



**CITY OF LAGUNA HILLS
CITY COUNCIL/PLANNING AGENCY
REGULAR MEETING AGENDA
OCTOBER 14, 2014
Closed Session at 6:00 PM (*when scheduled*)
General Business Session at 7:00 PM**

Andrew Blount, Mayor

**Dore J. Gilbert, M.D., Mayor Pro Tempore
Randal Bressette, Council Member**

**Melody Carruth, Council Member
Barbara Kogerman, Council Member**

Location: City Council Chamber, 24035 El Toro Road, Laguna Hills, California 92653

Any person wishing to address the City Council/Planning Agency on any matter, whether or not it appears on this Agenda, is asked to complete a pink "Request to Speak" form available on the table at the back of the Chamber. The completed form is to be submitted to the City Clerk prior to an individual being heard by the City Council/Planning Agency. Completion of the form is voluntary. All persons may attend the meeting regardless of whether this form is completed.

Members of the public wishing to address the City Council can do so during the Public Comments portion of the Agenda with a time limitation of three minutes per person, an overall time limit of ten minutes for any one subject, and a total time limit of thirty minutes for Public Comments. If you are commenting on an Agenda item, your comments will be heard at the time that item is scheduled on the Agenda. If you are addressing the City Council on an item not listed on the Agenda, the City Council is prohibited by law from discussing or taking any action on that item.

CLOSED SESSION - CONVENING AT 6:00 PM

CALL TO ORDER

Resolution No. 96-04-09-1 established rules of decorum for public meetings held by the City of Laguna Hills. Resolution No. 96-04-09-1 is available on the table at the back of the City Council Chamber.

ROLL CALL

ANNOUNCEMENT OF CLOSED SESSION ITEMS

A. PUBLIC EMPLOYEE PERFORMANCE EVALUATION

Pursuant to Government Code Section 54957(b)(1)
Public Employee Title: City Manager - Annual Performance Evaluation

PUBLIC COMMENT ON CLOSED SESSION ITEMS

ADJOURN TO CITY COUNCIL CONFERENCE ROOM

CONVENE INTO CLOSED SESSION

RECONVENE TO CITY COUNCIL CHAMBER

RECESS

GENERAL BUSINESS - RECONVENING AT 7:00 PM

CALL TO ORDER

Resolution No. 96-04-09-1 established rules of decorum for public meetings held by the City of Laguna Hills. Resolution No. 96-04-09-1 is available on the table at the back of the City Council Chamber.

PLEDGE OF ALLEGIANCE: COUNCIL MEMBER CARRUTH

ROLL CALL OF CITY COUNCIL MEMBERS

CLOSED SESSION REPORT

1. PRESENTATIONS AND PROCLAMATIONS

1.1 LAGUNA HILLS HIGH SCHOOL STUDENT LIAISON

RECOMMENDATION: THAT THE CITY COUNCIL RECEIVE AN ORAL REPORT FROM LAGUNA HILLS HIGH SCHOOL STUDENT LIAISON DANIEL BUSHNER.

1.2 LAGUNA HILLS 3/5 MARINE SUPPORT COMMITTEE

RECOMMENDATION: THAT THE CITY COUNCIL RECEIVE AN UPDATE FROM CHAIR KAREN ROBBINS ON THE 3/5 DARK HORSE COMMITTEE.

2. PUBLIC COMMENTS

This is the time to address the City Council on any matter not listed on this Agenda that is within the subject matter jurisdiction of the City Council. Public Comments are limited to three minutes per person, an overall time limit of ten minutes for any one subject, and a total time limit of thirty minutes.

3. CONSENT CALENDAR

All matters listed under "CONSENT CALENDAR" are considered to be routine and will be enacted by one motion approving the recommendation listed on the Agenda. There will be no separate discussion unless Members of the City Council or Staff request specific items be removed from the Consent Calendar.

3.1 WAIVE READING IN FULL OF ALL ORDINANCES AND RESOLUTIONS ON THE AGENDA

RECOMMENDATION: THAT THE CITY COUNCIL WAIVE READING IN FULL OF ALL ORDINANCES AND RESOLUTIONS ON THE AGENDA AND DECLARE THAT SAID TITLES WHICH APPEAR ON THE PUBLIC AGENDA SHALL BE DETERMINED TO HAVE BEEN READ BY TITLE AND FURTHER READING WAIVED.

3.2 APPROVAL OF MINUTES FOR SEPTEMBER 23, 2014

RECOMMENDATION: THAT THE CITY COUNCIL APPROVE THE MINUTES OF THE SEPTEMBER 23, 2014, REGULAR MEETING.

3.3 APPROVAL OF WARRANT REGISTER FOR PERIOD ENDED OCTOBER 14, 2014

RECOMMENDATION: THAT THE CITY COUNCIL APPROVE THE WARRANT REGISTER IN THE AMOUNT OF \$314,789.92.

3.4 PROGRESS PAYMENT NO. 2 FOR TURF RENOVATION LAGUNA HILLS COMMUNITY CENTER AND SPORTS COMPLEX, CIP NO. 238B

RECOMMENDATION: THAT THE CITY COUNCIL APPROVE PROGRESS PAYMENT NO. 2, IN THE NET AMOUNT OF \$950.00, TO SPORTS FIELD SERVICES, FOR TURF RENOVATION AT THE LAGUNA HILLS COMMUNITY CENTER AND SPORTS COMPLEX, CIP NO. 238B, ACCEPT THE 2014 PROJECT PHASE ONE AS COMPLETE AND AUTHORIZE THE RELEASE OF RETENTION IN 35 DAYS FOLLOWING THE RECORDATION OF A NOTICE OF CESSATION OF LABOR IF NO LIENS HAVE BEEN FILED.

3.5 SUPPORT OF PROPOSITION NO. 1, THE WATER QUALITY, SUPPLY, AND INFRASTRUCTURE IMPROVEMENT ACT OF 2014, ON THE NOVEMBER 4, 2014, GENERAL ELECTION.

RECOMMENDATION: THAT THE CITY COUNCIL ADOPT A RESOLUTION ENTITLED: "A RESOLUTION OF THE CITY COUNCIL OF THE CITY OF LAGUNA HILLS, CALIFORNIA, SUPPORTING PROPOSITION NO. 1 ON THE NOVEMBER 4, 2014, GENERAL ELECTION."

ITEMS REMOVED FROM THE CONSENT CALENDAR

4. PLANNING AGENCY

4.1 ROLL CALL OF PLANNING AGENCY MEMBERS

4.2 PUBLIC COMMENTS

This is the time to address the Planning Agency on any matter not listed on this Agenda that is within the subject matter jurisdiction of the Planning Agency. Public Comments are limited to three minutes per person, an overall time limit of ten minutes for any one subject, and a total time limit of thirty minutes.

4.3 APPROVAL OF MINUTES FOR SEPTEMBER 23, 2014

RECOMMENDATION: THAT THE PLANNING AGENCY APPROVE THE MINUTES OF THE SEPTEMBER 23, 2014, REGULAR MEETING.

4.4 ADMINISTRATIVE REPORTS

4.5 PLANNING AGENCY PUBLIC HEARINGS

PLANNING AGENCY ADJOURNMENT**5. CITY COUNCIL PUBLIC HEARINGS****6. ADMINISTRATIVE REPORTS**

6.1 City Manager

6.2 City Attorney

6.2.1 FIRST READING AND INTRODUCTION OF AN ORDINANCE TO AMEND CHAPTER 5-28 OF TITLE 5 OF THE LAGUNA HILLS MUNICIPAL CODE (SMOKING AND SALE OF TOBACCO PRODUCTS) TO REGULATE THE USE AND SALE OF E-CIGARETTES IN THE SAME MANNER AS TOBACCO PRODUCTS

RECOMMENDATION: THAT THE CITY COUNCIL INTRODUCE FOR FIRST READING, READ BY TITLE ONLY, AND WAIVE FURTHER READING, AN ORDINANCE ENTITLED: "AN ORDINANCE OF THE CITY OF LAGUNA HILLS, CALIFORNIA, AMENDING CHAPTER 5-28 OF TITLE 5 OF THE LAGUNA HILLS MUNICIPAL CODE TO REGULATE THE USE AND SALE OF E-CIGARETTES IN THE SAME MANNER AS TOBACCO PRODUCTS."

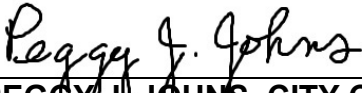
7. MATTERS AGENDIZED AND PRESENTED BY CITY COUNCIL MEMBERS AND MAYOR

8. CITY COUNCIL MEMBER COMMENTS**ADJOURNMENT**

The next Regular Meeting of the City Council will be October 28, 2014, in the City Council Chamber, located at 24035 El Toro Road, Laguna Hills, California.

CERTIFICATION

I, PEGGY J. JOHNS, City Clerk of the City of Laguna Hills, do hereby certify that a copy of the foregoing Agenda was posted at Laguna Hills City Hall, Laguna Hills Community Center, and the Courtyard at La Paz Center by October 10, 2014, at 5:00 PM.



PEGGY J. JOHNS, CITY CLERK

October 10, 2014

DATE

In compliance with the Americans with Disabilities Act, if you need special assistance to participate in this meeting, you should contact the office of the City Clerk at (949) 707-2635. Notification 48 hours prior to the meeting will enable the City to make reasonable arrangements to assure accessibility to this meeting.

Materials related to an item on this Agenda submitted to the City Council after distribution of the agenda packet are available for public inspection in the City Clerk's Office at 24035 El Toro Road, Laguna Hills, California, during normal business hours.

City Council Members receive no additional compensation or stipend as a result of simultaneously convening meetings of the Laguna Hills Planning Agency.

**CITY OF LAGUNA HILLS, CALIFORNIA
CITY COUNCIL/PLANNING AGENCY
REGULAR MEETING
MINUTES
SEPTEMBER 23, 2014**

GENERAL BUSINESS - CONVENING AT 7:00 PM

CALL TO ORDER

Mayor Pro Tempore Gilbert called the Regular Meeting of the City Council of the City of Laguna Hills, California, to order at 7:00 PM in the Laguna Hills City Council Chamber.

PLEDGE OF ALLEGIANCE: Council Member Bressette

ROLL CALL OF CITY COUNCIL MEMBERS

Present: Mayor Pro Tempore Gilbert, Council Member Bressette, Council Member Carruth, and Council Member Kogerman.

Absent: Mayor Blount

CLOSED SESSION REPORT

There was no Closed Session scheduled.

1. PRESENTATIONS AND PROCLAMATIONS

1.1 SPOTLIGHT ON LOCAL BUSINESS

THE CITY COUNCIL RECEIVED AN ORAL REPORT FROM JEFF EARL, STORE MANAGER FOR THE NEW FRESH MARKET.

1.2 LAGUNA HILLS HIGH SCHOOL STUDENT LIAISON

THE CITY COUNCIL RECEIVED AN ORAL REPORT FROM LAGUNA HILLS HIGH SCHOOL STUDENT LIAISON DANIEL BUSHNER.

1.3 PROCLAMATION, FIRE PREVENTION WEEK, OCTOBER 5, 2014 - OCTOBER 11, 2014

MAYOR PRO TEMPORE GILBERT AND COUNCIL MEMBER BRESSETTE PRESENTED A PROCLAMATION TO BATTALION CHIEF MICHAEL CONTRERAS FROM THE ORANGE COUNTY FIRE AUTHORITY, PROCLAIMING OCTOBER 5, 2014, THROUGH OCTOBER 11, 2014, AS FIRE PREVENTION WEEK.

2. PUBLIC COMMENTS

There were no Public Comments.

3. CONSENT CALENDAR

MOTION TO APPROVE THE CONSENT CALENDAR, WITH COUNCIL MEMBER BRESSETTE REMOVING ITEM NO. 3.2, AND COUNCIL MEMBER KOGERMAN REMOVING ITEM NO. 3.3, BY M/COUNCIL MEMBER KOGERMAN, S/COUNCIL MEMBER CARRUTH.

APPROVED BY A VOTE OF 4-0-1 (MAYOR BLOUNT ABSENT).

3.1 WAIVE READING IN FULL OF ALL ORDINANCES AND RESOLUTIONS ON THE AGENDA

THE CITY COUNCIL WAIVED READING IN FULL OF ALL ORDINANCES AND RESOLUTIONS ON THE AGENDA AND DECLARED THAT SAID TITLES WHICH APPEAR ON THE PUBLIC AGENDA SHALL BE DETERMINED TO HAVE BEEN READ BY TITLE AND FURTHER READING WAIVED.

3.4 PROPOSED LEASE RENEWAL WITH CAROL BEHRENS FOR 24031 EL TORO ROAD, SUITE 304, LAGUNA HILLS, CALIFORNIA

THE CITY COUNCIL APPROVED THE LEASE WITH CAROL BEHRENS FOR 24031 EL TORO ROAD, SUITE 304, LAGUNA HILLS, CALIFORNIA, AND AUTHORIZED THE CITY MANAGER TO EXECUTE THE LEASE.

3.5 PROPOSED LEASE RENEWAL WITH DAYLE MCINTOSH CENTER FOR THE DISABLED, INC., FOR 24031 EL TORO ROAD, SUITE 300, LAGUNA HILLS, CALIFORNIA

THE CITY COUNCIL APPROVED A LEASE WITH DAYLE MCINTOSH CENTER FOR THE DISABLED, INC., FOR 24031 EL TORO ROAD, SUITE 300, LAGUNA HILLS, CALIFORNIA, AND AUTHORIZED THE CITY MANAGER TO EXECUTE THE LEASE.

