effects of using an electronic cigarette ad lib for 7 minutes on haemodynamic parameters and myocardial function, compared to the effects of smoking a tobacco cigarette.

Methods

Study sample

The study sample consisted of consecutive healthy subjects visiting our hospital for routine examinations that volunteered to participate. All participants were asymptomatic, had normal physical examination and resting electrocardiogram and were not taking any medications. Smokers (group SM) were included if they were smoking for at least 5 years and were consuming at least 15 cigarettes per day. The reason for including only heavy smokers was that a study examining the characteristics of electronic cigarette consumers showed that most electronic cigarette users were formerly heavy smokers [8]. Electronic cigarette users (group ECIG) were included if they had quit smoking and were using electronic cigarettes with nicotine-containing liquid for at least 1 month, according to self-report. To avoid potential compensatory effects from using lower nicotine-containing liquid, participants were included if they were daily consumers of similar "strength" liquids (9-12 mg/ml nicotine concentration) to that used in the study (11 mg/ml). Exclusion criteria were: presence of any major risk factor for cardiovascular disease (i.e. diabetes, hypertension, hyperlipidemia and

family history of premature coronary artery disease), history of endocrine disorders, body-mass index > 30 kg/m² and more than occasional alcohol intake. Additional exclusion criteria were derived from the echocardiography studies: elevated LV mass index (>115 g/m² for males and > 95 g/m² for females), abnormal LV function (LV ejection fraction < 55%) and more than mild valve regurgitation.

In total, 81 subjects were eligible to participate. Three smokers did not present for the scheduled evaluation. One electronic cigarette user was excluded because of moderate aortic regurgitation and ascending aorta dilatation due to bicuspid aortic valve. One smoker was excluded due to mildly depressed ejection fraction and hypokinesia of LV lateral wall. The final study sample consisted of 76 subjects, 40 electronic cigarette users (3 females) and 36 smokers (3 females). Written informed consent was obtained from all subjects for participation in the study, and the protocol was approved by the ethics committee of Onassis Cardiac Surgery Center.

Materials

All smokers were asked to use one commercially-available tobacco cigarette of the same nicotine (1.0 mg), tar (10 mg) and carbon monoxide (10 mg) yields. Electronic cigarette users were asked to use a commercially-available device with liquid containing 11 mg/ml nicotine concentration. The device used was an eGo-T battery (Nobacco, Athens, Greece) with an eGo-C atomiser (Alter Ego, Athens, Greece). It is considered a "second-generation" device. Unlike cigarette-like devices which consist of a small battery and a polyfil-containing atomiser (commonly called "cartomiser"), the electronic cigarette used in this study is a multi-piece system (Figure 1). It consists of a 650 mAh rechargeable lithium battery, delivering 3.5 volts to the atomiser (measured by a volt-meter), and an atomiser consisting of 4 parts: the tank which stores the liquid (capacity of approximately 1.1 ml), the atomiser body, the atomiser head which includes the resistance, and the atomiser cap. It is a manually-activated device, by pressing a button; it does not produce any vapour when not activated by the user.

The electronic cigarette liquid used in the study contained 11 mg/ml nicotine and is considered "medium strength" according to manufacturer's report (USA Mix Med, formerly known as MLB-Med, Nobacco, Athens, Greece). It is sold in 20 ml bottles. It was the only liquid tested by an independent laboratory (National Center for Scientific Research "Demokritos", mass spectrometry and dioxin analysis laboratory) at the time of study initiation [9]. According to the laboratory report, the contents were: propylene glycol (α -propylene glycol or 1,2-propanediol) in a concentration > 60%, linalool (3,7-dimethylocta-1,6-dien-3-ol) in a concentration < 5%, nicotine (<10%), tobacco essence (<5%), and methyl vanillin (4-hydroxy-

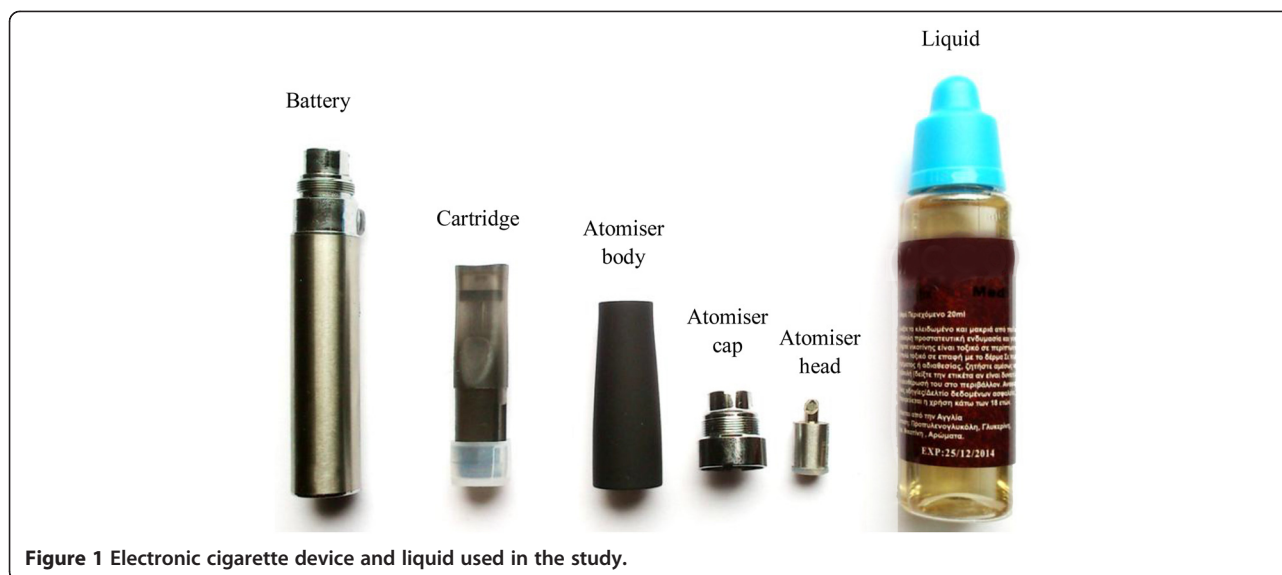


Figure 1 Electronic cigarette device and liquid used in the study.

3-methoxybenzaldehyde) at <1%. No tobacco-specific nitrosamines or polycyclic aromatic hydrocarbons were detected.

For every participant, a new cartridge and atomiser head was used. One of the researchers filled the cartridge with 1 ml of liquid; subsequently it was positioned in the atomiser and the participant started using it. The battery was fully charged before being used by each subject.

Study protocol

Participants presented to the echocardiographic laboratory after fasting and refraining from alcohol and caffeine consumption for 4 hours; they were also asked to refrain from smoking and electronic cigarette use for 4 hours before the study.

Participants were allowed to rest for 5 minutes before initiating the echocardiographic examination. A baseline echocardiographic examination was performed in smokers, who were then transferred to a room next to the echocardiography laboratory and smoked 1 tobacco cigarette. For electronic cigarette users, after the baseline echocardiogram they were asked to use the electronic cigarette ad lib for 7 minutes in another room which was not used by smokers, to avoid environmental exposure to smoke. Subsequently, all participants returned to the echocardiography laboratory and, after 5 minutes of rest, a second echocardiogram was performed in both groups.

Heart rate and BP were measured before and during each echocardiographic examination. The Brinkman index was calculated (product of number of cigarettes smoked daily and years of smoking) according to participants' self-report. Echocardiograms were performed using a commercially available system (Vivid 7, GE Vingmed, Horten, Norway). Studies were digitally recorded on hard disk for

offline analysis using dedicated software (Echopac, GE Medical Systems, Horten, Norway) by a single, blinded to the protocol, experienced echocardiographer. Reported values represent the average of 3 consecutive beats.

Two-dimensional echocardiographic measurements

The echocardiographic examinations were performed according to recent guidelines [9]. LV dimensions, septal and posterior wall thickness were measured from standard 2-dimensional images at parasternal long-axis view. LV mass was indexed to body-surface area. Ejection fraction was evaluated from the apical four and two-chamber views using the Simpson's rule [10]. Left atrial (LA) antero-posterior diameter was also measured.

Doppler flow and tissue Doppler velocity measurements

From transmitral flow measurements, peak early (E) and late (A) velocities, their ratio (E/A) and E wave deceleration time (DT) were estimated. Ejection time was estimated by recording LV outflow tract velocity. By simultaneously recording aortic and mitral flows using continuous-wave Doppler the isovolumetric relaxation time (IVRT) was measured, and was then corrected to heart rate by dividing it with the square root of R-R interval (IVRTc).

Pulsed-wave Doppler tissue velocities were measured by placing a 1.5 mm sample volume at the lateral, septal, anterior and inferior insertion sites of the mitral leaflets. Systolic (S_m), early diastolic (E_m) and late diastolic (A_m) peak velocities were measured and averaged from the 4 sites. The ratio of early-to-late annular velocity (E_m/A_m) and early mitral flow to early diastolic mitral annular velocity (E/E_m) were also determined.

Myocardial performance index was measured by two methods (Figure 2): using Doppler flow velocity

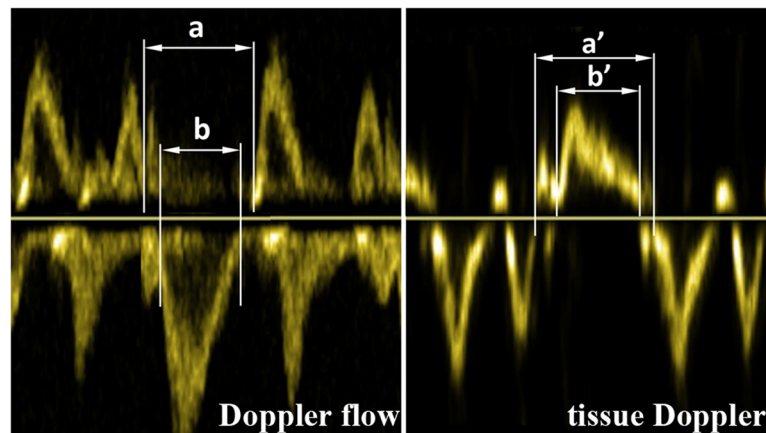


Figure 2 Myocardial performance index, measured by two methods: (1) Doppler flow velocity measurements of mitral inflow and left ventricular outflow tract; the index was derived by the formula: $MPI = (a-b)/b$, and (2) Pulsed-wave tissue Doppler measurements of mitral annulus velocity; the index was derived from the formula: $MPI_t = (a'-b')/b'$.

measurements as described by Tei et al. [11] (MPI) and using pulsed-wave tissue Doppler measurements of mitral annulus velocities (MPI_t) [12].

To check for reproducibility of measurements, the intraobserver mean percent error (the absolute difference between two measurements divided by their mean) was calculated from 10 randomly selected studies 15 days later, analyzed by the same blinded echocardiographer who performed all measurements. The results were $5.1 \pm 2.9\%$ for IVRT, $3.5 \pm 2.5\%$ for MPI, $3.6 \pm 2.2\%$ for MPI_t and $2.6 \pm 1.9\%$ for Em.

Longitudinal deformation measurements

Longitudinal deformation measurements were performed by analyzing two-dimensional echocardiographic images using the method of speckle tracking echocardiography [13]. End-diastole was defined as the peak of the R wave on the electrocardiographic trace; end-systole (aortic valve closure) was defined from pulsed-wave Doppler tracing at the LV outflow tract as the end of systolic forward flow. Subjects with inadequate tracking of more than one LV segment in each view were excluded from the analysis. By averaging segmental values in all views, end-systolic global strain (GS) was measured. Global peak longitudinal systolic (SR_s), early diastolic (SR_e) and late diastolic (SR_a) strain rate were measured. The intraobserver mean percent error of longitudinal deformation measurements in our laboratory was $3.1 \pm 1.5\%$ for GS, $3.6 \pm 1.8\%$ for SR_s, $3.9 \pm 1.9\%$ for SR_e and $3.6 \pm 2.0\%$ for SR_a.

Statistical analysis

The Kolmogorov-Smirnov tests were applied to assess the normality of data; all parameters were normally distributed except from daily cigarette consumption. Continuous variables were expressed as mean \pm SD or

median (interquartile range). Categorical variables were expressed as number (percentage). Inter-group comparisons of baseline characteristics data were made by unpaired Student's t-test and Mann-Whitney test; Fisher's exact test was used for categorical variables.

Repeated measurements analysis of variance (ANOVA) was used in order to evaluate changes in parameters before and after smoking one cigarette or using the electronic cigarette device (before-use and after-use measurements). Changes in echocardiographic and deformation parameters that were significantly different between the two study groups from analysis of variance were further analyzed using linear regression analyses, in order to find if the effect of smoking was significant after adjusting for changes in heart rate and systolic BP. For every parameter, a different linear regression analysis was performed. Change (Δ) in parameter was the dependent variable; group (SM vs. ECIG) and change in heart rate and systolic BP were the independent variables. All P values reported are two-tailed. Statistical significance was set at 0.05 and analyses were conducted using SPSS statistical software (version 18.0, SPSS Inc., Chicago, USA).

A repeated measures ANOVA power analysis was conducted. For this design, 76 participants (40 in the smokers group and 36 in the electronic cigarette users group) achieved a power of 0.90 for the between-subjects main effect at an effect size of 0.30; a power of 0.90 for the within-subjects main effect at an effect size of 0.15; and a power of 0.90 for the interaction effect at an effect size of 0.15.

Results

Both groups had similar baseline characteristics (Table 1). Electronic cigarette users had quit smoking for 97 ± 50 days and were using electronic cigarettes for $100 \pm$

Table 1 Baseline characteristics of the study population

Characteristic	Smokers (n = 36)	Electronic cigarette users (n = 40)	P-value
Males n (%)	32 (88.9)	36 (90)	1.000 ^a
Age (years)	36 ± 5	35 ± 5	0.764
Body mass index (kg/m ²)	24.8 ± 2.3	25.3 ± 2.4	0.304
Body surface area (m ²)	2.03 ± 0.15	2.00 ± 0.18	0.322
Smoking duration (years)	16 ± 5	17 ± 5	0.571
Cigarette consumption (n/d) ^b	20 (20–26)	30 (20–35)	0.004 ^c
Brinkman index	371 ± 132	493 ± 228	0.005
Electronic cigarette use duration ^d		6 ± 4	
Systolic BP (mmHg)	123.0 ± 9.8	123.9 ± 8.6	0.653
Diastolic BP (mmHg)	75.8 ± 5.6	75.6 ± 6.1	0.834
Heart rate (beats/m)	67.5 ± 7.9	67.1 ± 10.3	0.841
Pressure-rate product	8308 ± 1235	8312 ± 1363	0.989
Glucose (mmol/l)	4.51 ± 0.34	4.44 ± 0.35	0.410
Total cholesterol (mmol/l)	4.85 ± 0.21	4.77 ± 0.30	0.177
LDL cholesterol (mmol/l)	2.99 ± 0.23	2.91 ± 0.26	0.175
HDL cholesterol (mmol/l)	1.38 ± 0.15	1.38 ± 0.18	0.943
Triglycerides (mmol/l)	1.05 ± 0.14	1.04 ± 0.18	0.693
Ejection fraction (%)	63 ± 5	62 ± 4	0.463
LA diameter (mm)	35 ± 4	34 ± 3	0.359
LV mass index (g/m ²)	64 ± 10	65 ± 13	0.663

BP, blood pressure, LVEDV, left ventricular end-diastolic volume; LVESV, left ventricular end-systolic volume; LDL, low-density lipoprotein; HDL, high-density lipoprotein; LA, left atrium.

^aFisher's exact test; ^bValues expressed as median (interquartile range);

^cMann-Whitney test; ^dDuration expressed in months.

49 days. They had higher lifetime smoking exposure, with Brinkman index 33% higher compared to smokers, due to higher daily cigarette consumption when they were smokers.