3.6 PROPOSED LEASE RENEWAL WITH WINDSTONE BEHAVIORAL HEALTH, A CALIFORNIA CORPORATION, FOR 24031 EL TORO ROAD, SUITE 250, LAGUNA HILLS, CALIFORINA

THE CITY COUNCIL APPROVED THE LEASE WITH WINDSTONE BEHAVIORAL HEALTH, A CALIFORNIA CORPORATION, FOR 24031 EL TORO ROAD, SUITE 250, LAGUNA HILLS, CALIFORNIA, AND AUTHORIZED THE CITY MANAGER TO EXECUTE THE LEASE.

3.7 PROGRESS PAYMENT NO. 9 FOR LA PAZ OPEN SPACE PROJECT, CIP NO. 615A

THE CITY COUNCIL APPROVED PROGRESS PAYMENT NO. 9, IN THE NET AMOUNT OF \$1,140.00, TO ENVIRONMENTAL CONSTRUCTION, INC., FOR LA PAZ OPEN SPACE IMPROVEMENTS, CIP NO. 615A.

3.8 APPLICATION TO THE ORANGE COUNTY TRANSPORTATION AUTHORITY FOR FUNDS FOR THE ARTERIAL PAVEMENT MANAGEMENT PROGRAM

THE CITY COUNCIL ADOPTED RESOLUTION NO. 2014-09-23-1, A RESOLUTION OF THE CITY COUNCIL OF THE CITY OF LAGUNA HILLS, CALIFORNIA, AUTHORIZING APPLICATION FOR FUNDS FOR THE ARTERIAL PAVEMENT MANAGEMENT PROGRAM FUNDED WITH REGIONAL SURFACE TRANSPORTATION PROGRAM FUNDING UNDER THE MOVING AHEAD FOR PROGRESS IN THE 21ST CENTURY FEDERAL TRANSPORTATION ACT FOR THE ARTERIAL HIGHWAY PAVEMENT REHABILITATION - VARIOUS LOCATIONS PROJECT.

3.9 GOVERNMENT CODE SECTION 66006 - DEVELOPMENT IMPACT FEES ANNUAL REPORT

THE CITY COUNCIL APPROVED THE DEVELOPMENT IMPACT FEES ANNUAL REPORT PURSUANT TO GOVERNMENT CODE SECTION 66006.

3.10 PROGRESS PAYMENT NO. 1 FOR CITYWIDE PAVEMENT REHABILITATION PROJECT, CIP NO. 101-I

THE CITY COUNCIL APPROVED PROGRESS PAYMENT NO. 1, IN THE NET AMOUNT OF \$231,550.49, TO ALL AMERICAN ASPHALT, FOR CITYWIDE PAVEMENT REHABILITATION PROJECT, CIP NO. 101-I.

ITEMS REMOVED FROM THE CONSENT CALENDAR

3.2 APPROVAL OF MINUTES FOR SEPTEMBER 9, 2014

Council Member Bressette removed this item from the Consent Calendar to register his abstention on approval of the Minutes, as he was absent at that meeting.

THE CITY COUNCIL APPROVED THE MINUTES OF THE SEPTEMBER 9, 2014, REGULAR MEETING, BY M/COUNCIL MEMBER CARRUTH, S/COUNCIL MEMBER KOGERMAN.

APPROVED BY A VOTE OF 3-0-1-1 (COUNCIL MEMBER BRESSETTE ABSTAINED, MAYOR BLOUNT ABSENT).

3.3 APPROVAL OF WARRANT REGISTER FOR PERIOD ENDED SEPTEMBER 23, 2014

Council Member Kogerman removed this item from the Consent Calendar to inquire about the City's Moulton Niguel water bill for July and August, and when the City would realize a savings from the artificial turf installation project, and asked about water conservation measures. Assistant City Manager White gave an explanation on the invoice for July and August, and indicated staff was continuing to carefully monitor water usage throughout the City.

THE CITY COUNCIL APPROVED THE WARRANT REGISTER IN THE AMOUNT OF \$1,632,620.90, BY M/COUNCIL MEMBER CARRUTH, S/COUNCIL MEMBER KOGERMAN.

APPROVED BY A VOTE OF 4-0-1 (MAYOR BLOUNT ABSENT).

4. PLANNING AGENCY

Mayor Pro Tempore Gilbert recessed the City Council meeting and acting in the capacity of Vice Chair, called the meeting of the Planning Agency of the City of Laguna Hills, California, to order at 7:20 PM.

4.1 ROLL CALL OF PLANNING AGENCY MEMBERS

Present: Vice Chair Gilbert, Agency Member Bressette, Agency Member Carruth, and Agency Member Kogerman

Absent: Chair Blount

4.2 PUBLIC COMMENTS

There were no Public Comments.

4.3 APPROVAL OF MINUTES FOR SEPTEMBER 9, 2014

THE PLANNING AGENCY APPROVED THE MINUTES OF THE SEPTEMBER 9, 2014, REGULAR MEETING, BY M/AGENCY MEMBER CARRUTH, S/AGENCY MEMBER KOGERMAN.

APPROVED BY A VOTE OF 3-0-1-1 (AGENCY MEMBER BRESSETTE ABSTAINED, CHAIR BLOUNT ABSENT).

4.4 ADMINISTRATIVE REPORTS

There were no Administrative Reports.

4.5 PLANNING AGENCY PUBLIC HEARINGS

4.5.1 CONDITIONAL USE PERMIT/PARKING USE PERMIT (CUP/PUP) NO. 7-14-2924, A REQUEST BY ADVANCE BEAUTY COLLEGE TO ESTABLISH A BEAUTY COLLEGE IN THE FORMER CLAIM JUMPER BUILDING IN THE COURTYARD AT LA PAZ SHOPPING CENTER AT 25332 MCINTYRE STREET IN THE COMMUNITY COMMERCIAL ZONE

Vice Chair Gilbert opened the Public Hearing.

Vern Jones, on behalf of Advance Beauty College, spoke in support of the project and answered questions from the Planning Agency.

Tam Nguyen, Applicant and Owner of Advance Beauty College, spoke in support of the project and answered questions from the Planning Agency.

Peter Haddad, Architect, answered questions from the Planning Agency about the exterior elements of the project.

Vice Chair Gilbert closed the Public Hearing.

THE PLANNING AGENCY ADOPTED RESOLUTION NO. PA2014-09-23-1, A RESOLUTION OF THE PLANNING AGENCY OF THE CITY OF LAGUNA HILLS, CALIFORNIA, APPROVING CONDITIONAL USE PERMIT/PARKING USE PERMIT (CUP/PUP) NO. 7-14-2924, A REQUEST BY ADVANCE BEAUTY COLLEGE TO ESTABLISH A BEAUTY COLLEGE IN THE FORMER CLAIM JUMPER BUILDING IN THE COURTYARD AT LA PAZ SHOPPING CENTER AT 25332 MCINTYRE STREET IN THE COMMUNITY COMMERCIAL (CC) ZONE, BY M/AGENCY MEMBER BRESSETTE, S/AGENCY MEMBER KOGERMAN. APPROVED BY A VOTE OF 3-1-1 (AGENCY MEMBER CARRUTH VOTING NO, AND CHAIR BLOUNT ABSENT).

PLANNING AGENCY ADJOURNMENT

Mayor Pro Tempore Gilbert reconvened the City Council meeting at 8:00 PM. All Council Members were present, with the exception of Mayor Blount.

5. CITY COUNCIL PUBLIC HEARINGS

There were no Public Hearings.

6. ADMINISTRATIVE REPORTS

6.1 City Manager

The City Manager was not present at the City Council meeting.

7. MATTERS AGENDIZED AND PRESENTED BY CITY COUNCIL MEMBERS AND MAYOR

There were no matters agendized and presented by City Council Members and Mayor.

8. CITY COUNCIL MEMBER COMMENTS

COUNCIL MEMBER BRESSETTE

Council Member Bressette recommended, if allowed by law, that staff include a map of the project and a link to the City's website on the actual Public Hearing Notice that is mailed to the residents, in order to provide access to the Planning documents.

COUNCIL MEMBER KOGERMAN

Council Member Kogerman stated that she was concerned about illicit massage establishments in Laguna Hills, and that there was a new state law that returned local control over these establishments back to the cities. She asked if City Attorney Simonian would be bringing a new Ordinance forward to amend the City's Municipal Code. City Attorney Simonian indicated that AB1147 was signed by the Governor and would go into effect on January 15, 2015. City Attorney Simonian indicated his firm was reviewing the new law and was collectively determining how best to proceed. He would bring back a report and Ordinance to the City Council in the near future.

Council Member Kogerman stated that she attended an ACC-OC event held at the Laguna Hills Community Center on Thursday, September 18, 2014, and the ACC-OC was very complimentary to the Laguna Hills staff in helping conduct this event. Council Member Kogerman was proud to welcome everyone to the event on behalf of the City of Laguna Hills, and thanked staff for their assistance.

ADJOURNMENT

There being no further business before the City Council at this session, Mayor Pro Tempore Gilbert declared the meeting adjourned at 8:08 PM

PEGGY J. JOHNS, CITY CLERK

ATTEST:

ANDREW BLOUNT, MAYOR

APPROVED AT MEETING OF _____



City of Laguna Hills City Council Meeting Agenda Staff Report

DATE: OCTOBER 14, 2014
TO: MAYOR AND COUNCIL MEMBERS
FROM: DONALD J. WHITE, ASSISTANT CITY MANAGER
ISSUE: APPROVAL OF WARRANT REGISTER FOR PERIOD ENDED OCTOBER 14, 2014.

RECOMMENDATION: THAT THE CITY COUNCIL APPROVE THE WARRANT REGISTER IN THE AMOUNT OF \$314,789.92.

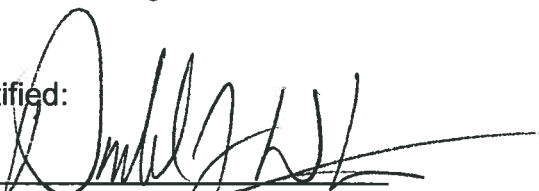
SUMMARY:

In accordance with Government Code Section 37202, the attached Warrant Register reflects the disbursements of the City of Laguna Hills for the period reported thereon. The Assistant City Manager certifies and attests to its accuracy and the availability of funds for the payment thereof. These warrants are hereby submitted to the City Council for approval of payment.

Prepared by:

JANICE MATEO REYES
Finance Manager

Certified:


DONALD J. WHITE
Assistant City Manager

10-7-14
DATE

FISCAL IMPACT:

The warrant register total is \$314,789.92.

ATTACHMENTS:

1. Warrant Register

Check Register Report

Warrant Register 10/14/14

Date: 10/07/2014

Time: 9:56 am

Page: 1

CITY OF LAGUNA HILLS

BANK: UNION BANK- GENERAL

Check Number	Check Date	Status	Void/Stop Date	Vendor Number	Vendor Name	Check Description	Amount
UNION BANK- GENERAL Checks							
8807980	09/18/2014	Printed		A-0249	ALISO MEADOWS CONDOMINIUM ASN.	Pmt #3 13/14, Aliso Mead Rehab	5,040.00
8807981	09/18/2014	Printed		C-0023	COX COMMUNICATION	Signal System, Aug '14	179.00
8807982	09/18/2014	Printed		C-1146	CYBERSOURCE CORPORATION	Gateway Expense, Aug '14	29.00
8807983	09/18/2014	Printed		I-0942	IRVINE RANCH WATER DISTRICT	Water Usage, Parks, Jul-Aug'14	174.81
8807984	09/18/2014	Printed		M-1513	MEEHAN, DANIEL	Petty Cash Replenish, Jul-Aug	282.72
8807985	09/18/2014	Printed		R-1964	REFUND, COMMUNITY DEV FEES	Refund, Permit Fees, CR# 49037	90.00
8807986	09/18/2014	Printed		R-1964	REFUND, COMMUNITY DEV FEES	Refund, C&D Deposit, CR# 48749	2,390.50
8807987	09/18/2014	Printed		R-1966	REFUND, FAC. SECURITY RENTAL	J. Diaz, V# 2003259.002	294.00
8807988	09/18/2014	Printed		R-1889	REFUND,FACILITY RENTAL DEPOSIT	A. Guiao, V# 2003263.002	345.00
8807989	09/18/2014	Printed		R-1889	REFUND,FACILITY RENTAL DEPOSIT	M. Miranda, V# 2003266.002	100.00
8807990	09/18/2014	Printed		S-1902	SAN DIEGO GAS & ELECTRIC	ST Lites, TC, Comm Ctr, Aug	29,729.86
8807991	09/18/2014	Printed		S-1949	SMART & FINAL	Program Supplies, Cs, Aug '14	113.73
8807992	09/18/2014	Printed		S-1904	SOUTHERN CALIFORNIA EDISON	ST Lites, Traffic Control, Aug	9,177.62
8807993	09/18/2014	Printed		S-1907	SPRINT	Communication Expense, CS,Aug	108.13
8807994	09/22/2014	Printed		D-0561	DOCU-TRUST	Offsite Data Storage, Jun '14	55.00
8807995	09/22/2014	Printed		S-2239	SOCAL OFFICE TECHNOLOGIES	Copier Usage, CC,04/14-7/14/14	1,454.09
8807996	09/25/2014	Printed		A-0277	ALICEA, MIA	Contract Inst Svcs., Dance	21,238.00
8807997	09/25/2014	Printed		A-0249	ALISO MEADOWS CONDOMINIUM ASN.	Pmt #4 13/14, Aliso Mead Rehab	8,000.00
8807998	09/25/2014	Printed		A-0304	AU-YEUNG, MELISSA	Travel Advance, ICSC, Sep '14	187.50
8807999	09/25/2014	Printed		C-1177	CANON FINANCIAL SERVICES, INC.	Lease - Copier, CH, Aug -Sep	442.82
8808000	09/25/2014	Printed		C-1159	CHANTARANGSU, DAVID	Travel Advance, ICSC, Sep '14	187.50
8808001	09/25/2014	Printed		C-0023	COX COMMUNICATION	T1 Line- Civic Center, Oct '14	308.02
8808002	09/25/2014	Printed		E-0504	EL TORO WATER DISTRICT	Water Usage, Parks, Aug '14	18,853.66
8808003	09/25/2014	Printed		H-0934	HOME DEPOT	Program Supplies, CS, Sep '14	140.09
8808004	09/25/2014	Printed		M-1546	MAILFINANCE, INC.	Lease - Mailing Equip,Aug-Oct	583.26
8808005	09/25/2014	Printed		M-1388	MOBILE MINI, INC.	Storage Rental Fee,9/16-10/13	83.16
8808006	09/25/2014	Printed		R-1964	REFUND, COMMUNITY DEV FEES	Refund, CUP Fees, CR# 48753	1,150.00
8808007	09/25/2014	Printed		R-1964	REFUND, COMMUNITY DEV FEES	Refund, Pool Bond, CR# 48762	250.00
8808008	09/25/2014	Printed		R-1889	REFUND,FACILITY RENTAL DEPOSIT	C. Vargas, V# 2003271.002	500.00
8808009	09/25/2014	Printed		R-1939	REYES, JANICE MATEO	Petty Cash Replenish, Sep '14	898.03
8808010	09/25/2014	Printed		S-1904	SOUTHERN CALIFORNIA EDISON	Traffic Control, Aug '14	672.45
8808011	09/25/2014	Printed		T-2681	TOTALFUNDS BY HASLER	Postage Replenishment, Aug '14	1,000.00
8808012	09/25/2014	Printed		W-2300	WHITE, DONALD	Travel Advance, ICSC, Sep '14	187.50
8808013	10/02/2014	Printed		A-0254	A. C. LANDSCAPE, INC.	Irrigation Repairs, Sept '14	6,000.00
8808014	10/02/2014	Printed		A-0138	ALL CITY MANAGEMENT, INC.	Crossing Guard Svc,08/31-9/13	2,585.52
8808015	10/02/2014	Printed		A-0359	ANDERSON PENNA PARTNERS, INC.	Professional Services, Aug '14	8,455.00
8808016	10/02/2014	Printed		A-0331	AT&T MOBILITY	Wireless Service, Sep '14	62.54
8808017	10/02/2014	Printed		A-0309	AT&T- CALNET 2	Alicia-PDV Signal, Sep '14	1,060.13
8808018	10/02/2014	Printed		B-0304	BEE MAN, THE	Bee Removal, Parks, Sept '14	250.00
8808019	10/02/2014	Printed		B-0332	BRAME, MARILYN	Contract Inst Svcs, Drawing	196.00
8808020	10/02/2014	Printed		C-0412	C&D ELECTRIC, INC.	Lighting Repairs, Parks, Sep	65.00
8808021	10/02/2014	Printed		S-2162	CARLSEN, SANDY	Mileage Reimb.,Cty Clk,Sep	6.78
8808022	10/02/2014	Printed		C-1022	CDW GOVERNMENT, INC.	Computer Back-up Warranty	650.00
8808023	10/02/2014	Printed		C-1139	COMPLETE OFFICE OF CALIFORNIA	Computer Supplies, Sep '14	863.46
8808024	10/02/2014	Printed		C-0023	COX COMMUNICATION	T-1 Line Civic Ctr Sep '14	832.59
8808025	10/02/2014	Printed		D-0461	DATA TICKET, INC.	Processing Fee, Park Cit, Aug	947.89
8808026	10/02/2014	Printed		D-0561	DOCU-TRUST	Offsite Data Storage, Sep '14	55.00
8808027	10/02/2014	Printed		E-0595	ECLIPSE MESSENGER SERVICE, INC	Delivery Service, Sep '14	23.92

Check Register Report

Warrant Register 10/14/14

Date: 10/07/2014

Time: 9:56 am

Page: 2

CITY OF LAGUNA HILLS

BANK: UNION BANK- GENERAL

Check Number	Check Date	Status	Void/Stop Date	Vendor Number	Vendor Name	Check Description	Amount
UNION BANK- GENERAL Checks							
8808028	10/02/2014	Printed		E-0554	ECONOMICS, INC.	Prof Svcs, Recycling Prog,Aug	4,970.01
8808029	10/02/2014	Printed		E-0553	ELKINS, CHRISTINA	Contract Inst Svcs., Dance	34.30
8808030	10/02/2014	Printed		G-0720	GRC ASSOCIATES, INC.	Aliso Meadows Rehab, May-Jul	11,050.00
8808031	10/02/2014	Printed		H-0805	HARRINGTON GEOTECH ENGINEERING	Prof Fees, Engineering, Sep	3,400.00
8808032	10/02/2014	Printed		H-0829	HARTZOG & CRABILL, INC.	Traf Sig Mgmt Svs, Aug	1,459.61
8808033	10/02/2014	Printed		H-0848	HDL, COREN & CONE	CAFR Services FV 13/14	695.00
8808034	10/02/2014	Printed		H-0804	HINDERLITER, DE LLAMAS & ASSOC	Sales Tax 3rdQtr,AuditSales1st	1,967.11
8808035	10/02/2014	Printed		H-0955	HR GREEN CALIFORNIA, INC.	Professional Svcs, CIP # 101	7,313.60
8808036	10/02/2014	Printed		I-0979	ISDOC	Qtrly Meeting	17.00
8808037	10/02/2014	Printed		J-1057	JAMEY CLARK, INC.	Park Repairs, Sep '14	4,100.63
8808038	10/02/2014	Printed		G-0709	JOE A. GONSALVES & SON	Legislative Services, Oct	2,900.00
8808039	10/02/2014	Printed		C-1007	LAW ENFORCEMENT	Fingerprint ID Sys-AFIS, Sep	840.48
8808040	10/02/2014	Printed		L-1372	LOPEZ, MICHAEL	AV Repair, CC, Sep '14	25.00
8808041	10/02/2014	Printed		C-0448	LUCY, STEVEN	Program Expense, CS, 10/17/14	450.00
8808042	10/02/2014	Printed		M-1552	MARTIN-RUSK, DINA	Contract Instr Svcs, Zumba	47.60
8808043	10/02/2014	Printed		M-1397	MOGAN, SANDI	Mileage Reimb., Cty Cl, Jul-Sep	37.29
8808044	10/02/2014	Printed		N-1474	NIEVES LANDSCAPE, INC.	Landscape Maintenance, Oct	74,238.05
8808046	10/02/2014	Printed		O-1546	OFFICE SOLUTIONS	Office Supplies, Sep '14	908.43
8808047	10/02/2014	Printed		O-1500	ORANGE COUNTY REGISTER	Subscription,CS,9/26-12/26	82.84
8808048	10/02/2014	Printed		O-1575	ORANGE COUNTY REGISTER-FREEDOM	Legal Advertising, Aug '14	901.96
8808049	10/02/2014	Printed		O-1587	OUTDOOR SIGN SYSTEMS, INC.	Monument Repair, Deposit	3,046.89
8808050	10/02/2014	Printed		P-1729	PACIFIC TECHNOLOGIC SYSTEMS	Hardware Support, Sep '14	240.00
8808051	10/02/2014	Printed		P-1788	PACK, DWAYNE	Program Expense, 1/2 Marathon	1,150.00
8808052	10/02/2014	Printed		C-1003	PARKING VIOLATIONS	Parking Fee Surcharge, Aug '14	3,441.00
8808053	10/02/2014	Printed		R-1830	RALPHS GROCERY COMPANY	Program Supplies, CS, Sep '14	52.28
8808054	10/02/2014	Printed		R-1943	RAMIREZ, CHRISTINA	Mileage Reimb., Admin,Jul-Sep	13.16
8808055	10/02/2014	Printed		R-1889	REFUND,FACILITY RENTAL DEPOSIT	M. Arellano, V# 2003275.002	500.00
8808056	10/02/2014	Printed		R-1889	REFUND,FACILITY RENTAL DEPOSIT	N. Pino, V# 2003277.002	445.00
8808057	10/02/2014	Printed		R-1889	REFUND,FACILITY RENTAL DEPOSIT	Olympica Gym, V# 2003278.002	1,000.00
8808058	10/02/2014	Printed		R-1855	RICHARD FISHER ASSOCIATES	On-Call Architectural Svcs,Sep	3,189.86
8808059	10/02/2014	Printed		S-1904	SOUTHERN CALIFORNIA EDISON	ST Lites, Traffic Control, Sep	1,182.36
8808060	10/02/2014	Printed		S-2250	SPARKLETTES	Operating Supplies, CS, Sep'14	68.06
8808061	10/02/2014	Printed		S-2220	SPORTS FIELD SERVICES	Professional Svcs, CIP # 238	950.00
8808062	10/02/2014	Printed		S-2201	SUNSET PROPERTY SERVICES	Street Sweeping, Sep '14	107.16
8808063	10/02/2014	Printed		T-2002	TAB PRODUCTS COMPANY	Office Supplies, City Clerk	2,271.75
8808064	10/02/2014	Printed		C-1001	TRAFFIC SIGNAL MAINTENANCE	Traffic Signal Maint, Apr '14	26,864.03
8808065	10/02/2014	Printed		U-2163	USA DANCE, INC.	Contract Inst Svcs, Dancing	21.00
8808066	10/02/2014	Printed		W-2422	WELLS FARGO FINANCIAL LEASING	Lease-Copier, Property Taxes	83.74
8808067	10/02/2014	Printed		W-2302	WEST PUBLISHING CORPORATION	Subscription, City Clk, Aug	181.00
8808068	10/02/2014	Printed		R-1801	WOODRUFF, SPRADLIN & SMART	Professional Svcs, Legal, Aug	26,543.29
8808069	10/02/2014	Printed		X-2400	XEROX CORPORATION	Lease-Copier, CH, Sep	486.63
8808070	10/02/2014	Printed		Z-2606	ZUMAR INDUSTRIES, INC.	Wayfinding Signage, Maint.	1,214.52

Total Checks: 90

Checks Total (excluding void checks):

314,789.92

Total Payments: 90

Bank Total (excluding void checks):

314,789.92

Total Payments: 90

Grand Total (excluding void checks):

314,789.92



City of Laguna Hills City Council Meeting Agenda Staff Report

DATE: OCTOBER 14, 2014

TO: MAYOR AND COUNCIL MEMBERS

**FROM: KENNETH H. ROSENFELD
DIRECTOR OF PUBLIC SERVICES/CITY ENGINEER**

**ISSUE: PROGRESS PAYMENT NO. 2 FOR TURF RENOVATION LAGUNA HILLS
COMMUNITY CENTER AND SPORTS COMPLEX, CIP NO. 238B**

RECOMMENDATION: THAT THE CITY COUNCIL APPROVE PROGRESS PAYMENT NO. 2, IN THE NET AMOUNT OF \$950.00, TO SPORTS FIELD SERVICES, FOR TURF RENOVATION AT THE LAGUNA HILLS COMMUNITY CENTER AND SPORTS COMPLEX, CIP NO. 238B, ACCEPT THE 2014 PROJECT PHASE ONE AS COMPLETE AND AUTHORIZE THE RELEASE OF RETENTION IN 35 DAYS FOLLOWING THE RECORDATION OF A NOTICE OF CESSATION OF LABOR IF NO LIENS HAVE BEEN FILED.

SUMMARY:

Work on the Turf Renovation Laguna Hills Community Center and Sports Complex, CIP No. 238B, began on July 7, 2014, and has been completed by Sports Field Services. Work performed in August was the completion of the turf maintenance phase. The soccer fields were opened for public use in mid-September. The contractor has submitted the second progress payment for approval. This phase of the two-phase project has been completed with the second phase scheduled for summer 2016. It is proposed that staff record a Notice of Cessation of Labor to allow for the release of the phase one retention in 35 days if no liens are filed.

BACKGROUND:

A routine monthly action for capital improvement projects is the submission, review, and approval of the contractor's invoice. Procedurally, field staff verifies the contractor's quantities and matches them with the submitted invoice. The unit prices and total costs of the project are confirmed by the office staff and a progress payment is then processed. A five-percent (5%) retention is withheld from each payment to assure final performance of the work. The contractor for the project, Sports Field Services, has submitted the first progress payment for the subject project as follows:

ITEM #	DESCRIPTION	QUANTITY	UNIT	\$	AMOUNT
7	Turf Maintenance	1	LS	\$ 1,000.00	\$ 1,000.00
Total To Date				\$ 74,200.00	
Less Prior Billing				<u>\$ 73,200.00</u>	
Total This Period				\$ 1,000.00	\$ 1,000.00
Less 5% Retention					<u>\$ (50.00)</u>
Due					\$ 950.00

The 2014 project phase one has now been completed. The Contractor is on contract to perform this same work in summer of 2016 as a second project phase. It is recommended the City Council accept this first project phase as complete. Staff will then record a Notice of Cessation of Labor to allow for the release of retention for project phase one in 35 days if no liens have been filed.

FISCAL IMPACT:

The progress payment is within the Capital Improvement Program Budget for the Turf Renovation Laguna Hills Community Center and Sports Complex, CIP No. 238B.