Changes in haemodynamic, Doppler echocardiography and longitudinal deformation measurements for the study groups are presented in Tables 2 and 3. Baseline measurements were similar between groups for all parameters.

After-use values of systolic BP, heart rate and pressure-rate product were elevated in the SM group but not in the ECIG group (Table 2). The overall change from baseline was significantly different between the two groups. In contrast, diastolic BP increased equally in both groups.

From Doppler flow echocardiographic measurements (Table 2), E velocity and DT remained unchanged after use in both groups. A velocity was increased and E/A was decreased in SM, but the overall change was not significantly different between the two groups ($P = 0.317$ and $P = 0.053$, respectively). IVRT, IVRTc and MPI were increased after smoking one cigarette in the SM group, and the degree of change was significantly different

between the two study groups ($P = 0.001$, $P < 0.001$ and $P = 0.001$ respectively). The after-use levels of IVRTc and MPI were greater in SM compared to ECIG, as was shown by the between-groups analysis.

Concerning Doppler tissue velocity measurements (Table 3), Sm and Am remained unchanged after use in both groups. However, Em was significantly reduced in SM group after smoking. It was lower when compared to ECIG after using the device, and the degree of change was significantly different between the two groups ($P < 0.001$). Em/Am was reduced and E/Em was increased in SM, but the difference of the overall change between the two groups was statistically significant for Em/Am only ($P = 0.011$). MPIt increased after smoking in SM; the degree of change was significantly different between the two groups ($P < 0.001$), with after-use levels being significantly higher in SM compared to ECIG ($P = 0.019$).

Longitudinal deformation measurements (Table 3) were feasible in 37 electronic cigarette users and 34 smokers. No difference in GS, SRs and SRa was observed in ECIG and SM after use. However, SRe was significantly reduced in SM post-smoking, with the degree of change being statistically significant between groups ($P < 0.001$).

The results of multiple linear regression analyses are displayed in Table 4. Even after adjusting for changes in systolic BP and heart rate, changes in IVRT, IVRTc, MPI, Em, MPIt and SRe were significantly higher in SM group.

Discussion

This is the first study to examine the acute effects of electronic cigarette use on myocardial function. No adverse effects on LV myocardial function were observed after using electronic cigarette with nicotine-containing liquid for 7 minutes. On the contrary, significant changes in diastolic function parameters were found after smoking 1 tobacco cigarette.

The acute adverse effects of smoking on myocardial relaxation were originally observed in coronary artery disease patients [14], with acute impairment of coronary vasomotion implicated as the main cause [15]. Such effects on diastolic function are also detected in healthy smokers [5-7]. Cigarette smoke contains significant amounts of free radicals, promoting oxidative stress and inflammation [16]. At the cellular level, decreased function of myocardial mitochondria [17] and DNA damage [18] has been observed. These mechanisms may be implicated in delaying myocardial relaxation from acute use and promoting atherosclerosis and cardiovascular disease from chronic use. In this study, several parameters commonly used for evaluating diastolic function [19] and longitudinal deformation measurements which are considered more sensitive in detecting pathology [20] were significantly altered after smoking inhalation.

Electronic cigarettes were invented in 2003, but awareness and use has significantly increased over the past

Table 2 Haemodynamic and Doppler flow measurements in electronic cigarette users (ECIG, n = 40) and smokers (SM, n = 36), before and after device and cigarette use respectively

Parameter	Before use	After use	Change	P-value ^a	P-value ^b
Systolic BP (mmHg)					
ECIG	123.9 ± 8.6	124.6 ± 9.9	0.7 ± 4.6	0.374	< 0.001
SM	123.0 ± 9.8	129.6 ± 9.2	6.6 ± 5.2	< 0.001	
P-value ^c	0.653	0.025			
Diastolic BP (mmHg)					
ECIG	75.6 ± 6.1	78.5 ± 5.9	3.0 ± 3.6	< 0.001	0.079
SM	75.8 ± 5.6	80.2 ± 5.8	4.4 ± 3.3	< 0.001	
P-value ^c	0.834	0.209			
Heart rate (beats/m)					
ECIG	67.1 ± 10.3	67.5 ± 10.6	0.4 ± 4.8	0.649	< 0.001
SM	67.5 ± 7.9	73.5 ± 6.8	5.9 ± 4.7	< 0.001	
P-value ^c	0.841	0.005			
Pressure-rate product					
ECIG	8312 ± 1363	8397 ± 1462	84 ± 708	0.456	< 0.001
SM	8308 ± 1235	9556 ± 1084	1248 ± 840	< 0.001	
P-value ^c	0.989	< 0.001			
E (cm/s)					
ECIG	70.1 ± 12.5	71.4 ± 13.2	1.2 ± 5.0	0.130	0.132
SM	72.9 ± 8.5	72.2 ± 10.2	-0.6 ± 6.1	0.565	
P-value ^c	0.268	0.756			
A (cm/s)					
ECIG	51.1 ± 10.2	52.7 ± 9.8	1.6 ± 5.6	0.083	0.317
SM	50.4 ± 8.8	53.3 ± 9.1	2.9 ± 5.7	0.007	
P-value ^c	0.774	0.764			
E/A					
ECIG	1.41 ± 0.29	1.37 ± 0.26	-0.03 ± 0.14	0.171	0.053
SM	1.49 ± 0.32	1.39 ± 0.30	-0.10 ± 0.16	0.001	
P-value ^c	0.235	0.809			
DT (ms)					
ECIG	173 ± 11	174 ± 14	1 ± 8	0.581	0.570
SM	170 ± 16	172 ± 16	3 ± 10	0.086	
P-value ^c	0.448	0.719			
IVRT (ms)					
ECIG	74.6 ± 9.5	73.6 ± 9.9	-1.0 ± 5.7	0.275	0.001
SM	73.0 ± 8.7	77.7 ± 13.5	5.6 ± 9.2	< 0.001	
P-value ^c	0.450	0.132			
IVRTc (ms)					
ECIG	78.9 ± 11.8	77.7 ± 11.6	-1.2 ± 6.9	0.286	< 0.001
SM	77.3 ± 10.1	86.1 ± 16.4	10.4 ± 10.1	< 0.001	
P-value ^c	0.524	0.011			

Table 2 Haemodynamic and Doppler flow measurements in electronic cigarette users (ECIG, n = 40) and smokers (SM, n = 36), before and after device and cigarette use respectively (Continued)

MPI					
ECIG	0.39 ± 0.07	0.38 ± 0.06	-0.01 ± 0.04	0.330	0.001
SM	0.40 ± 0.05	0.43 ± 0.06	0.03 ± 0.04	0.002	
P-value ^c	0.355	0.001			

BP, blood pressure; E, mitral flow early diastolic velocity; A, mitral flow late diastolic velocity; DT, deceleration time of early mitral flow; IVRT, isovolumetric relaxation time; IVRTc, IVRT corrected to heart rate; MPI, myocardial performance index estimated by Doppler flow echocardiography.

^aP-value for time effect.

^bRepeated measurements ANOVA. Effects reported are significant differences between the two groups in the degree of change in each particular variable.

^cP-value for group effect.

3 years [21]. They do not contain tobacco and their use does not involve combustion. However, lack of research on their health effects has generated significant controversy over their safety. FDA and WHO issued public statements in 2009, expressing concern and recommending that electronic cigarette use should be avoided. WHO has specifically asked for studies to be performed before regulation or even ban is imposed. Cahn and Siegel summarized the results of 16 studies evaluating the chemical composition of liquids used for electronic cigarettes [22]. Nitrosamines were found in only two of the studies, at levels similar to those present in nicotine patch; a recent review indicated that the levels of nitrosamines in electronic cigarettes were up to 1800 times lower compared to tobacco cigarettes [23]. The main constituents, besides nicotine, were propylene glycol and glycerine, which are also present in tobacco cigarettes; however, the combustion process from smoking leads to production of acrolein, acetaldehyde and formaldehyde, which promote oxidative stress and have cardiotoxic properties [24]. In electronic cigarettes, such chemicals may be formed from the heating process during liquid evaporation; however, the levels found were lower compared to tobacco cigarettes by orders of magnitude [25]. This may explain the results from laboratory studies, in which electronic cigarette vapour was significantly less cytotoxic compared to cigarette smoke on cultured cells [26,27]. Cardiotoxic substances like nitrosamines, heavy metals and polycyclic aromatic hydrocarbons were not detected in the liquid used in this study [9]. These parameters may explain the differences in diastolic function observed between smokers and electronic cigarette users after smoking and device use. Moreover, a study evaluating the effects of smoking compared to nicotine delivered by gum showed that nicotine alone did not cause acute changes in diastolic function [28]. It seems that nicotine absorption rate is lower from electronic compared to tobacco cigarette use [29], even when using new-generation devices [30]; the difference in haemodynamic response between the two groups may be attributed to this. However, haemodynamic parameters cannot explain the differences in diastolic function parameters,

since linear regression analyses revealed that changes in Doppler and deformation parameters were associated with cigarette smoking even after adjusting for changes in systolic BP and heart rate.

From a public health perspective, epidemiological studies have shown that tobacco harm reduction strategy and products may be promising regarding cardiovascular disease risk reduction [31]. Electronic cigarettes are unique since they are the only products that do not contain tobacco, while they mimic the act of smoking and provide motor and sensory stimulation. Thus, they may deal with both the chemical (nicotine delivery) and behavioural components of cigarette addiction [22] and studies indicate that they may be effective in promoting smoking cessation [32,33]. This study provides the first clinical evidence that electronic cigarettes have less acute adverse effects on myocardial function when compared to tobacco cigarettes.

Some limitations apply to this study. A small sample size was studied, and examination focused only on immediate effects. The results do not indicate that electronic cigarettes are absolutely safe for the cardiovascular system. Other parameters known to be adversely affected by acute smoking, such as coronary microvascular and endothelial function or vascular distensibility, were not examined. Moreover, the parameters examined are affected mainly by heart rate changes. Although heart rate was not included as a covariate in the repeated-measures ANOVA, the linear regression analysis showed that changes in diastolic function were significantly different between groups independently of the changes in heart rate and systolic BP. This can be explained by the small difference in post-use heart rate between groups of only 6 beats per minute. Studies on long-term effects are necessary; however, more time of use is needed before any such studies are published since electronic cigarettes were introduced to the market in recent years and there is a substantial delay between smoking initiation and development of clinically-evident disease. We asked subjects to use the electronic cigarette for 7 minutes. It is unknown whether more time of use could have had a different impact. However, timing was based on the approximate time of smoking 1 regular

Table 3 Tissue Doppler velocity and longitudinal deformation measurements in electronic cigarette users (ECIG, n = 40) and smokers (SM, n = 36), before and after device and cigarette use respectively*

Parameter	Before use	After use	Change	P-value ^a	P-value ^b
Sm (cm/s)					
ECIG	9.7 ± 1.6	9.9 ± 1.6	0.2 ± 0.7	0.171	0.613
SM	9.7 ± 1.4	9.7 ± 1.5	-0.8 ± 1.1	0.571	
P-value ^c	0.896	0.723			
Em (cm/s)					
ECIG	12.7 ± 1.9	12.9 ± 2.1	0.2 ± 0.7	0.095	< 0.001
SM	12.8 ± 2.1	11.9 ± 1.5	-0.7 ± 1.4	< 0.001	
P-value ^c	0.892	0.032			
Am (cm/s)					
ECIG	9.7 ± 1.7	9.9 ± 1.6	0.2 ± 0.8	0.122	0.441
SM	9.3 ± 1.2	9.4 ± 1.3	0.1 ± 0.6	0.801	
P-value ^c	0.212	0.099			
Em/Am					
ECIG	1.34 ± 0.29	1.33 ± 0.28	-0.01 ± 0.13	0.540	0.011
SM	1.40 ± 0.28	1.30 ± 0.24	-0.08 ± 0.13	0.004	
P-value ^c	0.408	0.655			
E/Em					
ECIG	5.60 ± 1.04	5.61 ± 1.11	0.01 ± 0.47	0.869	0.052
SM	5.83 ± 0.95	6.10 ± 0.98	0.29 ± 0.74	0.021	
P-value ^c	0.311	0.044			
MPIt					
ECIG	0.48 ± 0.08	0.47 ± 0.09	-0.01 ± 0.04	0.080	< 0.001
SM	0.49 ± 0.06	0.52 ± 0.07	0.03 ± 0.05	0.004	
P-value ^c	0.654	0.019			
GS (%)					
ECIG	-21.1 ± 1.9	-21.5 ± 1.6	-0.4 ± 1.2	0.059	0.087
SM	-21.0 ± 2.6	-20.7 ± 3.1	0.2 ± 1.7	0.441	
P-value ^c	0.769	0.192			
SRs (s⁻¹)					
ECIG	-1.13 ± 0.10	-1.14 ± 0.11	-0.01 ± 0.07	0.362	0.613
SM	-1.08 ± 0.13	-1.10 ± 0.13	-0.2 ± 0.1	0.150	
P-value ^c	0.059	0.115			
SRe (s⁻¹)					
ECIG	1.47 ± 0.25	1.49 ± 0.23	0.01 ± 0.08	0.347	< 0.001
SM	1.43 ± 0.25	1.35 ± 0.24	-0.08 ± 0.12	< 0.001	
P-value ^c	0.493	0.022			
SRa (s⁻¹)					
ECIG	0.88 ± 0.20	0.89 ± 0.18	0.01 ± 0.08	0.462	0.441
SM	0.86 ± 0.14	0.88 ± 0.14	0.03 ± 0.09	0.111	
P-value ^c	0.536	0.796			

*Longitudinal deformation measurements were performed in 37 electronic cigarette users and 34 smokers.

Sm, mitral annulus systolic velocity; Em, mitral annulus early diastolic velocity; Am, mitral annulus late diastolic velocity; MPIt, myocardial performance index estimated by tissue Doppler echocardiography; GS, global longitudinal strain; SRs, peak systolic strain rate; SRe, peak early diastolic strain rate; SRa, peak late diastolic strain rate.

^aP-value for time effect.

^bRepeated measurements ANOVA. Effects reported are significant differences between the two groups in the degree of change in each particular variable.

^cP-value for group effect.

Table 4 Results from linear regression analyses for the effect of group (smokers vs. electronic cigarette users) on changes (Δ) of Doppler echocardiography measurements, after adjusting for changes in systolic blood pressure and heart rate

Dependent variable	β^*	SE**	P-value
Δ IVRT (ms)	4.64	2.12	0.032
Δ IVRTc (ms)	5.46	2.34	0.022
Δ MPI	0.03	0.01	0.013
Δ Em (cm/s)	-0.87	0.25	0.001
Δ MPI _{lt}	0.04	0.01	0.001
Δ SRe (s^{-1})	-0.06	0.03	0.039

*Regression coefficient for the comparison of SM group to ECIG group, adjusted for changes in systolic blood pressure and heart rate.

**Standard Error.

cigarette; in fact, it took smokers 5 minutes to smoke one cigarette while electronic cigarette users were asked to use the device for a longer time. Additionally, experienced users were examined, who use the device more intensively than novice users [34]. Unfortunately, there are no other means of comparing electronic with tobacco cigarette use. Although plasma nicotine levels were not measured, the haemodynamic response observed suggests that the nicotine delivery rate from electronic cigarettes is lower and slower compared to tobacco cigarettes. This has been validated by studies performed recently [30,35]. The results of this study are not necessarily applicable to all liquids available in the market. If non-pharmaceutical grade nicotine is used, several tobacco impurities may be present and inhaled by the user. The same applies for other liquid constituents [21]. Finally, although all subjects were considered healthy based on history taking, clinical examination, resting ECG and echocardiogram, it cannot be excluded that some subjects may suffer from subclinical coronary artery disease. However, there was no indication to perform any additional examinations in the study population.