City of Laguna Hills

City Council Meeting Agenda

Staff Report

DATE: OCTOBER 14, 2014

TO: MAYOR AND COUNCIL MEMBERS

FROM: KENNETH H. ROSENFELD
DIRECTOR OF PUBLIC SERVICES/CITY ENGINEER

ISSUE: SUPPORT OF PROPOSITION NO. 1, THE WATER QUALITY, SUPPLY, AND INFRASTRUCTURE IMPROVEMENT ACT OF 2014, ON THE NOVEMBER 4, 2014, GENERAL ELECTION

RECOMMENDATION: THAT THE CITY COUNCIL ADOPT A RESOLUTION ENTITLED: "A RESOLUTION OF THE CITY COUNCIL OF THE CITY OF LAGUNA HILLS, CALIFORNIA, SUPPORTING PROPOSITION NO. 1 ON THE NOVEMBER 4, 2014, GENERAL ELECTION."

SUMMARY:

Proposition No. 1, the Water Quality, Supply, and Infrastructure Improvement Act of 2014, was recently approved by the State Legislature and will appear on the November 4, 2014, General Election ballot. This measure provides funding for water related projects such as water conservation, groundwater recharge, storm water capture and reuse, Clean Water Act compliance, watershed restoration, water storage and conveyance and water recycling and reuse. Given the expansive nature of the State's drought and reduced water supply, Proposition No. 1 will aid communities to fund water infrastructure related improvements for long term water supply reliability and storm water quality improvements. While the City is not a water supplier, the City should support the investment in the water infrastructure for the benefit of our community and residents. The League of California Cities has recommended that all cities take a support position on Proposition No. 1. A Resolution in support of the Proposition is provided for City Council consideration. Staff also plans to post non-partisan information about Proposition No. 1 on the City's website as an educational aid to voters.

BACKGROUND:

Proposition No. 1 will be on the November 4, 2014, General Election ballot and will, if approved by the voters, provide a total of \$7.545 billion in bond funding for water related projects such as water conservation, groundwater recharge, stormwater capture and

reuse, Clean Water Act Compliance, watershed restoration, water storage and conveyance and water recycling and reuse. The \$7.545 billion in funding would come from the issuance of \$7.12 billion in new general obligation (GO) bonds and the reallocation of \$425 million in existing bond funds previously approved by voters. The League of California Cities recommends that all cities support the passage of Proposition No. 1.

Funding for water projects would be subject to the following breakdown:

Clean, Safe, and Reliable Drinking Water: \$520 million

- \$260 million deposit in the State Water Pollution Control Revolving Fund Small Community Grant Fund for grants for wastewater treatment projects. Priority shall be given to projects that serve disadvantaged communities and severely disadvantaged communities, and to projects that address public health hazards.
- \$260 million for grants and loans for public water system infrastructure improvements to meet safe drinking water standards, ensure affordable drinking water, or both. Priority shall be given to projects that provide treatment for contamination or access to an alternate drinking water source or sources for small community water systems or state small water systems in disadvantaged communities whose drinking water source is impaired by chemical and nitrate contaminants and other health hazards.

Protecting River, Lakes, Streams, Coastal Waters, and Watersheds: \$1.495 billion

- \$327.5 million for Conservancies to fund projects that restore, enhance, and protect watersheds.
- \$100 million to protect and enhance urban creeks.
- \$20 million shall be made available for a competitive program to fund multi-benefit watershed and urban rivers enhancement projects in urban watersheds that increase regional and local water self-sufficiency and that meet at least two of the following objectives: Promote groundwater recharge and water reuse, reduce energy consumption, use soils, plants, and natural processes to treat runoff, create or restore native habitat, and/or increase regional and local resiliency and adaptability to climate change. At least 25 percent of the funds available pursuant to this section shall be allocated for projects that benefit disadvantaged communities. Up to 10 percent of the funds available pursuant to this section may be allocated for project planning.
- \$87 million to the Department of Fish and Wildlife for water quality, ecosystem restoration, and fish protection facilities that benefit the Delta.

Regional Water Security, Climate, and Drought Preparedness: \$810 million

- \$510 million for hydrologic regions identified in the Water Action Plan for regional self-reliance security; grants and loans for projects included in an IRWM plan.
- \$100 million for grants and loans for water conservation and efficiency plans, projects, and programs.
- \$200 million for grants for multi-benefit stormwater management projects.

Statewide Water System Operational Improvement and Drought Preparedness: \$2.7 billion

- \$2.7 billion for surface and subsurface water storage.

Water Recycling: \$725 million

- \$725 million for grants and loans for water recycling and advanced treatment projects.

Groundwater Sustainability: \$900 million

- \$720 million for competitive grants, and loans for, projects to prevent or clean up the contamination of groundwater that serves or has served as a source of drinking water. Funds may also be used for projects necessary to protect public health by preventing or reducing the contamination of groundwater that serves or has served as a major source of drinking water for a community.
- \$80 million for grants for treatment and remediation activities that prevent or reduce the contamination of groundwater that serves as a source of drinking water.
- \$100 million of grants for projects that develop and implement groundwater plans.

Flood Management: \$395 million

- \$295 million to reduce the risk of levee failure and flood in the Delta.

Proposition No. 1 will provide opportunities for the City of Laguna Hills to improve storm water quality and will allow the Water Agencies that serve our community to improve their water supply infrastructure. Proposition No. 1 will allow for statewide enhancements for water supply to reduce future impacts from drought conditions. The League of California Cities has provided a model Resolution, attached, for City Council consideration in support of Proposition No. 1. In addition, due to its importance, staff plans to post non-partisan educational information about this Proposition on the City's website.

FISCAL IMPACT:

The passage of Proposition No. 1 may allow the City of Laguna Hills to access grant funding for improvements to storm water quality in an amount to be determined.

RESOLUTION NO. 2014-

A RESOLUTION OF THE CITY COUNCIL OF
THE CITY OF LAGUNA HILLS, CALIFORNIA,
SUPPORTING PROPOSITION NO. 1 ON THE
NOVEMBER 4, 2014, GENERAL ELECTION

The City Council of the City of Laguna Hills, California, hereby finds, determines, declares, and resolves as follows:

WHEREAS, the State of California is facing a severe multiyear drought due to a variety of factors not limited to record dry conditions and below average rainfall; and,

WHEREAS, on January 17, 2014, California Governor Jerry Brown declared a drought state of emergency; and,

WHEREAS, the drought has, and will continue to have significant impacts on local agency ability to provide reliable and clean drinking water to the communities they serve; and,

WHEREAS, the Legislature approved and Governor Brown signed the Water Quality, Supply and Infrastructure Improvement Act of 2014, which will appear as Proposition No. 1 on the November 4, 2014, ballot; and,

WHEREAS, Proposition No. 1 will provide a total of \$7.545 billion in bond funding (\$7.12 billion in new general obligation (GO) bonds and the reallocation of \$425 million in existing bond funds previously approved by voters) for water related projects that will benefit local communities such as water conservation, groundwater recharge, stormwater capture and reuse, watershed restoration, water storage and conveyance and water recycling and reuse; and,

WHEREAS, Proposition No. 1 contains several provisions providing significant funding opportunities to disadvantaged communities and economically distressed areas that have been hardest hit by the drought; and,

WHEREAS, the intent of Proposition 1 aligns with statewide priorities to provide a comprehensive water management plan which will benefit the City of Laguna Hills.

NOW, THEREFORE, THE CITY COUNCIL OF THE CITY OF LAGUNA HILLS, CALIFORNIA, DOES RESOLVE, DECLARE, DETERMINE, AND ORDER AS FOLLOWS:

The City Council of the City of Laguna Hills hereby supports Proposition No. 1 on the November 4, 2014, General Election.

PASSED, APPROVED, AND ADOPTED this 14th day of October 2014.

ANDREW BLOUNT, MAYOR

ATTEST:

PEGGY J. JOHNS, CITY CLERK

STATE OF CALIFORNIA)
COUNTY OF ORANGE) ss
CITY OF LAGUNA HILLS)

I, Peggy J. Johns, City Clerk of the City of Laguna Hills, California, DO
HEREBY CERTIFY that the foregoing is a true and correct copy of Resolution No.
2014- __ adopted by the City Council of the City of Laguna Hills, California, at a Regular
Meeting thereof held on the 14th day of October 2014, by the following vote:

AYES:

NOES:

ABSENT:

ABSTAIN:

(SEAL)

PEGGY J. JOHNS, CITY CLERK

3.3 APPROVAL OF WARRANT REGISTER FOR PERIOD ENDED SEPTEMBER 23, 2014

Council Member Kogerman removed this item from the Consent Calendar to inquire about the City's Moulton Niguel water bill for July and August, and when the City would realize a savings from the artificial turf installation project, and asked about water conservation measures. Assistant City Manager White gave an explanation on the invoice for July and August, and indicated staff was continuing to carefully monitor water usage throughout the City.

THE CITY COUNCIL APPROVED THE WARRANT REGISTER IN THE AMOUNT OF \$1,632,620.90, BY M/COUNCIL MEMBER CARRUTH, S/COUNCIL MEMBER KOGERMAN.

APPROVED BY A VOTE OF 4-0-1 (MAYOR BLOUNT ABSENT).

4. PLANNING AGENCY

Mayor Pro Tempore Gilbert recessed the City Council meeting and acting in the capacity of Vice Chair, called the meeting of the Planning Agency of the City of Laguna Hills, California, to order at 7:20 PM.

4.1 ROLL CALL OF PLANNING AGENCY MEMBERS

Present: Vice Chair Gilbert, Agency Member Bressette, Agency Member Carruth, and Agency Member Kogerman

Absent: Chair Blount

4.2 PUBLIC COMMENTS

There were no Public Comments.

4.3 APPROVAL OF MINUTES FOR SEPTEMBER 9, 2014

THE PLANNING AGENCY APPROVED THE MINUTES OF THE SEPTEMBER 9, 2014, REGULAR MEETING, BY M/AGENCY MEMBER CARRUTH, S/AGENCY MEMBER KOGERMAN.

APPROVED BY A VOTE OF 3-0-1-1 (AGENCY MEMBER BRESSETTE ABSTAINED, CHAIR BLOUNT ABSENT).

4.4 ADMINISTRATIVE REPORTS

There were no Administrative Reports.

4.5 PLANNING AGENCY PUBLIC HEARINGS

4.5.1 CONDITIONAL USE PERMIT/PARKING USE PERMIT (CUP/PUP) NO. 7-14-2924, A REQUEST BY ADVANCE BEAUTY COLLEGE TO ESTABLISH A BEAUTY COLLEGE IN THE FORMER CLAIM JUMPER BUILDING IN THE COURTYARD AT LA PAZ SHOPPING CENTER AT 25332 MCINTYRE STREET IN THE COMMUNITY COMMERCIAL ZONE

Vice Chair Gilbert opened the Public Hearing.

Vern Jones, on behalf of Advance Beauty College, spoke in support of the project and answered questions from the Planning Agency.

Tam Nguyen, Applicant and Owner of Advance Beauty College, spoke in support of the project and answered questions from the Planning Agency.

Peter Haddad, Architect, answered questions from the Planning Agency about the exterior elements of the project.

Vice Chair Gilbert closed the Public Hearing.

THE PLANNING AGENCY ADOPTED RESOLUTION NO. PA2014-09-23-1, A RESOLUTION OF THE PLANNING AGENCY OF THE CITY OF LAGUNA HILLS, CALIFORNIA, APPROVING CONDITIONAL USE PERMIT/PARKING USE PERMIT (CUP/PUP) NO. 7-14-2924, A REQUEST BY ADVANCE BEAUTY COLLEGE TO ESTABLISH A BEAUTY COLLEGE IN THE FORMER CLAIM JUMPER BUILDING IN THE COURTYARD AT LA PAZ SHOPPING CENTER AT 25332 MCINTYRE STREET IN THE COMMUNITY COMMERCIAL (CC) ZONE, BY M/AGENCY MEMBER BRESSETTE, S/AGENCY MEMBER KOGERMAN. APPROVED BY A VOTE OF 3-1-1 (AGENCY MEMBER CARRUTH VOTING NO, AND CHAIR BLOUNT ABSENT).

PLANNING AGENCY ADJOURNMENT

Mayor Pro Tempore Gilbert reconvened the City Council meeting at 8:00 PM. All Council Members were present, with the exception of Mayor Blount.

5. CITY COUNCIL PUBLIC HEARINGS

There were no Public Hearings.

6. ADMINISTRATIVE REPORTS

6.1 City Manager

The City Manager was not present at the City Council meeting.



City of Laguna Hills

City Council Meeting Agenda

Staff Report

DATE: OCTOBER 14, 2014

TO: MAYOR AND COUNCIL MEMBERS

**FROM: GREGORY E. SIMONIAN
CITY ATTORNEY**

ISSUE: FIRST READING AND INTRODUCTION OF AN ORDINANCE TO AMEND CHAPTER 5-28 OF TITLE 5 OF THE LAGUNA HILLS MUNICIPAL CODE (SMOKING AND SALE OF TOBACCO PRODUCTS) TO REGULATE THE USE AND SALE OF E-CIGARETTES IN THE SAME MANNER AS TOBACCO PRODUCTS

RECOMMENDATION: THAT THE CITY COUNCIL INTRODUCE FOR FIRST READING, READ BY TITLE ONLY, AND WAIVE FURTHER READING, AN ORDINANCE ENTITLED: "AN ORDINANCE OF THE CITY OF LAGUNA HILLS, CALIFORNIA, AMENDING CHAPTER 5-28 OF TITLE 5 OF THE LAGUNA HILLS MUNICIPAL CODE TO REGULATE THE USE AND SALE OF E-CIGARETTES IN THE SAME MANNER AS TOBACCO PRODUCTS."

SUMMARY:

At its April 8, 2014 meeting, the City Council discussed the potential regulation of E-Cigarettes and expressed the desire for additional information concerning the secondhand health effects of E-Cigarette use. The Council directed staff to continue to monitor the status of scientific research on the health effects of E-Cigarettes, and to bring back a report in six months, along with a draft Ordinance to amend the City's current Smoking Ordinance to include regulation of E-Cigarettes in the same manner as other tobacco products. Pursuant to the City Council's direction, staff has continued to research the issue and to compile additional information and studies on the secondhand health effects of E-Cigarette use, and the City Attorney has prepared the attached proposed Ordinance for the City Council's consideration.

The proposed Ordinance would revise Chapter 5-28 of the Laguna Hills Municipal Code, entitled "Smoking and Sale of Tobacco Products" (the "Smoking Ordinance"), to regulate the use and vending of E-Cigarettes in the same manner as cigarettes and other conventional tobacco products. Specifically, the proposed Ordinance would amend the definitions of "smoking" and "tobacco product" in the City's Smoking Ordinance to include

E-Cigarettes, thereby prohibiting the use of E-Cigarettes in places of employment and certain places accessible to the public, and prohibiting the sale of E-Cigarettes by or through a vending machine or by means of a self-service display. The proposed Ordinance is included as **Exhibit 1**, and a "blackline" version of Chapter 5-28 showing the changes that would be made to Chapter 5-28 pursuant to the proposed Ordinance is included as **Exhibit 2**.

BACKGROUND:

Electronic cigarettes (or "E-Cigarettes") are battery-powered devices that deliver a nicotine-containing aerosol (commonly called vapor) to users by heating a liquid chemical solution. The liquid typically is made up of propylene glycol or glycerin, nicotine, and flavored chemicals. It is heated electronically and produces a chemical vapor that is inhaled and exhaled by the user without producing fire, smoke, ash or carbon monoxide. The process is often referred to as "vaping." E-Cigarettes are often designed to resemble conventional cigarettes, cigars, or pipes and their use typically emulates cigarette, cigar, or pipe smoking. E-Cigarettes come in many shapes and prices, ranging from disposable types that can be purchased at convenience stores for a few dollars and resemble real cigarettes to more complex vaporizers that can cost hundreds of dollars. As of early 2014, there were approximately 466 brands and 7,764 unique flavors of E-Cigarette products.

E-Cigarettes were introduced in China in 2003 and entered the U.S. market in 2008. Most E-Cigarettes come from China. Their use and popularity throughout the country have grown significantly since. Recently, E-Cigarettes have been the subject of frequent media coverage, public discussion and debate, and increasing scientific research. E-Cigarettes are unregulated. No quality control standards for the devices currently exist. There is presently no government oversight of these products and absent federal Food and Drug Administration (FDA) regulation, there is no way for the public health, medical community, or consumers to know what chemicals are contained in E-Cigarettes, and in what amounts and concentrations, or what the short and long term health implications might be.

Unlike conventional cigarettes, E-Cigarettes are not presently regulated by the federal government. In April of this year, however, the federal Food and Drug Administration (FDA) proposed new rules that would regulate E-Cigarettes as a drug, at the federal level, for the first time. As proposed, the rules would also do the following with respect to E-Cigarettes:

- ban their sale to minors (as California law already does);
- prohibit the distribution of free samples;
- ban vending machine sales except in places that never admit minors;
- require product registration;
- require a warning that they contain nicotine which is addictive; and
- require manufacturers to disclose their ingredients.

Unlike cigarettes, the proposed FDA rules would not regulate advertising or restrict child-oriented marketing of E-Cigarettes. The FDA is still evaluating public comment on the proposed rules, and they have not been finally adopted and are still subject to change. The FDA has long expressed concern about health risks connected to E-Cigarettes and it is continuing to study the issue. In the meantime, there is no indication in the proposed regulations of any intent to preempt local laws in this area. It is unknown when the FDA will complete its "rulemaking" process and whether such new rules will become the subject of future litigation. A compilation of information published to date on E-Cigarettes by the FDA is included at **Exhibit 3** to this staff report.

DISCUSSION:

Some states have enacted laws regulating E-Cigarette use and/or sales in a manner similar to traditional cigarettes. This is not the case in California, however. Although the State of California heavily regulates the sale of tobacco products and strictly limits where conventional cigarettes may be smoked, it has not extended most of these laws to E-Cigarettes. The only current State law pertaining to E-Cigarettes is Health and Safety Code Section 119405, which prohibits the sale of E-Cigarettes to minors. In each of the last two legislative sessions additional state legislation to further regulate E-Cigarettes was introduced, but ultimately was not approved.

In the absence of federal and state regulation, a number of California cities have adopted their own laws regulating the use and/or sale of E-Cigarettes. At last count, more than 140 cities in California had adopted or applied regulations to regulate E-Cigarette use and/or sales in some manner. Although the scope of these cities' regulations vary, a common approach has been to simply treat and regulate E-Cigarettes in the same manner as conventional cigarettes and other tobacco products.

The smoking and sale of tobacco products are currently regulated by the City pursuant to Chapter 5-28 of the Laguna Hills Municipal Code (the "Smoking Ordinance"). The City's Smoking Ordinance prohibits smoking in places of employment and in most public places. The list of places where smoking is currently prohibited under the City's Smoking Ordinance largely parallels State law and is extensive. Violation of these local smoking prohibitions is an infraction (unless there are four or more violations by the same person in one year, in which case the violation can be prosecuted as a misdemeanor). Under the City's Smoking Ordinance, business owners/operators are required to post "No Smoking" signs and to request that their patrons not smoke, but are not responsible for violations within their premises by patrons or citizens who continue to smoke despite such requests and the posting of signage. The City's Smoking Ordinance also expressly prohibits the sale or distribution of cigarettes and other tobacco products by or from vending machines or by means of a self-service display (i.e., all sales of tobacco products must be vendor-assisted); violation of these provisions is a misdemeanor.

Arguments For and Against Local Regulation of E-Cigarettes

Those opposed to placing local restrictions on E-Cigarette sales or use often make some or all of the following arguments:

- E-Cigarettes are an effective tool for some smokers to quit smoking.
- E-Cigarettes are a safer and less intrusive alternative to cigarettes – for both the user and those nearby.
- Local governments should not act to restrict E-Cigarettes until more is known about their health risks (or lack thereof).
- Local governments should wait for the FDA and/or the State to act before enacting their own regulations.

Those who favor local governments placing restrictions on E-Cigarette sales or use often make some or all of the following arguments:

- Neither the value of E-Cigarettes as therapeutic aids for smoking cessation nor their safety as cigarette replacements has been definitively established, and E-Cigarettes have not been approved by the FDA for use as a smoking cessation product.
- Because the marketing of E-Cigarettes is not regulated, consumers may be misled as to the safety and efficacy of E-Cigarettes.
- Because they glamorize smoking and contain nicotine, a highly addictive substance, E-Cigarettes may serve as a "gateway" to the use of cigarettes or other drugs.
- E-Cigarettes are popular among teens, are sometimes marketed to children, glamorize smoking in general, and lead to increased smoking of conventional cigarettes by children.
- E-Cigarettes are visually similar to conventional cigarettes, thereby creating problems in locations where smoking is currently prohibited including: (a) making enforcement of no-smoking laws difficult; (b) undermining compliance with smoking laws by giving the visual impression that the laws are being violated; and (c) undermining efforts to reduce smoking in general.
- The growing use of E-Cigarettes in public places where tobacco is now banned creates confusion among the public and gives the visual impression that smoking is again allowed in these locations. There is particular concern that youth may be influenced in this way and that E-Cigarettes may thus have the capacity to "re-normalize" tobacco use in a demographic that has had significant de-normalization of tobacco use previously. Said another way, the use of E-Cigarettes in smoke free locations threatens to undermine compliance with smoking regulations and reverse the progress that has been made in establishing a social norm that smoking is not permitted in certain locations.

- Although less harmful than conventional cigarettes, E-Cigarettes still emit toxic chemicals, metals, and particulates that are known to be hazardous to human health, both for users and those nearby.
- E-Cigarettes pose many still-unknown potential health risks, and until they are proven safe their use should be restricted similarly to that of traditional tobacco products.
- What E-Cigarette users actually exhale is not merely "water vapor."

The debate over these issues has played out in the media and in jurisdictions all over the country. **Exhibit 4** to this staff report contains a compilation of recent media articles about E-Cigarettes and E-Cigarette regulation that highlight the differing views, opinions, and conclusions reached on these and various other issues. The academic papers included in **Exhibits 5, 6 and 7** also provide more detailed analysis of many of the issues raised by both proponents and opponents of E-Cigarette regulation.

In 2013, the State of California's Tobacco Education and Research Oversight Committee (a legislatively mandated committee that monitors the use of Prop. 99 tobacco tax revenues) formally took the position that it "opposes the use of electronic cigarettes in all areas where other tobacco products are banned." (See, **Exhibit 8**). In addition, the American Heart Association recently issued a policy statement entitled, "Electronic Cigarettes: A Policy Statement from the American Heart Association," formally supporting the inclusion of E-Cigarettes in smoke-free air laws. (See, **Exhibit 6**). The American Cancer Society and the American Lung Association have taken similar positions, both of which advocate treating E-Cigarettes as tobacco products.

Recent Scientific Research Concerning the Second-Hand Health Effects of E-Cigarettes

The stated purpose of the smoking restrictions in the City's Smoking Ordinance is "to protect the public health and welfare from the harmful health effects associated with secondhand smoke." Accordingly, the City Council directed staff to compile research about the potential secondhand health effects of E-Cigarette vaping on bystanders.

There have been several scientific studies conducted in the last few years that have attempted to identify and quantify the level of secondhand exposure to harmful constituents from E-Cigarette vapor in some manner. In general, the available studies suggest that E-Cigarette vapor probably is significantly less harmful to bystanders than cigarette smoke, but is not altogether harmless. While E-Cigarettes may have fewer secondhand effects, available studies have shown that the exhaled vapor does contain carcinogens and toxic chemicals, as well as nicotine, and is therefore similar to secondhand smoke, negatively impacting bystanders. Specifically, various studies support the conclusion that:

- E-Cigarettes have been found to contain and emit carcinogens, toxic chemicals, and other particulates that are known to be hazardous to human

- health, both for users and those nearby, including chemicals known to cause cancer, such as chromium, nickel, lead, and zinc;
- particles generated by E-Cigarettes are similar in size distribution and number to the particles generated by conventional cigarettes;
- users of E-Cigarettes exhale some of these particles, which exposes bystanders to "passive vaping"; and
- E-cigarette emissions are not merely "harmless water vapor," as is frequently claimed in the marketing for E-Cigarettes, and can be a source of indoor air pollution.

In May 2014, researchers at the University of California, San Francisco ("UCSF") published one of the first comprehensive assessments of peer-reviewed published research on E-Cigarettes to date, entitled "E-Cigarettes: A Scientific Review." (See, **Exhibit 5**). The authors of the UCSF meta-analysis reviewed 84 prior scientific studies and stated conclusions and policy recommendations regarding E-Cigarettes. The work was a condensed version of a larger meta-study previously prepared for the World Health Organization. Based on their review of the prior scientific studies, the UCSF researchers determined that "e-cigarette aerosol is not merely 'water vapor' as is often claimed in the marketing for these products;" rather, it contains comparable size distribution and number of particles to cigarette smoke, with most particles in the ultra-fine range. The UCSF review also indicates that although few studies have directly measured the health effects of exposure to e-cigarette emissions, some show the ability of E-Cigarette aerosol "to result in biological effects;" however, "[l]ong-term biological effects are unknown at this time because e-cigarettes have not been in widespread use long enough for assessment." Ultimately, the UCSF researchers concluded that, "[a]lthough data is limited, it is clear that e-cigarette emissions are not merely 'harmless water vapor,' . . . and can be a source of indoor air pollution . . . [and] introducing e-cigarettes into clean air environments may result in population harm if use of the product reinforces the act of smoking as socially acceptable or if use undermines the benefits of smoke-free policies."

On August 24, 2014, the American Heart Association ("AHA") published a formal policy statement on E-Cigarettes. (See, **Exhibit 6**). Like the UCSF paper, the AHA's policy statement includes a meta-analysis of prior scientific research on the various public health questions implicated by E-Cigarette use, including the risks associated with secondhand exposure to E-Cigarette vapor. Based on their review of prior scientific studies on the secondhand E-Cigarette aerosol exposure, the paper's authors conclude as follows:

"Thus, secondhand exposure to e-cigarette aerosol exposes a nonsmoker to nicotine, particulates, and several potentially toxic organic chemicals, but at much lower levels than from conventional cigarette smoke. The biological effects of such an exposure are expected to be much less than that of secondhand smoke, but nonsmokers are exposed to some nicotine, and the regular use of e-cigarettes has the potential to substantially contaminate the environment with nicotine."

Ultimately, the AHA formally took the following position: "*The AHA considers e-cigarettes that contain nicotine to be tobacco products and therefore supports their regulation under existing laws relating to the use and marketing of tobacco products.*" Separately, the AHA expressed formal support for the inclusion of e-cigarettes in smoke-free air laws.

Finally, in a study published in August 2014 in the journal *Environmental Science, Process & Impacts*, researchers from the USC Viterbi School of Engineering, University of Wisconsin-Madison's Environmental Chemistry and Technology Program, and Cornell University's School of Mechanical and Aerospace Engineering, as well as the LARS Laboratorio di Ricerca Ambientale SIMG/ISDE and the Fondazione IRCCS Istituto Nazionale dei Tumori (National Institute of Cancer Research) Tobacco Control Unit in Milan, Italy, found that, despite a ten-fold decrease in overall exposure to carcinogenic particulate matter, secondhand vapor from E-Cigarettes contains increased levels of certain toxic metals, including chromium, which is absent from traditional cigarettes, nickel at levels four times higher than traditional cigarettes, and other toxic metals, such as lead and zinc, though in concentrations lower than traditional cigarettes. A copy of this recently published study is included with this staff report in **Exhibit 7**.