Conclusions

Although acute smoking inhalation caused a delay in LV myocardial relaxation in smokers, electronic cigarette use was found to have no such immediate effects in daily users of the device. This short-term beneficial profile of electronic cigarette compared to smoking, although not conclusive about its overall health-effects as a tobacco harm reduction product, provides the first evidence about the cardiovascular effects of this device. Since awareness and use of electronic cigarettes are continuously rising, more studies are urgently needed, focusing on the pathophysiological mechanisms of disease where smoking is implicated and ultimately on long-term effects. Such studies will provide additional scientific data to public health authorities so that they decide on the regulatory status of this product.

Competing interests

After this study was completed, the authors have performed studies using funds provided to the institution by e-cigarette companies.

Authors' contributions

KF was responsible for study conception and design. KF, DT and MS were responsible for data collection. SK was responsible for off-line measurements of echocardiographic parameters. KF, DT and VV were responsible for statistical analysis and interpretation. KF, DT and VV drafted the manuscript. All authors read and approved the manuscript.

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RESEARCH ARTICLE

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Peering through the mist: systematic review of what the chemistry of contaminants in electronic cigarettes tells us about health risks

Igor Burstyn

Abstract

Background: Electronic cigarettes (e-cigarettes) are generally recognized as a safer alternative to combusted tobacco products, but there are conflicting claims about the degree to which these products warrant concern for the health of the vapers (e-cigarette users). This paper reviews available data on chemistry of aerosols and liquids of electronic cigarettes and compares modeled exposure of vapers with occupational safety standards.

Methods: Both peer-reviewed and “grey” literature were accessed and more than 9,000 observations of highly variable quality were extracted. Comparisons to the most universally recognized workplace exposure standards, Threshold Limit Values (TLVs), were conducted under “worst case” assumptions about both chemical content of aerosol and liquids as well as behavior of vapers.

Results: There was no evidence of potential for exposures of e-cigarette users to contaminants that are associated with risk to health at a level that would warrant attention if it were an involuntary workplace exposures. The vast majority of predicted exposures are < <1% of TLV. Predicted exposures to acrolein and formaldehyde are typically <5% TLV. Considering exposure to the aerosol as a mixture of contaminants did not indicate that exceeding half of TLV for mixtures was plausible. Only exposures to the declared major ingredients – propylene glycol and glycerin – warrant attention because of precautionary nature of TLVs for exposures to hydrocarbons with no established toxicity.

Conclusions: Current state of knowledge about chemistry of liquids and aerosols associated with electronic cigarettes indicates that there is no evidence that vaping produces inhalable exposures to *contaminants* of the aerosol that would warrant health concerns by the standards that are used to ensure safety of workplaces. However, the aerosol generated during vaping as a whole (*contaminants plus declared ingredients*) creates personal exposures that would justify surveillance of health among exposed persons in conjunction with investigation of means to keep any adverse health effects as low as reasonably achievable. Exposures of bystanders are likely to be orders of magnitude less, and thus pose no apparent concern.

Keywords: Vaping, e-cigarettes, Tobacco harm reduction, Risk assessment, Aerosol, Occupational exposure limit

Background

Electronic cigarettes (also known as e-cigarettes) are generally recognized as a safer alternative to combusted tobacco products (reviewed in [1]), but there are conflicting claims about the degree to which these products warrant concern for the health of the vapers (e-cigarette users). A vaper inhales aerosol generated during heating

of liquid contained in the e-cigarette. The technology and patterns of use are summarized by Etter [1], though there is doubt about how current, complete and accurate this information is. Rather conclusive evidence has been amassed to date on comparison of the chemistry of aerosol generated by electronic cigarettes to cigarette smoke [2-8]. However, it is meaningful to consider the question of whether aerosol generated by electronic cigarettes would warrant health concerns on its own, in part because vapers will include persons who would not have been smokers and for whom the question of harm reduction

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from smoking is therefore not relevant, and perhaps more importantly, simply because there is value in minimizing the harm of those practicing harm reduction.

One way of approaching risk evaluation in this setting is to rely on the practice, common in occupational hygiene, of relating the chemistry of industrial processes and the emissions they generate to the potential worst case of personal exposure and then drawing conclusions about whether there would be interventions in an occupational setting based on comparison to occupational exposure limits, which are designed to ensure safety of unintentionally exposed individuals. In that context, exposed individuals are assumed to be adults, and this assumption appears to be suitable for the intended consumers of electronic cigarettes. "Worst case" refers to the maximum personal exposure that can be achieved given what is known about the process that generates contaminated atmosphere (in the context of airborne exposure considered here) and the pattern of interaction with the contaminated atmosphere. It must be noted that harm reduction notions are embedded in this approach since it recognizes that while elimination of the exposure may be both impossible and undesirable, there nonetheless exists a level of exposure that is associated with negligible risks. To date, a comprehensive review of the chemistry of electronic cigarettes and the aerosols they generate has not been conducted, depriving the public of the important element of a risk-assessment process that is mandatory for environmental and occupational health policy-making.

The present work considers both the contaminants present in liquids and aerosols as well as the declared ingredients in the liquids. The distinction between exposure to declared ingredients and contaminants of a consumer product is important in the context of comparison to occupational or environmental exposure standards. Occupational exposure limits are developed for unintentional exposures that a person does not elect to experience. For example, being a bread baker is a choice that does not involve election to be exposed to substances that cause asthma that are part of the flour dust (most commonly, wheat antigens and fungal enzymes). Therefore, suitable occupational exposure limits are created to attempt to protect individuals from such risk on the job, with no presumption of "assumed risk" inherent in the occupation. Likewise, special regulations are in effect to protect persons from unintentional exposure to nicotine in workplaces (<http://www.cdc.gov/niosh/docs/81-123/pdfs/0446.pdf>; accessed July 12, 2013), because in environments where such exposures are possible, it is reasonable to protect individuals who do not wish to experience its effects. In other words, occupational exposure limits are based on protecting people from involuntary and unwanted exposures, and thus can be seen as more stringent than the

standards that might be used for hazards that people intentionally choose to accept.

By contrast, a person who elects to lawfully consume a substance is subject to different risk tolerance, as is demonstrated in the case of nicotine by the fact that legally sold cigarettes deliver doses of nicotine that exceed occupational exposure limits [9]: daily intake of 20 mg of nicotine, assuming nearly 100% absorption in the lungs and inhalation of 4 m³ of air, corresponds to roughly 10 times the occupational exposure limit of 0.5 mg/m³ atmosphere over 8 hours [10]. Thus, whereas there is a clear case for applicability of occupational exposure limits to contaminants in a consumer product (e.g. aerosol of electronic cigarettes), there is no corresponding case for applying occupational exposure limits to declared ingredients desired by the consumer in a lawful product (e.g. nicotine in the aerosol of an electronic cigarette). Clearly, some limits must be set for voluntary exposure to compounds that are known to be a danger at plausible doses (e.g. limits on blood alcohol level while driving), but the regulatory framework should reflect whether the dosage is intentionally determined and whether the risk is assumed by the consumer. In the case of nicotine in electronic cigarettes, if the main reason the products are consumed is as an alternative source of nicotine compared to smoking, then the only relevant question is whether undesirable exposures that accompany nicotine present health risks, and the analogy with occupational exposures holds. In such cases it appears permissible to allow at least as much exposure to nicotine as from smoking before admitting to existence of new risk. It is expected that nicotine dosage will not increase in switching from smoking to electronic cigarettes because there is good evidence that consumers adjust consumption to obtain their desired or usual dose of nicotine [11]. The situation is different for the vapers who want to use electronic cigarettes without nicotine and who would otherwise not have consumed nicotine. For these individuals, it is defensible to consider total exposure, including that from any nicotine contamination, in comparison to occupational exposure limits. In consideration of vapers who would never have smoked or would have quit entirely, it must be remembered that the exposure is still voluntary and intentional, and comparison to occupational exposure limits is legitimate only for those compounds that the consumer does not elect to inhale.

The specific aims of this review were to:

1. Synthesize evidence on the chemistry of liquids and aerosols of electronic cigarettes, with particular emphasis on the contaminants.
2. Evaluate the quality of research on the chemistry of liquids and aerosols produced by electronic cigarettes.

3. Estimate potential exposures from aerosols produced by electronic cigarettes and compare those potential exposures to occupational exposure standards.

Methods

Literature search

Articles published in peer-reviewed journals were retrieved from *PubMed* (<http://www.ncbi.nlm.nih.gov/pubmed/>) available as of July 2013 using combinations of the following keywords: “electronic cigarettes”, “e-cigarettes”, “smoking alternatives”, “chemicals”, “risks”, “electronic cigarette vapor”, “aerosol”, “ingredients”, “e-cigarette liquid”, “e-cig composition”, “e-cig chemicals”, “e-cig chemical composition”, “e-juice electronic cigarette”, “electronic cigarette gas”, “electronic cigars”. In addition, references of the retrieved articles were examined to identify further relevant articles, with particular attention paid to non-peer reviewed reports and conference presentations. Unpublished results obtained through personal communications were also reviewed. The Consumer Advocates for Smoke-free Alternatives Association (CASAA) was asked to review the retrieved bibliography to identify any reports or articles that were missed. The papers and reports were retained for analysis if they reported on the chemistry of e-cigarette liquids or aerosols. No explicit quality control criteria were applied in selection of literature for examination, except that secondary reporting of analytical results was not used. Where substantial methodological problems that precluded interpretation of analytical results were noted, these are described below. For each article that contained relevant analytical results, the compounds quantified, limits of detection, and analytical results were summarized in a spreadsheet. Wherever possible, individual analytical results (rather than averages) were recorded (see Additional file 1). Data contained in Additional file 1 is not fully summarized in the current report but can be used to investigate a variety of specific questions that may interest the reader. Each entry in Additional file 1 is identified by a *Reference Manage ID* that is linked to source materials in a list in Additional file 2 (linked via *RefID*); copies of all original materials can be requested.

Comparison of observed concentrations in aerosol to occupational exposure limits

For articles that reported mass or concentration of specific compounds in the aerosol (generated by smoking machines or from volunteer vapers), measurements of compounds were converted to concentrations in the “personal breathing zone”,^a which can be compared to occupational exposure limits (OELs). The 2013 Threshold Limit Values (TLVs) [10] were used as OELs because they are the most up to date and are most widely recognized internationally when local jurisdictions do not establish their own regulations (see <http://www.ilo.org/safework/info/publications/>

WCMS_113329/lang-en/index.htm; accessed July 3, 2013). TLVs are more protective than those of US Occupational Safety and Health Administration’s Permissible Exposure Limits because TLVs are much more often updated with current knowledge. However, all OELs generally agree with each other because they are based on the same body of knowledge. TLVs (and all other OELs) aim to define environmental conditions to which nearly all persons can be exposed to all day over many years without experiencing adverse health effects. Whenever there was an uncertainty in how to perform the calculation, a “worst case” scenario was used, as is the standard practice in occupational hygiene, where the initial aim is to recognize potential for hazardous exposures and to err on the side of caution. The following assumptions were made to enable the calculations that approximate the worst-case personal exposure of a vaper (Equation 1):

1. Air the vaper breathes consists of a small volume of aerosol generated by e-cigarettes that contains a specific chemical plus pristine air;
2. The volume of aerosols inhaled from e-cigarettes is small compared to total volume of air inhaled;
3. The period of exposure to the aerosol considered was 8 hours for comparability to the standard working shift for which TLVs were developed (this does not mean only 8 hours worth of vaping was considered but, rather, a day’s worth of exposure was modeled as being concentrated into just 8 hours);
4. Consumption of 150 puffs in 8 hours (an upper estimate based on a rough estimate of 150 puffs by a typical vaper in a day [1]) was assumed. (Note that if vaping over 16 hours “day” was considered then air into which contaminants from vaping are diluted would have to increase by a factor of 2, thereby lowering estimated exposure; thus, the adopted approach is entirely still in line with “worst case” assessment);
5. Breathing rate is 8 liters per minute [12,13];
6. Each puff contains the same quantity of compounds studied.

$$\begin{aligned} [\text{mg}/\text{m}^3] &= \text{mg}/\text{puff} \times \text{puffs}/(8 \text{ hr day}) \\ &\quad \times 1/(\text{m}^3 \text{ air inhaled in 8 hr}) \end{aligned} \quad (1)$$

The only exception to this methodology was when assessing a study of aerosol emitted by 5 vapers in a 60 m³ room over 5 hours that seemed to be a sufficient approximation of worst-case “bystander” exposure [6]. All calculated concentrations were expressed as the most stringent (lowest) TLV for a specific compound (i.e. assuming the most toxic form if analytical report is ambiguous) and

expressed as “percent of TLV”. Considering that all the above calculations are approximate and reflecting that exposures in occupational and general environment can easily vary by a factor of 10 around the mean, we added a 10-fold safety factor to the “percent of TLV” calculation. This safety factor accounts for considerable uncertainty about the actual number and volume of puffs since the number of puffs is hard to estimate accurately with reports as high as 700 puffs per day [14]. Details of all calculations are provided in an Excel spreadsheet (see Additional file 3).

No systematic attempt was made to convert the content of the studied liquids into potential exposures because sufficient information was available on the chemistry of aerosols to use those studies rather than making the necessary simplifying assumptions to do the conversion. However, where such calculations were performed in the original research, the following approach was used: under the (probably false – see the literature on formation of carbonyl compounds below) assumption of no chemical reaction to generate novel ingredients, composition of liquids can be used to estimate potential for exposure if it can be established how much volume of liquid is consumed in given 8 hours, following an algorithm analogous to the one described above for the aerosols (Equation 2):

$$\begin{aligned} [\text{mg}/\text{m}^3] &= \text{mg}/(\text{mL liquid}) \times (\text{mL liquid})/\text{puff} \\ &\quad \times \text{puffs}/(8 \text{ hr day}) \\ &\quad \times 1/(\text{m}^3 \text{ air inhaled in 8 hr}) \end{aligned} \quad (2)$$

Comparison to cigarette smoke was not performed here because the fact that e-cigarette aerosol is at least orders of magnitude less contaminated by toxic compounds is uncontroversial [2-8].

The study adhered to the PRISMA guidelines for systematic reviews (<http://www.prisma-statement.org/>).

Results and discussion

General comments on methods

In excess of 9,000 determinations of single chemicals (and rarely, mixtures) were reported in reviewed articles and reports, typically with multiple compounds per electronic cigarette tested [2-8,15-43]. Although the quality of reports is highly variable, if one assumes that each report contains some information, this asserts that quite a bit is known about composition of e-cigarette liquids and aerosols. The only report that was excluded from consideration was work of McAuley *et al.* [24] because of clear evidence of cross-contamination – admitted to by the authors – with cigarette smoke and, possibly, reagents. The results pertaining to non-detection of tobacco-specific nitrosamines (TSNAs) are potentially

trustworthy, but those related to polycyclic aromatic hydrocarbons (PAH) are not since it is incredible that cigarette smoke would contain fewer PAHs, which arise from incomplete combustion of organic matter, than aerosol of e-cigarettes that do not burn organic matter [24]. In fairness to the authors of that study, similar problems may have occurred in other studies but were simply not reported, but it is impossible to include a paper in a review once it is known for certain that its quantitative results are not trustworthy. When in doubt, we erred on the side of trusting that proper quality controls were in place, a practice that is likely to increase appearance of atypical or erroneous results in this review. From this perspective, assessment of concordance among independent reports gains higher importance than usual since it is unlikely that two experiments would be flawed in the same exact manner (though of course this cannot be assured).