CONCLUSION:

Based on the City Council's prior direction and the research summarized above, the City Attorney has prepared for the City Council's consideration the proposed Ordinance (**Exhibit 1**) to regulate E-Cigarettes in the same manner as cigarettes and other tobacco products are currently regulated by the City's Smoking Ordinance.

ATTACHMENTS:

- Exhibit 1 - Proposed Ordinance
- Exhibit 2 - Blackline Showing Proposed Amendments to Chapter 5-28.
- Exhibit 3 - Compilation of Information Published by FDA Regarding E-Cigarettes.
- Exhibit 4 - Compilation of 2014 Media Articles Concerning E-Cigarettes.
- Exhibit 5 - Grana, R., Benowitz, N., Glantz, S., et al., (2014). "E-Cigarettes: A Scientific Review." *Circulation – Journal of the American Heart Association*, 129:1972-1986 (summarizing the results of several studies).
- Exhibit 6 - Bhatnagar, A., Whitsel, L.P., Ribisl, K.M., Bullen C., Chaloupka, F., Piano, M.R., Robertson, R.M., McAuley, T., Goff, D., Benowitz, N.; on behalf of the American Heart Association Advocacy Coordinating Committee, Council on Cardiovascular and Stroke Nursing, Council on Clinical Cardiology, and Council on Quality of Care and Outcomes Research.. (2014). "Electronic Cigarettes: A Policy Statement From the American Heart Association." *Circulation – Journal of the American Heart Association*, 130:....-.... Published online August 24, 2014.
- Exhibit 7 - Saffari, A., Daher, N., Ruprecht, A., et al. (2014). "Particulate Metals and Organic Compounds from Electronic and Tobacco-Containing Cigarettes:

Comparison of Emission Rates and Secondhand Exposure." *Environmental Science: Processes & Impacts* (Advance Article), DOI: 10.1039/c4em00415a.

- Exhibit 8 - State of California Tobacco Education and Research Oversight Committee. "Position on Electronic Cigarettes (e-cigarettes)." June 13, 2013.
- Exhibit 9 - Additional Materials Cited in Findings of Proposed Ordinance.

EXHIBIT 1

ORDINANCE NO. 2014-

AN ORDINANCE OF THE CITY OF LAGUNA HILLS,
CALIFORNIA, AMENDING CHAPTER 5-28 OF TITLE 5 OF
THE LAGUNA HILLS MUNICIPAL CODE TO REGULATE
THE USE AND SALE OF E-CIGARETTES IN THE SAME
MANNER AS TOBACCO PRODUCTS

THE CITY COUNCIL OF THE CITY OF LAGUNA HILLS, CALIFORNIA,
HEREBY FINDS AND DETERMINES AS FOLLOWS:

WHEREAS, electronic cigarettes, commonly known as e-cigarettes, e-cigars, e-cigarillos, e-pipes, and e-hookahs, are battery operated devices, which are designed to deliver nicotine, flavor, and/or other substances through a vapor inhaled by the user;¹ and

WHEREAS, electronic cigarettes often mimic conventional cigarettes, cigars, or pipes in shape, size, and color, with the user exhaling a smoke-like vapor similar in appearance to the exhaled smoke from cigarettes and other conventional tobacco products; and

WHEREAS, the awareness and use of electronic cigarettes has increased significantly amongst both adults and children in recent years;^{2,3,4} and

WHEREAS, neither the value of electronic cigarettes as therapeutic aids for smoking cessation nor their safety as cigarette replacements has been definitively established,⁵ and electronic cigarettes have not been approved by the United States Food and Drug Administration ("FDA") as a smoking cessation product; and

WHEREAS, unlike conventional tobacco products, electronic cigarettes are not currently regulated by the United States Food and Drug Administration (FDA), and clinical studies about the safety and efficacy of electronic cigarettes for their intended use have not been submitted to the FDA; for this reason, consumers and the public currently have no way of knowing whether electronic cigarettes are safe for their

¹ U.S. Food and Drug Administration. *Electronic Cigarettes (E-Cigarettes)*. Available at: www.fda.gov/newsevents/publichealthfocus/ucm172906.htm. Retrieved August 11, 2014.

² See e.g., Corey, C., Johnson, S., Apelberg, B., et al. (2013). "Notes from the Field: Electronic Cigarette Use Among Middle and High School Students - United States, 2011- 2012." *Morbidity and Mortality Weekly Report (MMWR)*, 62(35):729-730.

³ King, B.A., Alam, S., and Promoff, G., et al. (2013). "Awareness and Ever Use of Electronic Cigarettes Among U.S. Adults, 2010-2011." *Nicotine and Tobacco Research*.

⁴ Grana, R., Benowitz, N., Glantz, S., et. al., (2014). "E-Cigarettes: A Scientific Review." *Circulation – Journal of the American Heart Association*, 129:1972-1986.

⁵ World Medical Association. *Statement on Electronic Cigarettes and Other Electronic Nicotine Delivery Systems*. October 2012.

intended use, what types or concentrations of potentially harmful chemicals the products contain, and/or what dose of nicotine the products deliver;⁶ and

WHEREAS, although potentially safer than traditional cigarettes, electronic cigarettes have been found to contain and emit chemicals and particulates that are known to be hazardous to human health, both for users and those nearby, including chemicals known to cause cancer^{7,8,9,10};

WHEREAS, available data and studies show that particles generated by e-cigarettes are similar in size distribution and number to the particles generated by conventional cigarettes, that users of electronic cigarettes exhale some of these particles, which exposes bystanders to "passive vaping," and that electronic cigarette emissions are not merely "harmless water vapor," as is frequently claimed in the marketing for these products, and can be a source of indoor air pollution¹¹; and

WHEREAS, electronic cigarettes are often visually similar to cigarettes, thereby creating problems in locations where smoking is currently prohibited including: (a) making enforcement of no-smoking laws difficult; (b) undermining compliance with smoking laws by giving the visual impression that the laws are being violated; and (c) undermining efforts to reduce smoking in general; and

WHEREAS, a study published in the Journal of Environmental and Public Health suggests that electronic cigarettes "may have the capacity to 're-normalize' tobacco use in a demographic that has had significant denormalization of tobacco use previously"¹²; and

WHEREAS, the use of electronic cigarettes in smoke free locations threatens to undermine compliance with smoking regulations and reverse the progress that has been made in establishing a social norm that smoking is not permitted in certain locations; and

⁶ U.S. Food and Drug Administration. *FDA Warns Of Health Risk Posed By E-Cigarettes*. 2009. Available at: www.fda.gov/downloads/forconsumers/consumerupdates/UCM173430.pdf. Retrieved August 11, 2014.

⁷ U.S. Food and Drug Administration. Evaluation of e-cigarettes. May 4, 2009. Available at: www.fda.gov/downloads/drugs/scienceresearch/ucm173250.pdf. Retrieved August 11, 2014.

⁸ Cobb, N.K., Byron, J., and Abrams, D.B., et al. (2010) "Novel Nicotine Delivery Systems and Public Health: The Rise of the 'E-Cigarette.'" *American Journal of Public Health*, 100 (12): 2340-2342.

⁹ Grana, R., Benowitz, N., Glantz, S., et. al., (2014). "E-Cigarettes: A Scientific Review." *Circulation – Journal of the American Heart Association*, 129:1972-1986 (summarizing the results of several studies).

¹⁰ Saffari, A., Daher, N., Ruprecht, A., et al. (2014). "Particulate Metals and Organic Compounds From Electronic and Tobacco-Containing Cigarettes: Comparison of Emission Rates and Secondhand Exposure." *Environmental Science: Processes & Impacts* (Advance Article), DOI: 10.1039/c4em00415a.

¹¹ Grana, R., Benowitz, N., Glantz, S., et. al., (2014). "E-Cigarettes: A Scientific Review." *Circulation – Journal of the American Heart Association*, 129:1972-1986.

¹² McMillen, R., Maduka, J., and Winickoff, .J. (2012) "Use of Emerging Tobacco Products in the United States." *Journal of Environmental and Public Health*, DOI:10.1155/2012/989474.

WHEREAS, the State of California's Tobacco Education and Research Oversight Committee (TEROC) "opposes the use of electronic cigarettes in all areas where other tobacco products are banned;"¹³

WHEREAS, the American Heart Association considers electronic cigarettes that contain nicotine to be tobacco products and supports the inclusion of electronic cigarettes in smoke-free air laws;¹⁴ and

WHEREAS, although Health & Safety Code § 119405 law prohibits the sale of electronic cigarettes to minors, no other state law currently regulates the sale or use of electronic cigarettes; and

WHEREAS, the City is not preempted from prohibiting the use of electronic cigarettes in places where smoking of other conventional tobacco products is prohibited or from prohibiting the sale of electronic cigarettes from vending machines and from self-service displays, and such regulation of the use and sale of electronic cigarettes is a legitimate role of government relating to the health, safety, and welfare of its citizens; and

WHEREAS, it is the intent of the City Council, in enacting this ordinance, to provide for the public health, safety, and welfare by discouraging the use of electronic cigarettes around non-users, especially children; by protecting the public from involuntary exposure to secondhand byproducts of electronic cigarettes where they work and play; by facilitating uniform and consistent enforcement of smoke-free air laws; by reducing the potential for re-normalizing smoking in public places and places of employment; by reducing the potential for children to associate the use of electronic smoking devices with a normative or healthy lifestyle; and by regulating the sale and distribution of electronic cigarettes in the same manner as cigarettes and other traditional tobacco products.

NOW, THEREFORE, THE CITY COUNCIL OF THE CITY OF LAGUNA HILLS, CALIFORNIA, DOES HEREBY ORDAIN AS FOLLOWS:

SECTION 1. The above recitals are true and correct and hereby incorporated herein by reference.

¹³ State of California Tobacco Education and Research Oversight Committee. (2013). Position on Electronic Cigarettes (e-cigarettes). Available at: www.cdph.ca.gov/services/boards/teroc/Documents/Positions/TEROC%20Official%20Position%20of%20E-Cigs_June%202013_final.pdf. Retrieved August 11, 2014.

¹⁴ Bhatnagar, A., Whitsel, L.P., Ribisl, K.M., Bullen C., Chaloupka, F., Piano, M.R., Robertson, R.M., McAuley, T., Goff, D., Benowitz, N.; on behalf of the American Heart Association Advocacy Coordinating Committee, Council on Cardiovascular and Stroke Nursing, Council on Clinical Cardiology, and Council on Quality of Care and Outcomes Research.. (2014). "Electronic Cigarettes: A Policy Statement From the American Heart Association." *Circulation – Journal of the American Heart Association*, 130:....-.... Published online August 24, 2014.

SECTION 2. The City Council finds that the proposed Ordinance is not subject to the California Environmental Quality Act ("CEQA") Cal. Pub. Resources Code Section 21000 et seq.) pursuant to Section 15061(b)(3) of the State CEQA Guidelines (Cal. Code of Regs., Title 14, Section 15000 et seq.) because it can be seen with certainty that there is no possibility that this ordinance may have a significant effect on the environment.

SECTION 3. Section 5-28.010 of Chapter 5-28 of Title 5 of the Laguna Hills Municipal Code is hereby amended to add new subsection Q to read as follows:

"Q. The increasingly frequent use of electronic cigarettes, which emit a smoke-like vapor similar in appearance to the exhaled smoke from cigarettes and other conventional tobacco products and are largely unregulated by the federal or state government, involuntarily exposes members of the public to potentially dangerous secondhand byproducts, undermines enforcement of no-smoking laws, and threatens to undermine compliance with smoking regulations and reverse the progress that has been made in establishing a social norm that smoking is not permitted in certain locations. Therefore, it is appropriate to regulate the use, sale and distribution of electronic cigarettes in the same manner as cigarettes and other traditional tobacco products."

SECTION 4. Section 5-28.020 of Chapter 5-28 of Title 5 of the Laguna Hills Municipal Code is hereby amended to add a new definition for "electronic cigarette" to read as follows and to amend the definitions of "smoking" and "tobacco product" to include electronic cigarettes, as follows (additions shown in **bold/underline** text; deletions shown in strikeout text):

"Electronic cigarette" means an electronic and/or battery-operated device, the use of which may resemble the smoking of tobacco, that can be used to deliver nicotine or other substances through vapor inhaled by the user. The term includes any such device, whether manufactured, distributed, marketed, or sold as an electronic cigarette, an e-cigarette, an electronic cigar, an electronic cigarillo, an electronic pipe, an electronic hookah, or any other product name or descriptor, including any component, part or accessory of such a device, whether or not sold separately. The term does not include any inhaler or other device specifically approved by the United States Food and Drug Administration for therapeutic purposes or for use in the mitigation, treatment, or prevention of disease, where such product is marketed and sold solely for such an approved purpose.

"Smoking" means inhaling, exhaling, burning, or carrying any lighted cigarette, cigar, pipe, **operating electronic cigarette**, weed, plant, or other combustible substance in any manner or in any form.