It was judged that the simplest form of publication bias – disappearance of an entire formal study from the available literature – was unlikely given the exhaustive search strategy and the contested nature of the research question. It is clearly the case that only a portion of all industry technical reports were available for public access, so it is possible that those with more problematic results were systematically suppressed, though there is no evidence to support this speculation. No formal attempt was made to ascertain publication bias *in situ* though it is apparent that anomalous results do gain prominence in typical reviews of the literature: diethylene glycol [44,45] detected at non-dangerous levels (see details below) in one test of 18 of early-technology products by the US Food and Drugs Administration (FDA) [23] and one outlier in measurement of formaldehyde content of exhaled air [4] and aldehydes in aerosol generated from one e-cigarette in Japan [38]. It must be emphasized that the alarmist report of aldehydes in experiments presented in [38] is based on the concentration in generated aerosol rather than air inhaled by the vaper over prolonged period of time (since vapers do not inhale only aerosol). Thus, results reported in [38] cannot be the basis of any claims about health risk, a fallacy committed both by the authors themselves and commentators on this work [45].

It was also unclear from [38] what the volume of aerosol sampled was – a critical item for extrapolating to personal exposure and a common point of ambiguity in the published reports. However, in a personal exchange with the authors of [38] [July 11, 2013], it was clarified that the sampling pump drew air at 500 mL/min through e-cigarette for 10 min, allowing more appropriate calculations for estimation of health risk that are presented below. Such misleading reporting is common in the field that confuses concentration in the aerosol (typically measured

directly) with concentration in the air inhaled by the vaper (never determined directly and currently requiring additional assumptions and modeling). This is important because the volume of aerosol inhaled (maximum ~8 L/day) is small compared to the volume of air inhaled daily (8 L/min); this point is illustrated in the Figure 1.

A similar but more extreme consideration applies to the exposure of bystanders which is almost certainly several orders of magnitude lower than the exposure of vapers. In part this is due to the absorption, rather than exhalation, of a portion of the aerosol by the vapers: there is no equivalent to the “side-stream” component of exposure to conventional cigarettes, so all of the exposure to a bystander results from exhalation. Furthermore, any environmental contamination that results from exhalation of aerosol by vaper will be diluted into the air prior to entering a bystander’s personal breathing zone. Lastly, the number of puffs that affect exposure to bystander is likely to be much smaller than that of a vaper unless we are to assume that vaper and bystander are inseparable.

It is unhelpful to report the results in cigarette-equivalents in assessments that are not about cigarette exposure, as in [43], because this does not enable one to estimate exposures of vapers. To be useful for risk assessment, the results on the chemistry of the aerosols and liquids must be reported in a form that enables the calculations in Equations 1 and 2. It must be also be noted that typical investigations consisted of qualitative and quantitative phases such that quantitative data is available mostly on compounds that passed the qualitative screen. In the qualitative phase, presence of the

compounds above a certain limit of detection is determined. In the quantitative phase, the amount of only the compounds that are detected in the qualitative phase is estimated. This biased all reports on concentration of compounds towards both higher levels and chemicals which a particular lab was most adept at analyzing.

Declared Ingredients: comparison to occupational exposure limits

Propylene glycol and glycerin

Propylene glycol and glycerin have the default or precautionary 8-hour TLV of 10 mg/m³ set for all organic mists with no specific exposure limits or identified toxicity (http://www.osha.gov/dts/chemicalsampling/data/CH_243600.html; accessed July 5, 2013). These interim TLVs tend to err on the side of being too high and are typically lowered if evidence of harm to health accumulates. For example, in a study that related exposure of theatrical fogs (containing propylene glycol) to respiratory symptoms [46], “mean personal inhalable aerosol concentrations were 0.70 mg/m³ (range 0.02 to 4.1)” [47]. The only available estimate of propylene concentration of propylene glycol in the aerosol indicates personal exposure on the order of 3–4 mg/m³ in the personal breathing zone over 8 hours (under the assumptions we made for all other comparisons to TLVs) [2]. The latest (2006) review of risks of occupational exposure to propylene glycol performed by the Health Council of the Netherlands (known for OELs that are the most protective that evidence supports and based exclusively on scientific considerations rather than also accounting for feasibility as is the case for the

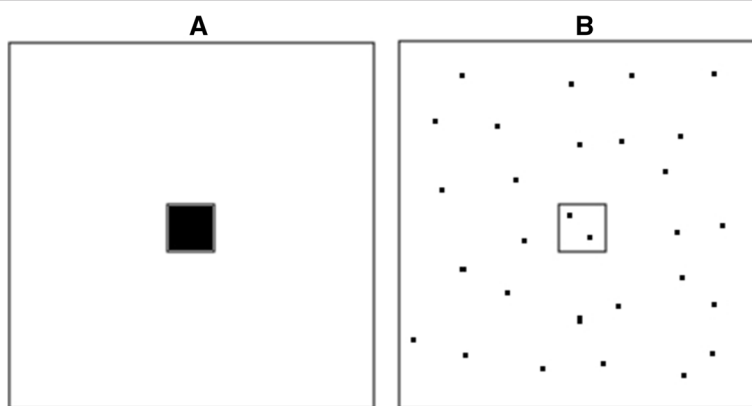


Figure 1 Illustrating the difference between concentrations in the aerosol generated by vaping and inhaled air in a day. *Panel A* shows a black square that represents aerosol contaminated by some compound as it would be measured by a “smoking machine” and extrapolated to dosage from vaping in one day. This black square is located inside the white square that represents total uncontaminated air that is inhaled in a day by a vaper. The relative sizes of the two squares are exaggerated as the volume of aerosol generated in vaping relative to inhaled air is much smaller than is illustrated in the figure. *Panel B* shows how exposure from contaminated air (black dots) is diluted over a day for appropriate comparison to occupational exposure limits that are expressed in terms of “time-weighted average” or average contamination over time rather than as instantaneous exposures. Exposure during vaping occurs in a dynamic process where the atmosphere inhaled by the vaper alternates between the smaller black and larger white squares in *Panel A*. Thus, the concentration of contaminants that a vaper is exposed to over a day is much smaller than that which is measured in the aerosol (and routinely improperly cited as reason for concern about “high” exposures).

TLVs) recommended exposure limit of 50 mg/m³ over 8 hours; concern over short-term respiratory effects was noted [<http://www.gezondheidsraad.nl/sites/default/files/200702OSH.pdf>; accessed July 29, 2013]. Assuming extreme consumption of the liquid per day via vaping (5 to 25 ml/day and 50-95% propylene glycol in the liquid),^b levels of propylene glycol in inhaled air can reach 1–6 mg/m³. It has been suggested that propylene glycol is very rapidly absorbed during inhalation [4,6] making the calculation under worst case scenario of all propylene glycol becoming available for inhalation credible. It must also be noted that when consuming low-nicotine or nicotine-free liquids, the chance to consume larger volumes of liquid increases (large volumes are needed to reach the target dose or there is no nicotine feedback), leading to the upper end of propylene glycol and glycerin exposure. Thus, estimated levels of exposure to propylene glycol and glycerin are close enough to TLV to warrant concern. However, it is also important to consider that propylene glycol is certainly not all absorbed because visible aerosol is exhaled in typical vaping. Therefore, the current calculation is in the spirit of a worst case assumption that is adopted throughout the paper.

Nicotine

Nicotine is present in most e-cigarette liquids and has TLV of 0.5 mg/m³ for average exposure intensity over 8 hours. If approximately 4 m³ of air is inhaled in 8 hours, the consumption of 2 mg nicotine from e-cigarettes in 8 hours would place the vaper at the occupational exposure limit. For a liquid that contains 18 mg nicotine/ml, TLV would be reached upon vaping ~0.1-0.2 ml of liquid in a day, and so is achieved for most anyone vaping nicotine-containing e-cigarettes [1]. Results presented in [25] on 16 e-cigarettes also argue in favor of exceedance of TLV from most any nicotine-containing e-cigarette, as they predict >2 mg of nicotine released to aerosol in 150 puffs (daily consumption figure adopted in this report). But as noted above, since delivery of nicotine is the purpose of nicotine-containing e-cigarettes, the comparison to limits on unintended, unwanted exposures does not suggest a problem and serves merely to offer complete context. If nicotine is present but the liquid is labeled as zero-nicotine [25,44], it could be treated as a contaminant, with the vaper not intending to consume nicotine and the TLV, which would be most likely exceeded, is relevant. However, when nicotine content is disclosed, even if inaccurately, then comparison to TLV is not valid. Accuracy in nicotine content is a concern with respect to truth in advertising rather than unintentional exposure, due to presumed (though not yet tested) self-regulation of consumption by persons who use e-cigarettes as a source of nicotine.

Overall, the declared ingredients in the liquid would warrant a concern by standards used in occupational

hygiene, provided that comparison to occupational exposure limits is valid, as discussed in the introduction. However, this is not to say that the exposure is affirmatively believed to be harmful; as noted, the TLVs for propylene glycol and glycerin mists is based on uncertainty rather than knowledge. These TLVs are not derived from knowledge of toxicity of propylene glycol and glycerin mists, but merely apply to any compound of no known toxicity present in workplace atmosphere. This aspect of the exposure from e-cigarettes simply has little precedent (but see study of theatrical fogs below). Therefore, the exposure will provide the first substantial collection evidence about the effects, which calls for monitoring of both exposure levels and outcomes, even though there are currently no grounds to be concerned about the immediate or chronic health effects of the exposure. The argument about nicotine is presented here for the sake of completeness and consistency of comparison to TLVs, but in itself does not affect the conclusions of this analysis because it should not be modeled as if it were a contaminant when declared as an ingredient in the liquid.

Contaminants

Polycyclic aromatic hydrocarbons

Polycyclic aromatic hydrocarbons (PAH) were quantified in several reports in aerosols [5,6,43] and liquids [7,19,42]. These compounds include well-known carcinogens, the levels of which are not subject to TLV but are instead to be kept “as low as reasonably achievable” [10]. For PAH, only non-carcinogenic pyrene that is abundant in the general environment was detected at 36 ng/cartridge in 5 samples of liquid [7]; PAHs were not detected in most of the analyses of aerosols, except for chrysene in the analysis of the aerosol of one e-cigarette [43].

Tobacco-specific nitrosamines

The same risk assessment considerations that exist for PAH also hold for carcinogenic tobacco-specific nitrosamines (TSNAs) [48] for which no occupational exposure limits exist because (a) these exposures do not appear to occur in occupational settings often enough to warrant development of TLVs, and (b) it is currently accepted in establishing TLVs that carcinogens do not have minimal thresholds of toxicity. As expected, because the TSNAs are contaminants of nicotine from tobacco leaf, there is also evidence of association between nicotine content of the liquid and TSNA concentrations, with reported concentrations <5 ng/cartridge tested [7]. Smaller studies of TSNA content in liquids are variable, with some not reporting any detectable levels [18,33,35] and others clearly identifying these compounds in the liquids when controlling for background contamination (n = 9) [23]. Analyses of aerosols indicate that TSNAs are present in amounts that can result in doses of < ng/day [5,33] to

$\mu\text{g/day}$ [8] (assuming 150 puffs/day) (see also [43]). The most comprehensive survey of TSNA content of 105 samples of liquids from 11 manufactures indicates that almost all tested liquids (>90%) contained TSNA in $\mu\text{g/L}$ quantities [36]. This is roughly equivalent to 1/1000 of the concentration of TSNA in modern smokeless tobacco products (like snus), which are in the ppm range [48]. For example, 10 $\mu\text{g/L}$ (0.01 ppm) of total TSNA in liquid [36] can translate to a daily dose of 0.025–0.05 μg from vaping (worst case assumption of 5 ml liquid/day); if 15 g of snus is consumed a day [49] with 1 ppm of TSNA [48] and half of it were absorbed, then the daily dose is estimated to be 7.5 μg , which is 150–300 times that due to the worst case of exposure from vaping. Various assumptions about absorption of TSNA alter the result of this calculation by a factor that is dwarfed in magnitude compared to that arising from differences considered above. This is reassuring because smokeless tobacco products, such as snus, pose negligible cancer risk [50], certainly orders of magnitude smaller than smoking (if one considers the chemistry of the products alone). In general, it appears that the cautious approach in face of variability and paucity of data is to seek better understanding of the predictors of presence of TSNA in liquids and aerosols so that measures for minimizing exposure to TSNA from aerosols can be devised. This can include considering better control by manufactures who extract the nicotine from tobacco leaf.

Volatile organic compounds

Total volatile organic compounds (VOC) were determined in aerosol to be non-detectable [3] except in one sample that appeared to barely exceed the background concentration of 1 mg/m^3 by 0.73 mg/m^3 [6]. These results are corroborated by analyses of liquids [19] and most likely testify to insensitivity of employed analytic methods for total VOC for characterizing aerosol generated by e-cigarettes, because there is ample evidence that specific VOC are present in the liquids and aerosols.^c Information on specific commonly detected VOC in the aerosol is given in Table 1. It must be observed that these reported concentrations are for analyses that first observed qualitative evidence of the presence of a given VOC and thus represent worst case scenarios of exposure when VOC is present (i.e. zero-level exposures are missing from the overall summary of worst case exposures presented here). For most VOC and aldehydes, one can predict the concentration in air inhaled by a vaper to be < 1% of TLV. The only exceptions to this generalization are:

- (a) acrolein: ~1% of TLV (average of 12 measurements) [40] and measurements at a mean of 2% of TLV (average of 150 measurements) [41] and

- (b) formaldehyde: between 0 and 3% of TLV based on 18 tests (average of 12 measurements at 2% of TLV, the most reliable test) [40] and an average of 150 results at 4% of TLV [41].

Levels of acrolein in exhaled aerosol reported in [6] were below 0.0016 mg/m^3 and correspond to predicted exposure of <1% of TLV (Table 2). It must re-emphasized that all calculations based on one electronic cigarette analyzed in [38] are best treated as qualitative in nature (i.e. indicating presence of a compound without any particular meaning attached to the reported level with respect to typical levels) due to great uncertainty about whether the manner in which the e-cigarette was operated could have resulted in overheating that led to generation of acrolein in the aerosol. In fact, a presentation made by the author of [38] clearly stated that the “atomizer, generating high concentration carbonyls, had been burned black” [40,41]. In unpublished work, [40] there are individual values of formaldehyde, acrolein and glyoxal that approach TLV, but it is uncertain how typical these are because there is reason to believe the liquid was overheated; considerable variability among brands of electronic cigarettes was also noted. Formaldehyde and other aldehydes, but not acrolein, were detected in the analysis one e-cigarette [43]. The overwhelming majority of the exposure to specific VOC that are predicted to result from inhalation of the aerosols lie far below action level of 50% of TLV at which exposure has to be mitigated according to current code of best practice in occupational hygiene [51].

Finding of an unusually high level of formaldehyde by Schripp *et al.* [4] – 0.5 ppm predicted vs. 15-minute TLV of 0.3 ppm (not given in Table 2) – is clearly attributable to endogenous production of formaldehyde by the volunteer smoker who was consuming e-cigarettes in the experimental chamber, since there was evidence of build-up of formaldehyde prior to vaping and liquids used in the experiments did not generate aerosol with detectable formaldehyde. This places generalizability of other findings from [4] in doubt, especially given that the only other study of exhaled air by vapers who were not current smokers reports much lower concentrations for the same compounds [6] (Table 2). It should be noted that the report by Romagna *et al.* [6] employed more robust methodology, using 5 volunteer vapers (no smokers) over an extended period of time. Except for benzene, acetic acid and isoprene, all calculated concentrations for detected VOC were much below 1% of TLV in exhaled air [6]. In summary, these results do not indicate that VOC generated by vaping are of concern by standards used in occupational hygiene.