"Tobacco product" means any manufactured substance made from the tobacco plant, including but not limited to cigarettes, cigars, pipe tobacco, smokeless tobacco products or any other form of tobacco or tobacco papers which may be utilized for smoking, chewing, inhalation, or other means of ingestion. **For purposes of this Chapter, the term "tobacco product" shall also include an electronic cigarette, as defined in this Chapter.**

SECTION 5. If any section, subsection, subdivision, sentence, clause, phrase, or portion of this Ordinance is, for any reason, held to be invalid or unconstitutional by the decision of any court of competent jurisdiction, such decision shall not affect the validity of the remaining portions of this Ordinance. The City Council hereby declares that it would have adopted this Ordinance and each section, subsection, subdivision, sentence, clause, phrase, or portion thereof, irrespective of the fact that any one or more section, subsection, subdivision, sentence, clause, phrase, or portion thereof be declared invalid or unconstitutional.

SECTION 6. The City Clerk shall certify to the adoption of this Ordinance and cause the same to be posted at the duly designated posting places within the City and published once within fifteen days after passage and adoption as may be required by law; or, in the alternative, the City Clerk may cause to be published a summary of this Ordinance and a certified copy of the text of this Ordinance shall be posted in the Office of the City Clerk five days prior to the date of adoption of this Ordinance; and, within fifteen days after adoption, the City Clerk shall cause to be published, the aforementioned summary and shall post a certified copy of this Ordinance, together with the vote for and against the same, in the Office of the City Clerk.

PASSED, APPROVED, AND ADOPTED this x day of x 2014.

ANDREW BLOUNT, MAYOR

ATTEST:

PEGGY J. JOHNS, CITY CLERK

STATE OF CALIFORNIA)
COUNTY OF ORANGE) ss
CITY OF LAGUNA HILLS)

I, Peggy J. Johns, City Clerk of the City of Laguna Hills, California, DO
HEREBY CERTIFY that the foregoing Ordinance No. 2014- was duly introduced and
placed upon its first reading at a Regular Meeting of the City Council on the 14th day of
October 2014, and that thereafter, said Ordinance was duly adopted and passed at a
Regular Meeting of the City Council held on the 28th day of October 2014, by the
following vote, to wit:

AYES:

NOES:

ABSENT:

ABSTAIN:

(SEAL)

PEGGY J. JOHNS, CITY CLERK

STATE OF CALIFORNIA)
COUNTY OF ORANGE) ss
CITY OF LAGUNA HILLS)

AFFIDAVIT OF POSTING
AND PUBLICATION

PEGGY J. JOHNS, being first duly sworn, deposes and says:

That she is the duly appointed and qualified City Clerk of the City of Laguna Hills;

That in compliance with State Laws of the State of California, ORDINANCE NO. 2014- x, being:

AN ORDINANCE OF THE CITY OF LAGUNA HILLS, CALIFORNIA,
AMENDING CHAPTER 5-28 OF TITLE 5 OF THE LAGUNA HILLS
MUNICIPAL CODE TO REGULATE THE USE AND SALE OF E-
CIGARETTES IN THE SAME MANNER AS TOBACCO PRODUCTS

on the 16th day of October 2014 was published in summary in the Register Newspaper and on the 7th day of November 2014, was published in summary in the Saddleback Valley News; and was, in compliance with City Resolution No. 2004-05-25-2, on the 15th day of October 2014 and the 29th day of October 2014, caused to be posted in summary in three places in the City of Laguna Hills, to wit:

Laguna Hills City Hall
Laguna Hills Community Center
Courtyard at La Paz Center

PEGGY J. JOHNS, CITY CLERK
Laguna Hills, California

EXHIBIT 2

Chapter 5-28 SMOKING AND SALE OF TOBACCO PRODUCTS

Sections:

- 5-28.010 Purpose and findings.
- 5-28.020 Definitions.
- 5-28.030 Prohibition of smoking in places accessible to the public.
- 5-28.040 Prohibition of smoking in places of employment.
- 5-28.050 Tobacco vending machines prohibited.
- 5-28.060 Self-service display—Requirement of vendor assisted sales.
- 5-28.070 Posting of signs—General.
- 5-28.080 Enforcement.
- 5-28.090 Violation—Penalty.
- 5-28.110 Citation authority.
- 5-28.120 Power to adopt more restrictive smoking policies.

5-28.010 Purpose and findings.

The purpose of this chapter is to protect the public health and welfare from the harmful health effects associated with secondhand smoke by regulating smoking in public places and places of employment. In addition, the purpose of this chapter is to reduce the availability of tobacco products to minors by banning the sale of tobacco products from vending machines and from self-service displays. This chapter is based on the following findings:

- A. Numerous studies have found that tobacco smoke is a major contributor to indoor air pollution.
- B. Studies have shown that breathing secondhand tobacco smoke is a significant health hazard for several populations, including children, elderly people, individuals with cardiovascular disease, individuals with impaired respiratory function, asthmatics, and those with obstructive airway disease.
- C. The Americans with Disabilities Act, which requires access for disabled persons in public places and work places, deems impaired respiratory function a disability.
- D. The Surgeon General of the United States found in a 1986 report that secondhand tobacco smoke is a cause of lung disease, including lung cancer, in healthy nonsmokers. The Surgeon General further found that the simple separation of smokers and nonsmokers within the same air space may reduce, but does not eliminate, the exposure of nonsmokers to secondhand tobacco smoke.
- E. Studies have shown that secondhand tobacco smoke is a cause of cardiovascular disease in healthy nonsmokers.

- F. Nonsmokers with allergies, respiratory disease, and those who suffer other ill effects of breathing secondhand smoke may experience a loss of job productivity or may be forced to take periodic sick leave because of reactions to secondhand tobacco smoke.
- G. Studies have shown some nonsmokers cannot dine in restaurants because of an adverse reaction to or annoyance from secondhand tobacco smoke.
- H. The EPA has designated secondhand smoke as a Class A carcinogen and a significant cause of respiratory problems in children.
- I. Prohibiting the sale of tobacco products through vending machines will help prevent cigarette use by minors, and by diminishing accessibility to tobacco products, will help promote a smoke-free environment.
- J. The Centers for Disease Control report that tobacco products are often the first drug used by minors who use alcohol and illegal drugs, that three out of four teenage smokers have tried to quit at least once but failed, and that although it is illegal in all states to sell tobacco products to minors, more than seventy-five (75) percent of underage tobacco users across the country are not asked to show proof of age when they purchase tobacco products in stores.
- K. The United States Department of Health and Human Services reports that the tobacco industry loses two million (2,000,000) smokers each year because they either quit smoking or die, and that those smokers are replaced by three thousand (3,000) youngsters who begin smoking every day.
- L. The Food and Drug Administration reports that if individuals do not begin to use tobacco as youngsters, they are highly unlikely to begin using tobacco products as adults, and that ninety (90) percent of all smokers begin smoking by age nineteen (19) and sixty (60) percent begin by age fourteen (14).
- M. Studies have shown that youth addiction to tobacco products is a public health problem with serious health consequences. In recognition of the Surgeon General's conclusion that nicotine is as addictive as cocaine or heroin, action is needed to curtail the easy access of minors to cigarettes and to other tobacco products.
- N. The California Youth Tobacco Survey reports that approximately fifty (50) percent of minors who smoke cigarettes purchase their own cigarettes from stores in their communities. Additionally, a significant number of studies have shown that there is a direct correlation between self-service tobacco displays and increased youth access to tobacco products. These studies have shown that self-service tobacco displays contribute to youth access by promoting shoplifting and illegal sales of tobacco to minors.
- O. Prohibiting the sale of tobacco products through self service displays will help prevent tobacco use by minors, and diminishing accessibility to tobacco products will help promote a smoke-free environment.

P. Numerous economic analyses examining the restaurant and hotel receipts and controlling for economic variables have shown either no difference or a positive economic impact after enactment of laws requiring workplaces to be smoke-free. Creation of smoke-free workplaces is sound economic policy and provides the maximum level of employee health and safety.

Q. The increasingly frequent use of electronic cigarettes, which emit a smoke-like vapor similar in appearance to the exhaled smoke from cigarettes and other conventional tobacco products and are largely unregulated by the federal or state government, involuntarily exposes members of the public to potentially dangerous secondhand byproducts, undermines enforcement of no-smoking laws, and threatens to undermine compliance with smoking regulations and reverse the progress that has been made in establishing a social norm that smoking is not permitted in certain locations. Therefore, it is appropriate to regulate the use, sale and distribution of electronic cigarettes in the same manner as cigarettes and other traditional tobacco products.

5-28.020 Definitions.

For the purposes of this chapter, the following words and phrases have the following meaning:

"Ashtray" means any receptacle or device used to hold, contain, or extinguish a cigarette, cigar, pipe, match, weed, plant, or other combustible substance in any form.

"Bar" means an area, which is devoted to the serving of alcoholic beverages and in which the service of food is only incidental to the consumption of alcoholic beverages, and for which the owner/operator has a valid ABC Type 61, 41, 42, 47, or 70 liquor license.

"Business" means any sole proprietorship, partnership, joint venture, corporation, or other business entity formed for profit-making purposes, including retail establishments where goods or services are sold, as well as professional corporations and other entities under which professional services are delivered and any nonprofit entity.

"Cigar lounge" means a private smokers' lounge that excludes minors consisting of an enclosed area in or attached to a retail or wholesale tobacco shop that is dedicated to the use of tobacco products, including but not limited to cigars and pipes.

"Dining area" means any area containing a counter or tables upon which food or beverage are consumed or served.

"Electronic cigarette" means an electronic and/or battery-operated device, the use of which may resemble the smoking of tobacco, that can be used to deliver nicotine or other substances through vapor inhaled by the user. The term includes any such device, whether manufactured, distributed, marketed, or sold as an electronic cigarette, an e-cigarette, an electronic cigar, an electronic cigarillo, an electronic pipe, an electronic hookah, or any other product name or descriptor, including any component, part or accessory of such a device, whether or not sold separately. The term does not include any inhaler or other device specifically approved by the United States Food and Drug

Administration for therapeutic purposes or for use in the mitigation, treatment, or prevention of disease, where such product is marketed and sold solely for such an approved purpose.

"Employee" means any person who is employed by any employer for direct or indirect monetary wages or profit, including those employed full-time, part-time, temporary, or contracted for from a third party; employee also means any person who serves as a volunteer for a business or nonprofit entity.

"Employer" means any person, business, or nonprofit entity, which employs the services of one or more persons, and includes the city of Laguna Hills.

"Enclosed" means closed in by a roof and four or more connected, floor-to-ceiling walls with appropriate openings for ingress or egress.

"Food service counter area" means a bar or counter area which is primarily devoted to the service of food and where the service of alcoholic beverages is only incidental thereto. Where the gross receipts from the sale of food is more than fifty (50) percent of the total gross receipts from the bar or counter area, it shall be conclusively presumed that the bar or counter area is primarily for the service of food.

"Mall" means any enclosed public walkway or hall area, which serves to connect retail or professional establishments.

"Minor" means any person less than eighteen (18) years of age.

"Parking garage" means an enclosed garage where members of the general public park their cars.

"Person" means any individual, corporation, nonprofit corporation, partnership, or unincorporated association.

"Place of employment" means any enclosed area under the control of an employer, which employees normally frequent during the course of employment. A private residence being used for home occupation purposes shall not be construed as a place of employment, except when the residence is being used for child day care and elder care which is licensed under the Health and Safety Code.

"Public place" means any area to which the public is invited or in which the public is permitted.

"Restaurant" means any eating establishment, organization, club, boardinghouse, or guest house which gives or offers food for sale to the public, guests, patrons, or employees as well as kitchens in which food is prepared on the premises for serving elsewhere, and includes outside dining areas, except that the term "restaurant" shall not include a "bar" as defined in this chapter. A restaurant includes, but is not limited to, a food service counter area, donut shop, sandwich shop, juice store, luncheonette, coffee shop, or fast food outlet of any type.

"Self-service display" means the open display of tobacco products that the public has access to without the intervention of a store employee, including but not limited to a rack, a shelf, or a counter top display.

"Service line" means any line at which one or more persons are waiting for or receiving service of any kind, whether or not such service involves the exchange of money.

"Smoking" means inhaling, exhaling, burning, or carrying any lighted cigarette, cigar, pipe, operating electronic cigarette, weed, plant, or other combustible substance in any manner or in any form.

"Sports arena" means an enclosed sports pavilion, gymnasium, health spa, boxing arena, swimming pool, roller and ice rink, bowling alley, and other similar places where members of the general public assemble to either engage in physical exercise, participate in athletic competition, or witness sports events.

"Tobacco product" means any manufactured substance made from the tobacco plant, including but not limited to cigarettes, cigars, pipe tobacco, smokeless tobacco products or any other form of tobacco or tobacco papers which may be utilized for smoking, chewing, inhalation, or other means of ingestion. **For purposes of this Chapter, the term "tobacco product" shall also include an electronic cigarette, as defined in this Chapter.**

"Tobacco retailer" means any person or business that operates a store, stand, booth, concession, or other place at which sales of tobacco, tobacco products, or tobacco paraphernalia are made to purchasers for consumption or use.

"Tobacco shop" means a business establishment whose principal purpose is the sale of tobacco products, including but not limited to, cigars, pipe tobacco, and smoking accessories.

"Tobacco vending machine" means any machine or device designed for or used either wholly or partly for the vending of cigarettes, cigars, tobacco, or tobacco products upon the insertion of coins, bills, or slugs.

"Vendor-assisted" means a purchase requiring a direct, face-to-face exchange between the store proprietor or employee and the customer, in which the store proprietor or employee assists the customer by supplying the tobacco product. The customer does not take possession of the tobacco product until after it is purchased.

"Work area" or "workplace" means any area of a place of employment enclosed by floor to ceiling walls in which two or more employees are assigned to perform work for an employer. (

5-28.030 Prohibition of smoking in places accessible to the public.