Diethylene glycol and ethylene glycol became a concern following the report of their detection by FDA [44], but these compounds are not detected in the majority of

Table 1 Exposure predictions based on analysis of aerosols generated by smoking machines: volatile organic compounds

Compound	N [#]	Estimated concentration in personal breathing zone		Ratio of most stringent TLV (%)		Reference
		PPM	mg/m ³	Calculated directly	Safety factor 10	
Acetaldehyde	1	0.005		0.02	0.2	[5]
	3	0.003		0.01	0.1	[4]
	12	0.001		0.004	0.04	[8]
	1	0.00004		0.0001	0.001	[3]
	1	0.0002		0.001	0.008	[3]
	150	0.001		0.004	0.04	[40,41]
	1	0.008		0.03	3	[38]
Acetone	1	0.002		0.0003	0.003	[38]
	150	0.0004		0.0001	0.001	[40,41]
Acrolein	12	0.001		1	13	[8]
	150	0.002		2	20	[40,41]
	1	0.006		6	60	[38]
Butanal	150	0.0002		0.001	0.01	[40,41]
Crotonaldehyde	150		0.0004	0.01	0.1	[40,41]
Formaldehyde	1	0.002		0.6	6	[5]
	3	0.008		3	30	[4]
	12	0.006		2	20	[8]
	1	<0.0003		<0.1	<1	[3]
	1	0.0003		0.1	1	[3]
	150	0.01		4	40	[40,41]
Glyoxal	1		0.002	2	20	[38]
	150		0.006	6	60	[40,41]
o-Methylbenzaldehyde	12		0.001	0.05	0.5	[8]
p,m-Xylene	12		0.00003	0.001	0.01	[8]
Propanal	3	0.002		0.01	0.1	[4]
	150	0.0006		0.002	0.02	[40,41]
	1	0.005		0.02	0.2	[38]
Toluene	12	0.0001		0.003	0.03	[8]
Valeraldehyde	150		0.0001	0.0001	0.001	[40,41]

[#]Average is presented when N > 1.

tests performed to date [3,15,17,19,23]. Ten batches of the liquid tested by their manufacture did not report any diethylene glycol above 0.05% of the liquid [42]. Methods used to detect diethylene glycol appear to be adequate to be informative and capable of detecting the compound in quantities < 1% of TLV [15,17,23]. Comparison to TLV is based on a worst case calculation analogous to the one performed for propylene glycol. For diethylene glycol, TLV of 10 mg/m³ is applicable (as in the case of all aerosols with no known toxicity by inhalation), and there is a recent review of regulations of this compound conducted for the Dutch government by the Health Council

of the Netherlands (jurisdiction with some of the most strict occupational exposure limits) that recommended OEL of 70 mg/m³ and noted lack of evidence for toxicity following inhalation [<http://www.gezondheidsraad.nl/sites/default/files/200703OSH.pdf>; accessed July 29; 2013]. In conclusion, even the quantities detected in the single FDA result were of little concern, amounting to less than 1% of TLV.

Inorganic compounds

Special attention has to be paid to the chemical form of compounds when there is detection of metals and other

Table 2 Exposure predictions for volatile organic compounds based on analysis of aerosols generated by volunteer vapers

Compound	N [#]	Estimated concentration in personal breathing zone (ppm)	Ratio of most stringent TLV (%)		Reference
			Calculated directly	Safety factor 10	
2-butanone (MEK)	3	0.04	0.02	0.2	[4]
	1	0.002	0.0007	0.007	[6]
2-furaldehyde	3	0.01	0.7	7	[4]
Acetaldehyde	3	0.07	0.3	3	[4]
Acetic acid	3	0.3	3	30	[4]
Acetone	3	0.4	0.2	2	[4]
Acrolein	1	<0.001	<0.7	<7	[6]
Benzene	3	0.02	3	33	[4]
Butyl hydroxyl toluene	1	4E-05	0.0002	0.002	[6]
Isoprene	3	0.1	7	70	[4]
Limonene	3	0.009	0.03	0.3	[4]
	1	2E-05	0.000001	0.00001	[6]
m,p-Xylen	3	0.01	0.01	0.1	[4]
Phenol	3	0.01	0.3	3	[4]
Propanal	3	0.004	0.01	0.1	[4]
Toluene	3	0.01	0.07	0.7	[4]

[#]Average is presented when N > 1.

elements by inductively coupled plasma mass spectrometry (ICP-MS) [8,26]. Because the parent molecule that occurs in the aerosol is destroyed in such analysis, the results can be misleading and not interpretable for risk assessment. For example, the presence of sodium (4.18 µg/10 puffs) [26] does not mean that highly reactive and toxic sodium metal is in the aerosol, which would be impossible given its reactivity, but most likely means the presence of the ubiquitous compound that contains sodium, dissolved table salt (NaCl). If so, the corresponding daily dose of NaCl that arises from these concentrations from 150 puffs is about 10,000 times lower than allowable daily intake according to CDC (<http://www.cdc.gov/features/dssodium/>; accessed July 4, 2013). Likewise, a result for presence of silica is meaningless for health assessment unless the crystalline form of SiO₂ is known to be present. When such ambiguity exists, a TLV equivalence calculation was not performed. We compared concentrations to TLVs when it was even remotely plausible that parent molecules were present in the aqueous solution. However, even these are to be given credence only in an extremely pessimistic analyst, and further investigation by more appropriate analytical methods could clarify exactly what compounds are present, but is not a priority for risk assessment.

It should also be noted that one study that attempted to quantify metals in the liquid found none above 0.1-0.2 ppm levels [7] or above unspecified threshold [19]. Table 3 indicates that most metals that were detected were present at <1% of TLV even if we assume that the

analytical results imply the presence of the most hazardous molecules containing these elements that can occur in aqueous solution. For example, when elemental chromium was measured, it is compared to TLV for insoluble chromium IV that has the lowest TLV of all chromium compounds. Analyses of metals given in [43] are not summarized here because of difficulty with translating reported units into meaningful terms for comparison with the TLV, but only mercury (again with no information on parent organic compound) was detected in trace quantities, while arsenic, beryllium, chromium, cadmium, lead and nickel were not. Taken as the whole, it can be inferred that there is no evidence of contamination of the aerosol with metals that warrants a health concern.

Consideration of exposure to a mixture of contaminants

All calculations conducted so far assumed only one contaminant present in clean air at a time. What are the implications of small quantities of various compounds with different toxicities entering the personal breathing zone at the same time? For evaluation of compliance with exposure limits for mixtures, Equation 3 is used:

$$OEL_{\text{mixture}} = \sum_{i=1}^n (C_i/TLV_i), \quad (3)$$

where C_i is the concentration of the i^{th} compound ($i = 1, \dots, n$, where $n > 1$ is the number of ingredients present in a mixture) in the contaminated air and TLV_i is the TLV for the i^{th} compound in the contaminated air; if

Table 3 Exposure predictions based on analysis of aerosols generated by smoking machines: inorganic compounds[#]

Element quantified	Assumed compound containing the element for comparison with TLV	N ^{##}	Estimated concentration in personal breathing zone (mg/m ³)	Ratio of most stringent TLV (%)		Reference
				Calculated directly	Safety factor 10	
Aluminum	Respirable Al metal & insoluble compounds	1	0.002	0.2	1.5	[26]
Barium	Ba & insoluble compounds	1	0.00005	0.01	0.1	[26]
Boron	Boron oxide	1	0.02	0.1	1.5	[26]
Cadmium	Respirable Cd & compounds	12	0.00002	1	10	[8]
Chromium	Insoluble Cr (IV) compounds	1	3E-05	0.3	3	[26]
Copper	Cu fume	1	0.0008	0.4	4.0	[26]
Iron	Soluble iron salts, as Fe	1	0.002	0.02	0.2	[26]
Lead	Inorganic compounds as Pb	1	7E-05	0.1	1	[26]
		12	0.000025	0.05	0.5	[8]
Magnesium	Inhalable magnesium oxide	1	0.00026	0.003	0.03	[26]
Manganese	Inorganic compounds, as Mn	1	8E-06	0.04	0.4	[26]
Nickel	Inhalable soluble inorganic compounds, as Ni	1	2E-05	0.02	0.2	[26]
		12	0.00005	0.05	0.5	[8]
Potassium	KOH	1	0.001	0.1	1	[26]
Tin	Organic compounds, as Sn	1	0.0001	0.1	1	[26]
Zinc	Zinc chloride fume	1	0.0004	0.04	0.4	[26]
Zirconium	Zr and compounds	1	3E-05	0.001	0.01	[26]
Sulfur	SO ₂	1	0.002	0.3	3	[26]

[#]The actual molecular form in the aerosol unknown and so worst case assumption was made if it was physically possible (e.g. it is not possible for elemental lithium & sodium to be present in the aerosol); there is no evidence from the research that suggests the metals were in the particular highest risk form, and in most cases a general knowledge of chemistry strongly suggests that this is unlikely. Thus, the TLV ratios reported here probably do not represent the (much lower) levels that would result if we knew the molecular forms.

^{##}Average is presented when N > 1.

$OE_{mixture} > 1$, then there is evidence of the mixture exceeding TLV.

The examined reports detected no more than 5–10 compounds in the aerosol, and the above calculation does not place any of them out of compliance with TLV for mixture. Let us imagine that 50 compounds with TLVs were detected. Given that the aerosol tends to contain various compounds at levels, on average, of no more than 0.5% of TLV (Tables 1 and 3), such a mixture with 50 ingredients would be at 25% of TLV, a level that is below that which warrants a concern, since the “action level” for implementation of controls is traditionally set at 50% of TLV to ensure that the majority of persons exposed have personal exposure below mandated limit [51]. Pellerino *et al.* [2] reached conclusions similar to this review based on their single experiment: contaminants in the liquids that warrant health concerns were present in concentrations that were less than 0.1% of that allowed by law in the European Union. Of course, if the levels of the declared ingredients (propylene glycol, glycerin, and nicotine) are considered, the action level would be met, since those ingredients are present in the concentrations that are near the action level. There are no known synergistic actions of the examined mixtures, so Equation 3 is therefore applicable. Moreover, there is

currently no reason to suspect that the trace amounts of the contaminants will react to create compounds that would be of concern.

Conclusions

By the standards of occupational hygiene, current data do not indicate that exposures to vapors from contaminants in electronic cigarettes warrant a concern. There are no known toxicological synergies among compounds in the aerosol, and mixture of the contaminants does not pose a risk to health. However, exposure of vapers to propylene glycol and glycerin reaches the levels at which, if one were considering the exposure in connection with a workplace setting, it would be prudent to scrutinize the health of exposed individuals and examine how exposures could be reduced. This is the basis for the recommendation to monitor levels and effects of prolonged exposure to propylene glycol and glycerin that comprise the bulk of emissions from electronic cigarettes other than nicotine and water vapor. From this perspective, and taking the analogy of work on theatrical fogs [46,47], it can be speculated that respiratory functions and symptoms (but not cancer of respiratory tract or non-malignant respiratory disease) of the vaper is of primary interest. Monitoring upper airway irritation of vapers and experiences of

unpleasant smell would also provide early warning of exposure to compounds like acrolein because of known immediate effects of elevated exposures (<http://www.atsdr.cdc.gov/toxprofiles/tp124-c3.pdf>; accessed July 11, 2013). However, it is questionable how much concern should be associated with observed concentrations of acrolein and formaldehyde in the aerosol. Given highly variable assessments, closer scrutiny is probably warranted to understand sources of this variability, although there is no need at present to be alarmed about exceeding even the occupational exposure limits, since occurrence of occasional high values is accounted for in established TLVs. An important clue towards a productive direction for such work is the results reported in [40,41] that convincingly demonstrate how heating the liquid to high temperatures generates compounds like acrolein and formaldehyde in the aerosol. A better understanding about the sources of TSNA in the aerosol may be of some interest as well, but all results to date consistently indicate quantities that are of no more concern than TSNA in smokeless tobacco or nicotine replacement therapy (NRT) products. Exposures to nicotine from electronic cigarettes is not expected to exceed that from smoking due to self-titration [11]; it is only a concern when a vaper does not intend to consume nicotine, a situation that can arise from incorrect labeling of liquids [25,44].

The cautions about propylene glycol and glycerin apply only to the exposure experienced by the vapers themselves. Exposure of bystanders to the listed ingredients, let alone the contaminants, does not warrant a concern as the exposure is likely to be orders of magnitude lower than exposure experienced by vapers. Further research employing realistic conditions could help quantify the quantity of exhaled aerosol and its behavior in the environment under realistic worst-case scenarios (i.e., not small sealed chambers), but this is not a priority since the exposure experienced by bystanders is clearly very low compared to the exposure of vapers, and thus there is no reason to expect it would have any health effects.

The key to making the best possible effort to ensure that hazardous exposures from contaminants do not occur is ongoing monitoring of actual exposures and estimation of potential ones. Direct measurement of personal exposures is not possible in vaping due to the fact the aerosol is inhaled directly, unless, of course, suitable biomarkers of exposure can be developed. The current review did not identify any suitable biomarkers, though cotinine is a useful proxy for exposure to nicotine-containing liquids. Monitoring of potential composition of exposures is perhaps best achieved through analysis of aerosol generated in a manner that approximates vaping, for which better insights are needed on how to modify “smoking machines” to mimic vaping given that there are documented differences in inhalation patterns [52] that depend

on features of e-cigarettes [14]. These smoking machines would have to be operated under a realistic mode of operation of the atomizer to ensure that the process for generation of contaminants is studied under realistic temperatures. To estimate dosage (or exposure in personal breathing zone), information on the chemistry of the aerosol has to be combined with models of the inhalation pattern of vapers, mode of operation of e-cigarettes and quantities of liquid consumed. Assessment of exhaled aerosol appears to be of little use in evaluating risk to vapers due to evidence of qualitative differences in the chemistry of exhaled and inhaled aerosol.

Monitoring of liquid chemistry is easier and cheaper than assessment of aerosols. This can be done systematically as a routine quality control measure by the manufacturers to ensure uniform quality of all production batches. However, we do not know how this relates to aerosol chemistry because previous researchers did not appropriately pair analyses of chemistry of liquids and aerosols. It is standard practice in occupational hygiene to analyze the chemistry of materials generating an exposure, and it is advisable that future studies of the aerosols explicitly pair these analyses with examination of composition of the liquids used to generate the aerosols. Such an approach can lead to the development of predictive models that relate the composition of the aerosol to the chemistry of liquids, the e-cigarette hardware, and the behavior of the vaper, as these, if accurate, can anticipate hazardous exposures before they occur. The current attempt to use available data to develop such relationships was not successful due to studies failing to collect appropriate data. Systematic monitoring of quality of the liquids would also help reassure consumers and is best done by independent laboratories rather than manufacturers to remove concerns about impartiality (real or perceived).

Future work in this area would greatly benefit from standardizing laboratory protocols (e.g. methods of extraction of compounds from aerosols and liquids, establishment of “core” compounds that have to be quantified in each analysis (as is done for PAH and metals), development of minimally informative detection limits that are needed for risk assessment, standardization of operation of “vaping machine”, etc.), quality control experiments (e.g. suitable positive and negative controls without comparison to conventional cigarettes, internal standards, estimation of % recovery, etc.), and reporting practices (e.g. in units that can be used to estimate personal exposure, use of uniform definitions of limits of detection and quantification, etc.), all of which would improve on the currently disjointed literature. Detailed recommendations on standardization of such protocols lie outside of scope of this report.

All calculations conducted in this analysis are based on information about patterns of vaping and the content

of aerosols and liquids that are highly uncertain in their applicability to “typical” vaping as it is currently practiced and says even less about future exposures due to vaping (e.g. due to development of new technology). However, this is similar to assessments that are routinely performed in occupational hygiene for novel technology as it relied on “worst case” calculations and safety margins that attempt to account for exposure variability. The approach adopted here and informed by some data is certainly superior to some currently accepted practices in the regulatory framework in occupational health that rely purely on description of emission processes to make claims about potential for exposure (e.g. [53]). Clearly, routine monitoring of potential and actual exposure is required if we were to apply the principles of occupational hygiene to vaping. Detailed suggestions on how to design such exposure surveillance are available in [54].

While vaping is obvious not an occupational exposure, occupational exposure standards are the best available option to use. If there were a standard for voluntary consumer exposure to aerosols, it would be a better fit, but no such standard exists. The only candidate standard is the occupational standard, which is conservative (more protective) when considered in the context of voluntary exposures, as argued above, and any suggestion that another standard be used needs to be concrete and justified.

In summary, analysis of the current state of knowledge about the chemistry of contaminants in liquids and aerosols associated with electronic cigarettes indicates that there is no evidence that vaping produces inhalable exposures to these contaminants at a level that would prompt measures to reduce exposure by the standards that are used to ensure safety of workplaces. Indeed, there is sufficient evidence to be reassured that there are no such risks from the broad range of the studied products, though the lack of quality control standards means that this cannot be assured for all products on the market. However, aerosol generated during vaping on the whole, when considering the declared ingredients themselves, if it were treated in the same manner as an emission from industrial process, creates personal exposures that would justify surveillance of exposures and health among exposed persons. Due to the uncertainty about the effects of these quantities of propylene glycol and glycerin, this conclusion holds after setting aside concerns about health effects of nicotine. This conclusion holds notwithstanding the benefits of tobacco harm reduction, since there is value in understanding and possibly mitigating risks even when they are known to be far lower than smoking. It must be noted that the proposal for such scrutiny of “total aerosol” is not based on specific health concerns suggested by compounds that resulted in exceedance of occupational exposure limits, but is instead a conservative posture in the face of unknown consequences of inhalation of appreciable

quantities of organic compounds that may or may not be harmful at doses that occur during vaping.

Key conclusions:

- Even when compared to workplace standards for involuntary exposures, and using several conservative (erring on the side of caution) assumptions, the exposures from using e-cigarettes fall well below the threshold for concern for compounds with known toxicity. That is, even ignoring the benefits of e-cigarette use and the fact that the exposure is actively chosen, and even comparing to the levels that are considered unacceptable to people who are not benefiting from the exposure and do not want it, the exposures would not generate concern or call for remedial action.
- Expressed concerns about nicotine only apply to vapers who do not wish to consume it; a voluntary (indeed, intentional) exposure is very different from a contaminant.
- There is no serious concern about the contaminants such as volatile organic compounds (formaldehyde, acrolein, etc.) in the liquid or produced by heating. While these contaminants are present, they have been detected at problematic levels only in a few studies that apparently were based on unrealistic levels of heating.
- The frequently stated concern about contamination of the liquid by a nontrivial quantity of ethylene glycol or diethylene glycol remains based on a single sample of an early-technology product (and even this did not rise to the level of health concern) and has not been replicated.
- Tobacco-specific nitrosamines (TSNA) are present in trace quantities and pose no more (likely much less) threat to health than TSNA from modern smokeless tobacco products, which cause no measurable risk for cancer.
- Contamination by metals is shown to be at similarly trivial levels that pose no health risk, and the alarmist claims about such contamination are based on unrealistic assumptions about the molecular form of these elements.
- The existing literature tends to overestimate the exposures and exaggerate their implications. This is partially due to rhetoric, but also results from technical features. The most important is confusion of the concentration in aerosol, which on its own tells us little about risk to health, with the relevant and much smaller total exposure to compounds in the aerosol averaged across all air inhaled in the course of a day. There is also clear bias in previous reports in favor of isolated instances of highest level of chemical detected

across multiple studies, such that average exposure that can be calculated are higher than true value because they are “missing” all true zeros.

- Routine monitoring of liquid chemistry is easier and cheaper than assessment of aerosols. Combined with an understanding of how the chemistry of the liquid affects the chemistry of the aerosol and insights into behavior of vapers, this can serve as a useful tool to ensure the safety of e-cigarettes.
- The only unintentional exposures (i.e., not the nicotine) that seem to rise to the level that they are worth further research are the carrier chemicals themselves, propylene glycol and glycerin. This exposure is not known to cause health problems, but the magnitude of the exposure is novel and thus is at the levels for concern based on the lack of reassuring data.

Endnotes

^aAtmosphere that contains air inhaled by a person.

^bThis estimate of consumption was derived from informal reports from vaping community; 5 ml/day was identified as a high but not rare quantity of consumption and 25 ml/day was the high end of claimed use, though some skepticism was expressed about whether the latter quantity was truly possible. High-quality formal studies to verify these figures do not yet exist but they are consistent with report of Etter (2012).

^cThe term “VOC” loosely groups together all organic compounds present in aerosol and because the declared ingredients of aerosol are organic compounds, it follows that “VOC are present”.

Additional files

Additional file 1: Summary of chemical analyses of e-cigarettes extracted from the literature.

Additional file 2: Key to identifying articles listed in Additional file 1.

Additional file 3: Calculations conducted to compare reported results to threshold limit values. Spreadsheet that implemented calculations summarized in the article.

Competing interests

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Authors' information

IB is trained in both occupational hygiene and epidemiology and thus is an expert in bring information that these two fields contribute to risk assessment and policy-making. IB does not and never has used any tobacco products. Current research was completed by him as independent research contract during otherwise unpaid summer months. IB is an Associate Professor at Drexel University and felt obliged to disclose his primary academic appointment but this work was completed outside of the structures of Drexel University.

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Estimating the Harms of Nicotine-Containing Products Using the MCDA Approach

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Key Words

Smoked tobacco products · Oral tobacco products · Electronic cigarettes · Multi criteria decision analysis · Harm assessment · ENDS (electronic nicotine delivery systems)

Abstract

Background: An international expert panel convened by the Independent Scientific Committee on Drugs developed a multi-criteria decision analysis model of the relative importance of different types of harm related to the use of nicotine-containing products. **Method:** The group defined 12 products and 14 harm criteria. Seven criteria represented harms to the user, and the other seven indicated harms to others. The group scored all the products on each criterion for their average harm worldwide using a scale with 100 defined as the most harmful product on a given criterion, and a score of zero defined as no harm. The group also assessed relative weights for all the criteria to indicate their relative importance. **Findings:** Weighted averages of the scores pro-

vided a single, overall score for each product. Cigarettes (overall weighted score of 100) emerged as the most harmful product, with small cigars in second place (overall weighted score of 64). After a substantial gap to the third-place product, pipes (scoring 21), all remaining products scored 15 points or less. **Interpretation:** Cigarettes are the nicotine product causing by far the most harm to users and others in the world today. Attempts to switch to non-combusted sources of nicotine should be encouraged as the harms from these products are much lower. © 2014 S. Karger AG, Basel

Introduction

The recreational use of tobacco remains one of the principal causes of chronic ill health and early death worldwide. The tobacco epidemic was largely reflected in more affluent Western countries but, increasingly, the illnesses associated with tobacco use have spread to the developing world [1]. Cigarettes are considered to be the most harm-

ful tobacco product although other forms of tobacco used recreationally may also result in harm to the user [2].

It is now widely accepted that the compulsive use of tobacco reflects the development of dependence upon the nicotine present in tobacco and many of the pharmacological interventions that are employed to aid smoking cessation target this dependence [3, 4]. However, in experimental animals, nicotine does not have the potent addictive properties that are required to explain the powerful addiction to tobacco experienced by many habitual smokers [5, 6]. Thus, it has been proposed that other pharmacologically active substances present in tobacco smoke and the conditioned sensory stimulation associated with inhaling tobacco smoke have a significant role in the development of dependence upon tobacco [7–10]. Pharmacological nicotine replacement products (NRT) were introduced as aids to smoking cessation in the late 1970s and continue to be used extensively in the treatment of tobacco dependence. Experience with these preparations suggests that their use is not associated with an increased risk of chronic obstructive pulmonary disease, lung cancer or cardiovascular disease [3, 11] although there are reports that nicotine may be metabolized to compounds that are potentially carcinogenic [12, 13]. Furthermore, studies with experimental animals suggest that the ingestion of nicotine during pregnancy can have adverse effects on the brain development of the fetus and the vulnerability of the progeny to nicotine dependence [14, 15]. Relatively little direct information is available for the effects of maternal nicotine on human development and behaviour. However, smokeless tobacco has been found to have a negative effect [16] and Bruin et al. [17] have argued that the possibility of adverse effects for both the mother and fetus of NRT use during pregnancy should not be disregarded. Thus, individual researchers have expressed differing opinions on the safety of pharmacological nicotine. Nevertheless, some 40 years' experience with NRT preparations suggest that they are safe and are not associated with significant adverse medical consequences [4]. This conclusion is consistent with the compelling evidence that many of the adverse health effects of inhaling tobacco smoke are caused by other components of the smoke such as nitrosamines, carbon monoxide and nitric oxide [18, 19]. Thus, despite some differences in opinion, it seems that tobacco use lends itself rather better than many other forms of addiction to a harm reduction approach using pharmacological interventions including therapeutic nicotine preparations.

Most attention with regard to the harmful effects of tobacco use has focused on cigarettes and the evidence that they cause chronic illness and early death is compelling.

However, other forms of tobacco use also need to be considered. There is good evidence, for example, that Swedish snus, a form of refined oral tobacco which is low in nitrosamines, is at worst only weakly associated with an increased risk of cancer or cardiovascular disease [20]. By contrast, other smokeless unrefined oral tobacco products seem to be associated with significantly more harm to the user [21]. For example, the chronic use of gutkha, a form of smokeless tobacco popular with members of the Asian community, is associated with the development of disorders of the oral mucosa and oral cancer [22]. Water pipes, widely used in the Middle East, are finding increasing favour in Western society. The potential toxic effects of water pipe smoke have not yet been fully evaluated although some concerns have been expressed about the potential adverse consequences for health of using this form of tobacco [23, 24]. Our understanding of the potential hazards associated with using electronic nicotine delivery systems (ENDS, e.g. E-cigarettes) is at a very early stage. These delivery systems are seen as an acceptable form of recreational nicotine use with a minimal potential for second-hand environmental contamination. Nevertheless, there is concern that these devices should not be introduced in an unregulated way until potential associated harms are adequately evaluated [25].

There remains a need for policy makers to become better informed of the relative harms of nicotine delivery systems in order to build a regulatory framework that minimizes harm. The aim of the current study was to convene a group of experts with expertise in the field of nicotine and tobacco research from different disciplines (animal and behavioural pharmacology, toxicology, medicine, psychiatry, policy and law) that could discuss and agree on the harmfulness of nicotine-containing products using a multi-criteria decision analysis (MCDA) model and, thus, provide a sound framework within which policy makers might work.

Methods

Study Design

The Independent Scientific Committee on Drugs selected experts from several different countries to ensure a diversity of expertise and perspective, as evident from the author list. The MCDA process [26] was conducted during a 2-day facilitated workshop held in London in July 2013. The MCDA model for the harm of psychoactive drugs developed by the Independent Scientific Committee on Drugs in 2010 [27] provided a starting point for this nicotine harm study, as it covered all the potential parameters of harm that might potentially be caused by any drug.

The MCDA process is a way to compare variables of harm in widely different areas where traditional metrics are not available. It works through a series of eight stages: (1) establishing context;

(2) agreeing on the products to be evaluated and producing definitions of these; (3) agreeing on the criteria on which the products were to be compared; (4) scoring the products on each criterion; (5) weighting the criteria; (6) calculating weighted scores to give an overall index of the harm of each product; (7) examining results and resolving any inconsistencies, and (8) exploring the sensitivity of the indices to different assessments of scores and weights.

The Context

The group recognized that there are regional and national differences in actual and perceived harm of nicotine products, so participants agreed to take a worldwide perspective and consider average harm.

The Nicotine Products

After considering many nicotine products and the criteria for comparing the products, the group discussed steps 2 and 3 above in a reciprocal and iterative way so that the final set of products was substantially different from one another in important ways. Table 1 gives the final agreement about the products and their definitions.

The Criteria of Harms

The group reviewed the 16 criteria that had first been agreed by the UK Advisory Council on the Misuse of Drugs [28] and used by the Independent Scientific Committee on Drugs in their 2010 decision conference on 20 psychoactive drugs [27]. All but two criteria were retained but where necessary were redefined to be relevant to nicotine products. The two that were dropped were drug-specific and drug-related mental impairment as it was thought that there was little evidence for these with any of the nicotine products.

The criteria against which the products were evaluated are shown at the extreme right of the harm tree in figure 1. The main objective was to determine an ordering of the products at the 'Product harms' node. The next level to the right provides separate harm groupings of the criteria: 'To users' (harm to those who are using the product) and 'To others' (harm as a consequence of the use of the product to others both directly and indirectly). Assessments of the harms for all products were made against the criteria given at the extreme right of the value tree. The final definitions are shown in table 2.

Scoring the Products

The group scored all products on all criteria. The scoring system used points out of 100, with 100 assigned to the most harmful product on a given criterion and zero representing 'no harm'.

In scaling the products, care is required to ensure that each successive point on the scale represents equal increments of harm. Thus, if a product is scored at 50, then it should be half as harmful as the product scored 100. Because zero represents no harm, this scale can be considered a ratio scale, which makes possible ratio comparisons of the weighted scales.

Weighting

Some criteria are more important expressions of harm than others, so weighting of the criteria is required. 'Swing weighting' provides weights that are meaningful in MCDA. As an analogy, both Fahrenheit and Celsius scales contain 0–100 portions, but the swing in temperature from 0 to 100 on the Fahrenheit scale is, of course, a smaller swing in temperature than 0–100 on a Celsius scale; it takes 5 Celsius units to equal 9 Fahrenheit units. The purpose of weighting is to ensure that the units of harm on the different harm

scales are equivalent, thus enabling weighted scores to be compared and combined across the criteria. Weights are scale factors.

To assess scale factors two steps in thinking must be separated. First, it is necessary to think about the difference in harm between the most and least harmful products on that criterion. The next step is to think about how much that difference in harm matters in a given context. 'How big is the difference in harm and how much do you care about that difference?' This is the question that was posed in comparing the 0-to-100 swing in harm on one scale with the 0-to-100 swing on another scale, assuming the harm is a worldwide average.

Swing weights for the User criterion were assessed first; the largest swing, on Product-specific morbidity, the difference between cigarettes and nasal sprays was assigned a weight of 100. Next, weights were judged for the criteria at the Other node: the largest swing, the difference between cigarettes and small cigars for Economic cost, was set at 100. Finally, those two 100's were compared by judging their swing weights. The swing for Product-re-

Table 1. The 12 products considered during the decision conference and their definitions

Cigarettes	manufactured and hand-rolled cigarettes in which the tobacco is wrapped in paper
Cigars	smoked cigars: roll of tobacco wrapped in tobacco leaf
Little and small cigars	used like a cigarette wrapped in tobacco leaf, sometimes with a filter (a product that has emerged in response to the US tobacco taxation system and would, in most jurisdictions be considered cigarettes)
Pipes	a tube with a small bowl at one end for smoking tobacco
Water pipe	a pipe where tobacco smoke is bubbled through water
Smokeless refined	non-snus (and other) smokeless refined tobacco products used orally, including moist chewing tobacco and snuff (common in USA)
Smokeless unrefined	non-snus (and other) smokeless unrefined tobacco products used orally, including chewing tobacco and dry snuff (products common in SE Asia)
Snus	a low nitrosamine and non-fermented smokeless tobacco product (popular in Scandinavia and now in USA)
ENDS	electronic nicotine delivery system products, e.g. e-cigs (electronic cigarettes either cigarette-like or personal vaporizers)
Oral products	oral nicotine delivery products (including NRT products)
Patch	dermal nicotine delivery products
Nasal sprays	nasal nicotine delivery products

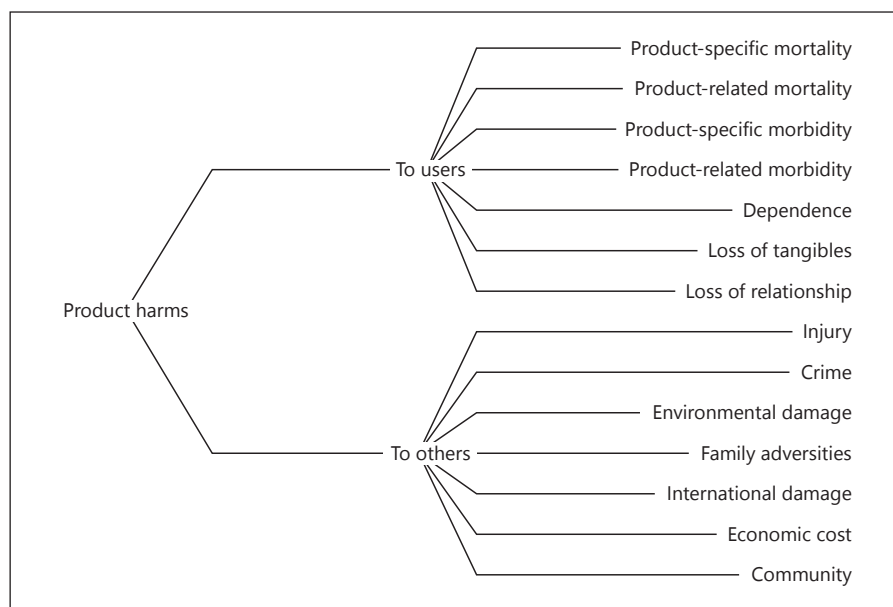


Fig. 1. Evaluation criteria organized by harms to users and harms to others.

Table 2. Definitions of the evaluation criteria for the nicotine products

Name	Description
Product-specific mortality	deaths directly attributed to product misuse or abuse as in the case of accidental and deliberate poisoning
Product-related mortality	deaths indirectly attributed to the product, e.g. death due to cancer, respiratory illness, cardiovascular disease and fire
Product-specific morbidity	damage (morbidity, chronic ill health) to physical health directly attributed to product misuse or abuse, e.g. ulcers, lung disease, heart disease
Product-related morbidity	damage to physical health indirectly attributed to product misuse or abuse, e.g. burns, allergies
Dependence	extent to which the product creates a propensity or urge to continue use despite adverse consequences and causes withdrawal symptoms on cessation
Loss of tangibles	extent of loss of tangible things (e.g. income, housing, job)
Loss of relationships	extent of loss of relationships with family and friends
Injury	the extent to which the product increases chances of injuries to others both directly and indirectly, e.g. traffic accident, fetal harm, second-hand smoke, accidental poisoning, burns
Crime	the extent to which the use of the product increases criminal behaviour (e.g. smuggling) directly or indirectly (at the population level, not the individual)
Environmental damage	the extent to which the use and production of this product causes environmental damage locally, e.g. fires, competition for arable land, cigarette stub pollution
Family adversities	the extent to which the use of the product causes family adversities, e.g. economic well-being, future prospects of children
International damage	the extent to which the use of the product contributes to damage at an international level, e.g. deforestation, contraband as criminal activity, counterfeiting
Economic cost	the extent to which the use of the product results in effects that create direct costs to countries (e.g. health-care costs, customs) and indirect costs (e.g. loss of productivity, absenteeism)
Community	the extent to which the use of the product creates decline in social cohesion and decline in the reputation of the community

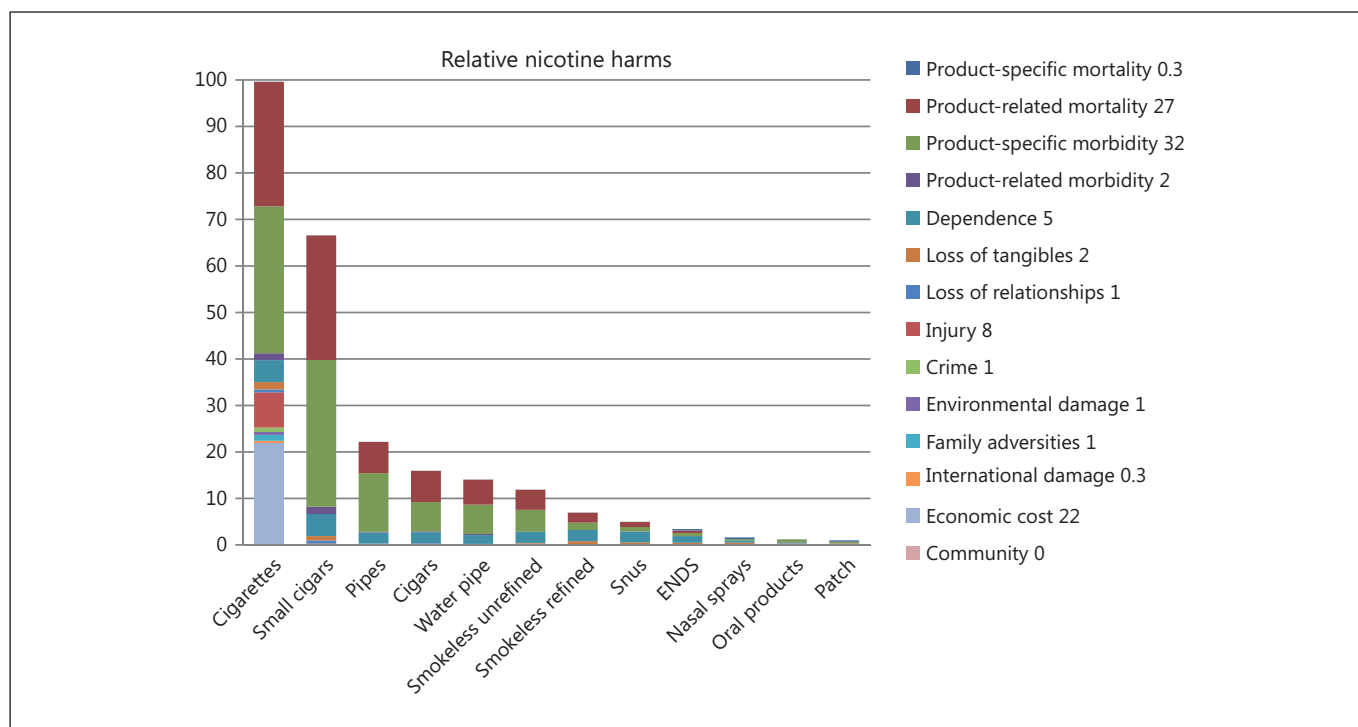


Fig. 2. Overall weighted scores for each of the products. Cigarettes, with an overall harm score of 99.6, are judged to be most harmful, and followed by small cigars at 67. The heights of the coloured portions indicate the part scores on each of the criteria. Product-related mortality, the upper dark red sections, are substantial contribu-

tors to those two products, and they also contribute moderately to cigars, pipes, water pipes, and smokeless unrefined. The numbers in the legend show the normalized weights on the criteria. Higher weights mean larger differences that matter between most and least harmful products on each criterion.

lated morbidity was weighted as the larger harm that matters, so its weight of 100 was retained. The swing for Economic cost was assessed as 70% of that, so the original weights for all the Economic criteria were multiplied by 0.70.

As scores and weights were agreed, they were input to the Hiview computer program¹, which normalized the weights so they summed to 100, calculated the weighted scores and displayed the results.

Results

Figure 2 shows the overall weighted scores of the nicotine products as stacked bar graphs. Cigarettes and small cigars are each several times more harmful than any of the other products. Similarly coloured sections of the bar graphs show a given criterion's weighted harm value as it contributes to the overall weighted scores of the nicotine products. Thus, Product-related mortality and Product-

specific morbidity are the main harms for cigarettes and small cigars, while Economic cost is also a substantial contributor to the overall harm for cigarettes.

The stacked bar graphs can also be shown for their separate contributions of harm 'To users' and harm 'To others'. Figure 3 gives the harm to users as the blue section, and harm to others as red. Harm to others makes a substantial contribution only to cigarettes, and virtually none to the other 11 products.

Why are cigarettes considered the most harmful? Figure 4 shows the contribution that each criterion makes to cigarettes' total weighted score. Each row in the display gives the part-score for that criterion (Wtd Diff), and it is the sum of those part scores that gives the overall score of 99.6. These part-scores determine the relative heights of each of the coloured bands for the cigarettes' bar graph in figure 4. Note that cigarettes were assigned harm scores of 100 on 12 of the 14 criteria, but that just five of those 14 collectively contribute a score of 92.7, nearly as much as the total of 99.6.

Both cigarettes and small cigars score 100 on three of the most important criteria: Product-specific morbidi-

¹An MCDA computer program first developed at the London School of Economics and Political Science and now available from Catalyze Ltd., www.catalyze.co.uk.

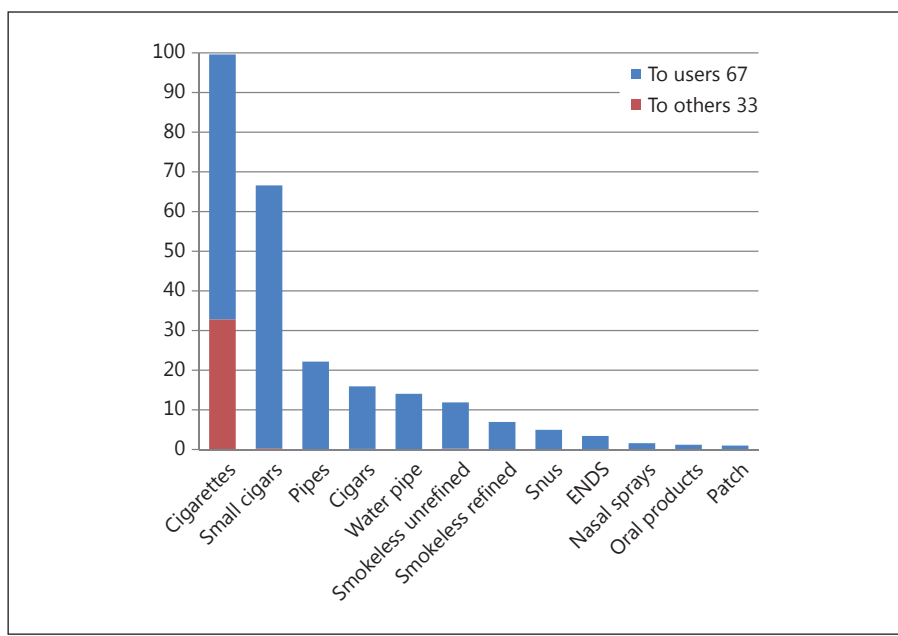


Fig. 3. The products ordered by their overall harm scores, with the stacked bar graphs showing the contribution to the overall score of harms to users and harm to others. The numbers in the legend show the sums of the normalized weights at each node.

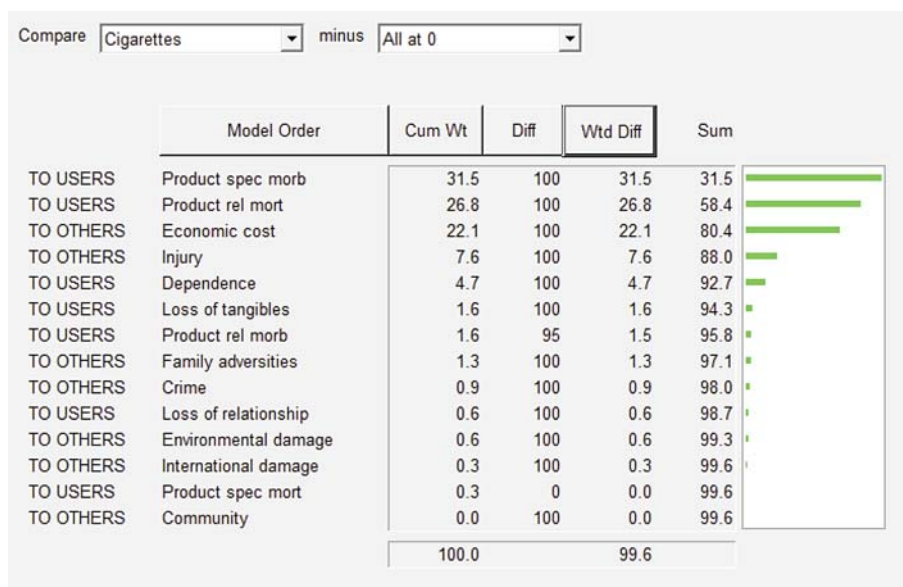


Fig. 4. The relative harms of cigarettes. The cumulative weight (Cum Wt) column shows the normalized weight for each criterion. The harm score for cigarettes, shown in the Diff column, on each criterion is multiplied by the cumulative weight of the corresponding criterion to give a weighted score (i.e., a part-score), shown in the Wtd Diff column. The lengths of the green bars are proportional to the weighted scores, so the longer the green bars, the more that harm matters for its effects from cigarettes.

ty, Product-related mortality and Dependence. Those three are harms to the users, criteria which do not take account of the extent of usage worldwide. However, cigarettes also score 100 on Economic cost and Injury, which are harms to others that do take account of global usage. It is those two criteria that account for the difference in the total scores of cigarettes compared to small cigars.

Discussion

Perhaps not surprisingly, given their massively greater use as compared with other products, cigarettes were ranked the most harmful, followed by small cigars as two thirds as harmful. It is only the relative lack of harm to others that positioned small cigars at two thirds the harm of cigarettes. For both these products the bulk of the

harm came from morbidity and mortality areas such as cancer, respiratory and cardiovascular disease, followed by Economic cost, Injury and Dependence. There was a big drop in harm from small cigars (67% of maximum relative harm, MRH) to pipes 22%. Within the tobacco products there was a gradual reduction in harm from water pipe, smokeless unrefined, smokeless refined to snus that has 5% of MRH. Among the purer non-tobacco vehicle products ENDS were rated to have only 4% of MRH and for the even purer NRTs the MRH was only rated at about 2%. Thus there is wide variability in harm among the combustible tobacco-based products, from cigarettes (100%) to water pipe (14%) and even more within the tobacco-based category, from cigarettes (100%) to snus (5%). Not surprisingly the purest products, NRTs, with few other ingredients than nicotine were the least harmful and pose little risk for intrinsic harm when used for the treatment of tobacco dependence. Indeed their use would bring significant benefits not just to users but also to non-smokers and society as a whole.

Clearly this exercise speaks to a continuum of harm from nicotine-containing products with cigarettes at one end and NRT products at the other end. The differences between the products are substantial and if policy actions could help to switch use away from cigarettes and other smoked products to purer nicotine products, such as NRT products, massive public health gains would occur.

There is also some evidence that the cigarettes are the most dependence-forming product and products with less harm also may be less dependence-forming [9]. An analogue can be found with alcohol where most countries have policies that steer consumption as much as possible to alcohol-containing beverages with a low alcohol content.

A limitation of this study is the lack of hard evidence for the harms of most products on most of the criteria. That is why we adopted the decision conferencing process: the group of experts worked face-to-face in a peer-review setting with impartial facilitation, sharing relevant data, knowledge and experience to ensure that all perspectives were heard. It is the combination of impartial facilitation, modelling (in this case, MCDA), and information technology (projecting the MCDA model for the group to observe as it was constructed and explored) that enables a group to outperform its members, thus providing the best collective expertise of the experts [28]. Another weakness might be the kind of sample of experts. There was no formal criterion for the recruitment of the

experts although care was taken to have raters from many different disciplines.

Even if data were available for all the harms of all the products on all the criteria, judgements would still be required to assess swing-weights. While the magnitude of harm of the most harmful product on each criterion can be informed by data, how much that worst-best difference matters requires an act of judgement. In this way, MCDA separates matters of fact from value judgements. As value judgements are at the heart of political debate, it might be instructive to engage in a public consultation exercise to allow different constituencies to express their views about the weights. This could be a first step in initiating a structured deliberative discourse about nicotine-containing products, as the politicians, the law and the public might weight the harm criteria differently [29]. In addition, including the benefits of using nicotine products along with the harmful criteria might provide insights into the nature of the benefit-harm balance.

The results of this study suggest that of all nicotine-containing products, cigarettes (and small cigars in the USA) are very much the most harmful. Interventions to reduce this pre-eminence are likely to bring significant benefits not just to users but also to non-smokers and society as a whole. Attempts to use other forms of nicotine such as ENDS and NRT to reduce cigarette smoking should be encouraged as the harms of these products are much lower.

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Disclosure Statement

The sponsor of the study had no role in any stage of the MCDA process or in the writing of this article, and was not present at the workshop. All authors had full access to all the data in the study, and had final responsibility for the decision to submit for publication.

K.F. has served as a consultant for most companies with an interest in tobacco dependence treatments. J.F. has served as a consultant to manufacturers of smoking cessation products (e.g. Pfizer, GSK, J & J, Novartis) and has received a research grant from Pfizer. R.P. has received lecture fees from Pfizer and GSK, a research grant from Pfizer, and he has served as a consultant for Pfizer, Global Health Alliance for treatment of tobacco dependence, and Arbi Group Srl., an e-cigarette distributor. All other authors have no conflicts of interest to declare.

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Editors' Note

The editors are aware that K.F. has connections with a company that is associated with one of the largest tobacco industries in the world (BAT: Nicoventures), but would like to notice that this stand-alone company produces smoking cessation products, i.e. electronic cigarettes, that are now in discussion to be regarded as a new form of NRT. NRT is widely accepted as a treatment of patients with tobacco dependence. Therefore, the editors decided that the potential conflict of interest of K.F. should not preclude acceptance and publication of this article. However, the scientific community has to discuss the demarcation between potential conflicts of interest related to companies producing addictive drugs and companies producing therapeutics.

Electronic cigarettes: achieving a balanced perspective

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ABSTRACT

Concerns have been raised that the advent of electronic cigarettes (e-cigarettes) may be harmful to public health, and smokers have been advised by important agencies such as the US Food and Drug Administration not to use them. This paper argues that, while more research is needed on the cost–benefit equation of these products and the appropriate level and type of regulation for them, the harms have tended thus far to be overstated relative to the potential benefits. In particular: concern over repeated inhalation of propylene glycol is not borne out by toxicity studies with this compound; risk of accidental poisoning is no different from many household devices and chemicals available in supermarkets; concern that e-cigarettes may promote continued smoking by allowing smokers to cope with no-smoking environments is countered by the observation that most smokers use these products to try to quit and their use appears to enhance quitting motivation; concerns over low nicotine delivery are countered by evidence that the products provide significant craving reduction despite this in some cases; and e-cigarettes may help reduce toxin exposure to non-smokers.

Keywords Electronic cigarette, harm reduction, nicotine.

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Electronic cigarettes, or 'e-cigarettes', look and feel like regular cigarettes but do not contain tobacco, require combustion or produce smoke. To date, they have not been manufactured by tobacco or pharmaceutical companies. e-Cigarettes are marketed to smokers as an alternative to regular cigarettes, offering the 'freedom to smoke anywhere'. e-Cigarettes are becoming increasingly popular, especially in locations with stronger tobacco control regulations [1]. The e-cigarette has been the cause of significant debate both in the United States and around the world. Although there are many staunch supporters of e-cigarettes, there appears to be even stronger and more powerful opposition from the US Food and Drug Administration (FDA) and many individuals in the tobacco control community who would prefer that e-cigarettes be regulated as drug-delivery devices or banned entirely from the market. In recent months, several commentaries on electronic cigarettes have been presented [2,3]. One recent paper [4] by Cobb & Abrams in the *New England Journal of Medicine* reviews many of the strongly held concerns of regulators and those in the tobacco control community regarding the potential perils

of e-cigarettes, but does little to examine the evidence of the potential promise of e-cigarettes.

The concerns of Cobb & Abrams focus on the limited evidence regarding both the safety and cessation benefit of e-cigarettes. They question the quality control standards of e-cigarette manufacturers, the impact of repeated propylene glycol (a major chemical component of some e-cigarettes) inhalation by humans, and the possibility of children (or adults) being harmed by inadvertently consuming large refill bottles or cartridges of e-cigarette liquid. Regarding quality control standards, Cobb & Abrams are correct, as the current standards of e-cigarette manufacturers have been quite variable, which could be a significant public safety concern. However, the impact of repeated propylene glycol vapor inhalation by humans, as it may be a throat irritant, though understandable, does not seem to be reason enough to remove these products from the market. Furthermore, animal studies on repeated propylene glycol vapor exposure indicate no deleterious effects [5], and the nicotine inhaler has similar side effects [6]. Finally, their concern regarding the possibility of accidental child

poisonings is also something that should be investigated and monitored. Currently, e-cigarette companies label their products with warnings to keep cartridges out of the reach of children. However, it is important to put this concern into context. Many household products are potentially dangerous to children if consumed, yet we do not ban these products. For example, if a child consumed a large bottle of cherry-flavored liquid acetaminophen, this too would be dangerous—if not deadly. Similar to e-cigarette labels, for consumer products that are hazardous to children we simply warn adults to keep them out of their reach.

On the topic of cessation benefit, Cobb & Abrams argue that there is no evidence that e-cigarettes are beneficial for cessation, and that there may be a risk that e-cigarettes will be used only in places where smoking is prohibited by current smokers (i.e. 'bridge products') or function as attractive starter products for young non-smokers. We agree that these concerns need to be addressed through continued thoughtful, rigorous scientific investigations. Current research investigating these concerns is limited, although not non-existent. Moreover, the research indicates some promising effects. For example, Cobb & Abrams argue that e-cigarettes are unlikely to be useful for smoking cessation because of ineffective nicotine delivery, as evidenced by low plasma levels of nicotine by the smokers who used them. However, the study [7] that they cite to support this argument actually showed that one e-cigarette brand was able to significantly reduce subjective craving for cigarettes despite low plasma levels of nicotine. Another study [8], not mentioned by Cobb & Abrams, found that e-cigarettes not only deliver nicotine effectively (more rapidly than a nicotine inhaler), but that they significantly reduce cigarette craving and number of cigarettes smoked at a level similar to that of nicotine replacement products. Furthermore, a recent clinical trial [9] published after the Cobb & Abrams article showed that e-cigarette use may motivate quitting. Among 40 smokers who were initially not interested in quitting but who were asked to use the e-cigarette *ad libitum*, 22.5% achieved sustained smoking abstinence (biochemically verified) at 6-month follow-up [9]. Furthermore, an additional 12.5% and 32.5% reduced their smoking by $\geq 80\%$ and $\geq 50\%$, respectively [9]. Several survey studies support these findings. In a large international survey of current, former or never users of e-cigarettes, 72% of users reported that e-cigarettes helped them to deal with cravings and withdrawal symptoms, 92% reported reductions in their smoking when using e-cigarettes, and only 10% reported that they experienced the urge to smoke tobacco cigarettes when using the e-cigarette [10]. Moreover, of more than 2000 former smokers in this survey, 96% reported that the e-cigarette helped them to stop smoking, and 79% reported fearing

that they would start smoking again if they stopped using it [10]. Consequently, removing e-cigarettes from the market or discouraging their use could harm public health by depriving smokers of a potentially important option for smoking cessation.

Although larger trials are needed to help answer questions regarding the possibility of dual use (i.e. smokers maintain current smoking levels and add e-cigarettes), the available evidence suggests that this is not the case. Research indicates that the vast majority of e-cigarette users use e-cigarettes for either complete (79%) or partial replacement (17%) of tobacco cigarettes [10]. In addition, fears that smokers will forego traditional cessation methods in favor of e-cigarettes has not been substantiated. A substantial number of current e-cigarette users report having tried to quit previously using nicotine replacement therapies (70%), bupropion (29%) and/or varenicline (18.6%) [10]. This finding, taken together with the Bullen *et al.* [8] finding that placebo e-cigarettes also reduced craving, withdrawal symptoms and number of cigarettes per day, suggests that e-cigarettes address an additional behavioral component (e.g. hand to mouth gesture, 'throat hit' of the vapor, exhaling visible vapor) beyond the pharmacological effect of nicotine provided by current FDA-approved therapies. As a result, for smokers who have failed to quit with current approved therapies, e-cigarettes offer an alternative method of quitting, or a method of supplementing these currently approved therapies. Moreover, withdrawing e-cigarettes from the market or discouraging ex-smokers who have quit by using these devices to discontinue their use and switch to approved forms of therapy is unlikely to be a boon for public health, as the current evidence suggests that e-cigarette users often have high levels of nicotine dependence and have tried and failed to quit smoking with multiple forms of approved cessation therapies [10]. It seems misguided to ask people to discontinue an approach that is working in favor of an approach that has already been ineffective for them.

Finally, an often unconsidered advantage of e-cigarettes is that they do not require combustion and therefore produce no second-hand smoke exposure (SHSe) to the user or to individuals in the smoker's environment. Second-hand smoke, especially in homes with children, poses a serious public health risk increasing the incidence of sudden infant death syndrome, respiratory illness, middle-ear disease and asthma [11,12]. Children aged between 3 and 11 years have the highest levels of SHSe, probably because they spend a majority of their time in close proximity to a caregiver who smokes [13–15]. Despite the strong national effort of introducing smoking bans in public spaces, children living with smokers have not experienced any reduction in their SHSe, as evidenced by serum cotinine levels [16].

Furthermore, clinical interventions aimed at reducing children's SHSe by targeting caregiver smoking behavior (i.e. cessation and/or smoking outside) often fail to produce long-term cessation and result in minimal to no reduction in SHSe for children, as measured by objective indicators such as urinary or serum cotinine or a child-worn passive smoke monitor [17]. A significant majority of parents return to smoking or do not maintain consistently smoke-free homes. As such, the current methods of reducing caregiver smoking behavior cannot be relied upon as the sole means of reducing children's SHSe. The use of e-cigarettes by caregivers who smoke and who are unable or unwilling to quit smoking by more traditional means may be a viable alternative method to reduce children's SHSe.

We contend that the initial evidence suggests that e-cigarettes offer more promise than peril, but more research needs to be conducted. The debate over e-cigarettes will no doubt continue. It is our hope that those participating in this debate report all sides of the issue, considering both the potential harm e-cigarettes could cause the user and the potential harm the tobacco control community could cause by dismissing the e-cigarette prematurely as a viable alternative for smoking cessation and second-hand smoke reduction. We also encourage e-cigarette investigators to draw conclusions within the appropriate context to prevent misleading conclusions. For example, the FDA held a press conference during which it warned consumers not to use e-cigarettes because of the presence of toxic chemicals, including diethylene glycol and carcinogens (tobacco-specific nitrosamines) [18]. What the FDA did not report was that it detected only trace levels of carcinogens (0.07–0.2% of the corresponding levels in cigarettes) [19,20] at levels similar to the nicotine patch and nicotine gum, and found diethylene glycol in only one of the 18 samples tested (a chemical that has not been found in any other brand since) [20]. Viewed in this context, instead of warning consumers not to use e-cigarettes we would argue that these data suggest that e-cigarettes may pose much lower carcinogenicity than regular cigarettes and are probably similar in carcinogenicity to FDA-approved nicotine replacement products. However, we recognize that stronger quality control standards need to be utilized by e-cigarette manufacturers to prevent human exposure to toxic chemicals, such as diethylene glycol. Indeed, some e-cigarette manufacturers are attending to safety concerns by making their products safer, such as using distilled water and glycerine instead of propylene glycol vapor. Overall, we hope that continued discussion about the promise and perils of e-cigarettes is based on a balanced view of the available science, rather than an ideology that opposes harm reduction without consideration of both sides of the issue, including potential public health benefits.

Declarations of interest

None.

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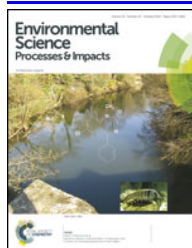
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Particulate metals and organic compounds from electronic and tobacco-containing cigarettes: comparison of emission rates and secondhand exposure

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In recent years, electronic cigarettes have gained increasing popularity as alternatives to normal (tobacco-containing) cigarettes. In the present study, particles generated by e-cigarettes and normal cigarettes have been analyzed and the degree of exposure to different chemical agents and their emission rates were quantified. Despite the 10-fold decrease in the total exposure to particulate elements in e-cigarettes compared to normal cigarettes, specific metals (e.g. Ni and Ag) still displayed a higher emission rate from e-cigarettes. Further analysis indicated that the contribution of e-liquid to the emission of these metals is rather minimal,

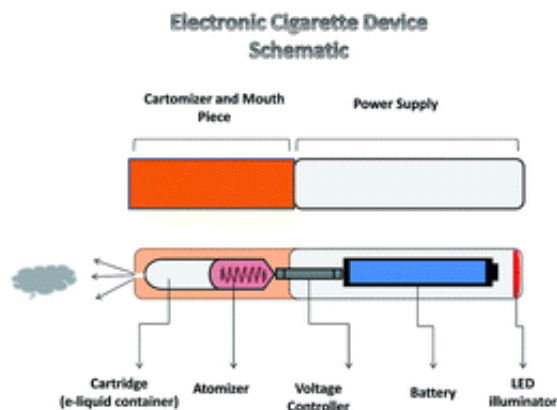
implying that they likely originate from other components of the e-cigarette device or other indoor sources. Organic species had lower emission rates during e-cigarette consumption compared to normal cigarettes. Of particular note was the non-detectable emission of polycyclic aromatic hydrocarbons (PAHs) from e-cigarettes, while substantial emission of these species was observed from normal cigarettes. Overall, with the exception of Ni, Zn, and Ag, the consumption of e-cigarettes resulted in a remarkable decrease in secondhand exposure to all metals and organic compounds. Implementing quality control protocols on the manufacture of e-cigarettes would further minimize the emission of metals from these devices and improve their safety and associated health effects.

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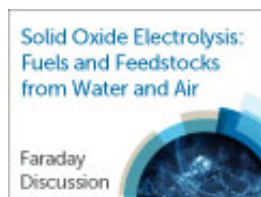
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Giorgio Romagna, Elena Aliffranchini, Elena Bocchietto, Stefano Todeschi, Mara Esposito, and Konstantinos E. Farsalinos

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Abstract

Context: Electronic cigarettes (ECs) are used as alternatives to smoking; however, data on their cytotoxic potential are scarce.**Objective:** To evaluate the cytotoxic potential of 21 EC liquids compared to the effects of cigarette smoke (CS).**Methods:** Cytotoxicity was evaluated according to UNI EN ISO 10993-5 standard. By activating an EC device, 200 mg of liquid was evaporated and was extracted in 20 ml of culture medium. CS extract from one cigarette was also produced. The extracts, undiluted (100%) and in five dilutions (50%, 25%, 12.5%, 6.25% and 3.125%), were applied to cultured murine fibroblasts (3T3), and viability was measured after 24-hour incubation by 3-[4,5-dimethylthiazol-2-yl]-2,5-diphenyltetrazolium bromide assay. Viability of less than 70% was considered cytotoxic.**Results:** CS extract showed cytotoxic effects at extract concentrations above 12.5% (viability: 89.1 ± 3.5% at 3.125%, 77.8 ± 1.8% at 6.25%, 72.8 ± 9.7% at 12.5%, 5.9 ± 0.9% at 25%, 9.4 ± 5.3% at 50% and 5.7 ± 0.7% at 100% extract concentration). Range of fibroblast viability for EC vapor extracts was 88.5–117.8% at 3.125%, 86.4–115.3% at 6.25%, 85.8–111.7% at 12.5%, 78.1–106.2% at 25%, 79.0–103.7% at 50% and 51.0–102.2% at 100% extract concentration. One vapor extract was cytotoxic at 100% extract concentration only (viability: 51.0 ± 2.6%). However, even for that liquid, viability was 795% higher relative to CS extract.**Conclusions:** This study indicates that EC vapor is significantly less cytotoxic compared tobacco CS. These results should be validated by clinical studies.

Keywords

Cytotoxicity, electronic cigarette, fibroblasts, in vitro, nicotine, smoking, tobacco harm reduction

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