Smoking is prohibited and is unlawful in the following public places and other public places similarly situated, including, but not limited to, the following areas:

- A. All enclosed areas (including lobbies, hallways, and other common areas) available to and customarily used by the general public, including, but not limited to, the public area of retail stores, a bank, and other service establishments;
- B. Elevators, escalators, and stairways;

- C. Public restrooms;
- D. Service lines;
- E. All reception and waiting areas;
- F. Galleries, libraries, and museums;
- G. Within any facility which is primarily used for, or designated for the primary purpose of, exhibiting any motion picture, stage drama, lecture, musical recital, or other similar performance;
- H. All enclosed areas available to and customarily used by the general public in hotels and motels, including, but not limited to, lobby and registration areas, hallways, dining areas, banquet and conference rooms, and retail shops; smoking may be permitted in sixty-five (65) percent of guest rooms at the discretion of the management;
- I. Public parks, sports arenas, and convention halls;
- J. Video arcades, bingo parlors, card rooms, game rooms, pool halls, dance halls, and other amusement centers;
- K. Child day care and elder care facilities as defined in the California Health and Safety Code and private residences while used as family day care homes;
- L. Rooms, chambers, or other enclosed areas where a meeting is being held which is or can be attended by the general public;
- M. Retail food marketing establishments, including grocery stores, supermarkets, and convenience stores;
- N. Restaurants, public and private, including outdoor patio and dining areas;
- O. Within twenty (20) feet of an outdoor dining or patio area;
- P. Theaters and theater-bar combinations;
- Q. Laundromats;
- R. Beauty shops, nail parlors, barber shops, or similar uses;
- S. Lobbies, hallways, and other common areas in apartment buildings, condominiums, retirement facilities, and nursing homes;
- T. Malls;

U. Polling places;

V. Parking garages;

W. Bars;

X. Public transportation facilities, including waiting areas and bus stops;

Y. Within twenty (20) feet of main entrances, exits, and operable windows of any building owned, leased, and occupied by the state, county, or city, and buildings of the University of California (UC), California State University (CSU), and California community colleges;

Z. Within all facilities and areas specified by state law, including workplaces, schools, tot lots, and playgrounds.

5-28.040 Prohibition of smoking in places of employment.

Except as otherwise prohibited by Section 5-28.030, smoking is also prohibited and is unlawful in all enclosed facilities within a place of employment. This includes common work areas, auditoriums, classrooms, conference and meeting rooms, private offices, elevators, hallways, medical facilities, cafeterias, employee lounges, stairs, restrooms, and all other enclosed facilities.

5-28.050 Tobacco vending machines prohibited.

No cigarette or other tobacco product may be sold, offered for sale, or distributed by or from a tobacco vending machine. No tobacco vending machines shall be placed or maintained in any public place or place of employment.

5-28.060 Self-service display—Requirement of vendor assisted sales.

It shall be unlawful for any person, business, or tobacco retailer to display for sale or to sell any tobacco product by means of a self-service display. All sales of any tobacco products shall be vendor-assisted. The provisions of this section shall not apply to tobacco shops and cigar lounges as defined in this chapter.

5-28.070 Posting of signs—General.

Every public place and place of employment where smoking is prohibited by this chapter shall have posted at every entrance a conspicuous sign clearly stating that smoking is prohibited, as follows:

A. Indoor Sign Requirements. "No Smoking" signs with letters of not less than one inch in height, and the international "No Smoking" symbol (consisting of a pictorial representation of a burning cigarette enclosed in a red circle with a red bar across it) shall be clearly posted (and visible from the interior) on every entrance door, or within five feet of an entrance door, and sufficiently and conspicuously posted at other appropriate locations within the building (i.e. kitchen, restroom, etc.) by the owner, operator, manager, or other person having control of such building or other place. Signs, which have been removed, shall be replaced within five working days.

B. Outdoor Sign Requirements. "No Smoking" signs, with letters of not less than one inch in height, and the international "No Smoking" symbol (consisting of a pictorial representation of a burning cigarette enclosed in a red circle with a red bar across it) shall be clearly posted (and visible from the exterior) on every entrance door, or within five feet of every entrance door, by the owner, operator, manager, or other person having control of such building or other facility. "No Smoking" signs, with letters of not less than one inch in height, and the international "No Smoking" symbol shall be posted in the outdoor dining areas, which specifically state that smoking is not allowed within twenty (20) feet of every outdoor area regulated by this chapter. In addition, a "No Smoking" sign or the international "No Smoking" symbol shall be attached to the top of every outdoor dining table, so that it is clearly visible. No ashtrays are allowed in any outdoor dining area. Signs, which have been removed, shall be replaced within five working days.

5-28.080 Enforcement.

The City Manager or his or her designee and the City Attorney shall enforce this chapter.

A. Registration of Complaints. Any citizen, employee, or business patron who desires to register a complaint under this chapter may initiate enforcement with the City Manager or his or her designee.

B. Inspection. As part of any certificate of use and occupancy application, the city's Community Development Department shall provide a copy of this chapter's regulations to the new business. At final inspection and prior to issuance of the certificate of use and occupancy permit, the Department shall verify that all requirements of this chapter have been complied with.

C. Duty to Orally Inform. Except under circumstances involving a risk of physical harm to the employer or any employee, an owner, manager, or authorized agent of any business regulated by this chapter, shall orally request a non-employee who is smoking to refrain from smoking where smoking is prohibited.

D. Responsibility of Businesses. It is unlawful for any person who owns, operates, manages, or otherwise controls the use of any business subject to the restrictions of this chapter, to fail to comply with its provisions. All ashtrays shall be removed from any area where smoking is prohibited in this chapter. However, the owner, operator, manager or other person having control of the area, of a business shall not be responsible for violations of this chapter within their premises by patrons or citizens who continue to smoke, provided that such patrons or citizens have been adequately orally informed that their actions are in violation of the law, and the owner, operator, manager, or other person having control of the area, has complied with the posting of signage and removal of ashtrays in accordance with this chapter.

5-28.090 Violation—Penalty.

A. Any person who violates any provision of Sections 5-28.010 through 5-28.040 and 5-28.080 of this chapter shall be subject to a citation and:

1. Upon the first violation shall be guilty of an infraction and, upon conviction, shall be subject to a fine not to exceed one hundred dollars (\$100.00) punishment in accordance with state law.

2. Upon the second violation within one year shall be guilty of an infraction and, upon conviction, shall be subject to a fine not to exceed two hundred dollars (\$200.00).

3. Upon the third violation within one year shall be guilty of an infraction and, upon conviction, shall be subject to a fine not to exceed two hundred fifty dollars (\$250.00).

B. Any person who violates any provision of Sections 5-28.010 through 5-28.040 and 5-28.080 of this chapter, and this is the fourth violation of this chapter within one year, shall be guilty of a misdemeanor and subject to punishment in accordance with state law.

C. Any person who violates the provisions of Section 5-28.050 of this chapter shall be guilty of a misdemeanor and subject to punishment in accordance with state law.

D. Any person who violates the provisions of Section 5-28.060 of this chapter shall be guilty of a misdemeanor and subject to punishment in accordance with state law.

5-28.110 Citation authority.

The City Manager and his or her designees shall have the authority to issue citations for violations of this chapter, however, such individuals shall only be deemed qualified to issue citations consistent with satisfying the requirements of Sections 1-28.020 and 9-98.040 of the Laguna Hills Municipal Code. The Chief of Police Services and police officers shall also have the authority to issue citations for violations of this chapter.

5-28.120 Power to adopt more restrictive smoking policies.

Notwithstanding any other provisions of this chapter, any owner, operator, manager, employer, or other person who controls any establishment or place of employment regulated by this chapter may adopt policies relating to smoking which are more restrictive than those provided therein.

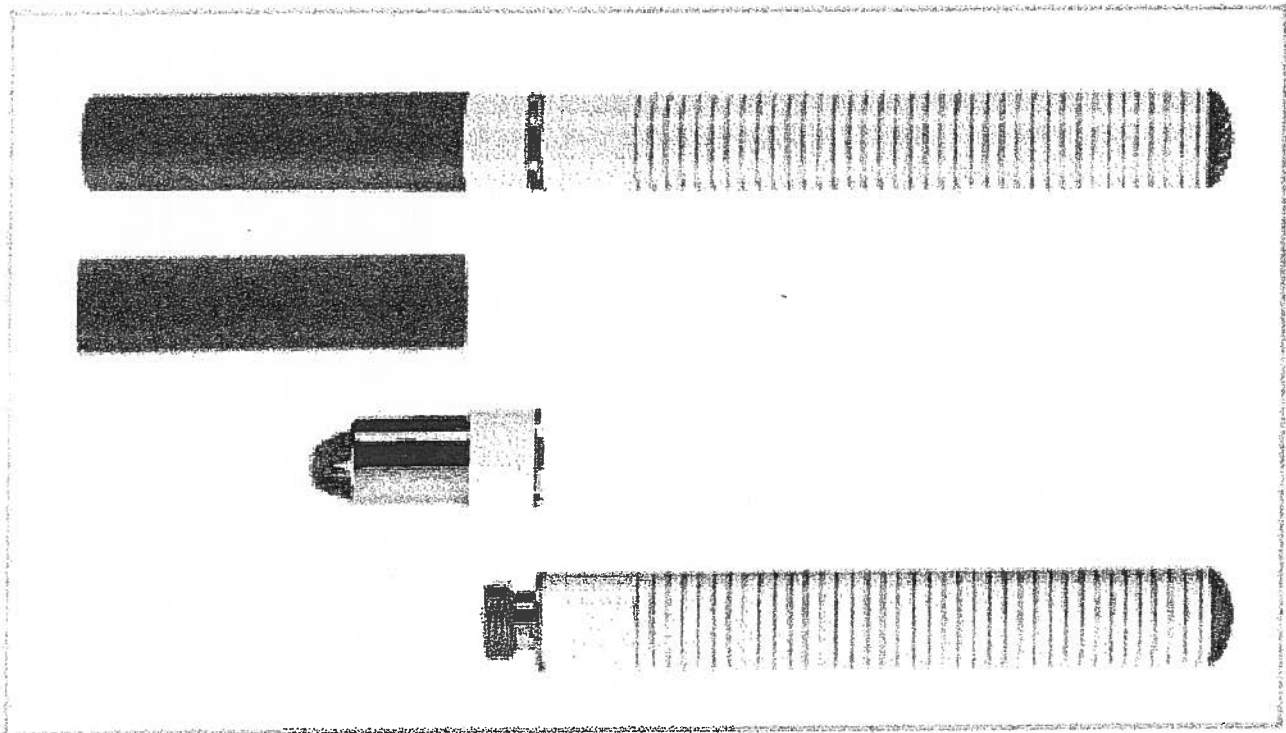
EXHIBIT 3

J.S. Food and Drug Administration
Protecting and Promoting *Your Health*

Electronic Cigarettes (e-Cigarettes)

What are electronic cigarettes?

Electronic cigarettes, also known as e-cigarettes, are battery-operated products designed to deliver nicotine, flavor and other chemicals. They turn chemicals, including highly addictive nicotine, into an aerosol that is inhaled by the user.



Most e-cigarettes are manufactured to look like conventional cigarettes, cigars, or pipes. Some resemble everyday items such as pens and USB memory sticks.

E-cigarettes have not been fully studied, so consumers currently don't know:

- the potential risks of e-cigarettes when used as intended,

- how much nicotine or other potentially harmful chemicals are being inhaled during use, or
- whether there are any benefits associated with using these products.

Additionally, it is not known whether e-cigarettes may lead young people to try other tobacco products, including conventional cigarettes, which are known to cause disease and lead to premature death.

FDA Regulation of e-Cigarettes

Only e-cigarettes that are marketed for therapeutic purposes are currently regulated by the FDA Center for Drug Evaluation and Research (CDER). Currently, the FDA Center for Tobacco Products (CTP) regulates

- cigarettes,
- cigarette tobacco,
- roll-your-own tobacco, and
- smokeless tobacco.

FDA has issued a proposed rule that would extend the agency's tobacco authority to cover additional products that meet the legal definition of a tobacco product, such as e-cigarettes. FDA's **Extending Authorities to Additional Tobacco Products webpage** ([/TobaccoProducts/Labeling/ucm388395.htm](http://TobaccoProducts/Labeling/ucm388395.htm)) offers more information on the proposed rule, including how to submit comments.

For more information on current regulation:

- **Tobacco Product Regulation** ([/TobaccoProducts/ResourcesforYou/ucm335294.htm](http://TobaccoProducts/ResourcesforYou/ucm335294.htm))
- **Nicotine-Containing Products** ([/Drugs/GuidanceComplianceRegulatoryInformation/ucm345928.htm](http://Drugs/GuidanceComplianceRegulatoryInformation/ucm345928.htm))

How to Comment

To comment on the proposed rule:

1. **Read the proposed rule** (<http://www.regulations.gov/#!documentDetail;D=FDA-2014-N-0189-20870>).
2. Through August 8, 2014, **go to Regulations.gov to submit comments**

(<http://www.regulations.gov#!submitComment;D=FDA-2014-N-0189-20870>).

Comment Now (<http://www.regulations.gov#!submitComment;D=FDA-2014-N-0189-20870>)

eCigarettes and Adverse Events

What is an Adverse Event?

An adverse event is an undesirable side effect or unexpected health or product quality problem that an individual believes was caused by the use of a tobacco product.

Reporting an Adverse Event

Anyone can report an adverse event to the FDA. In fact, these reports help us identify safety concerns with tobacco products that could cause health or safety problems beyond those normally associated with tobacco product use.

Please report adverse events with e-cigarettes via:

- The **HHS Safety Reporting Portal (<https://www.safetyreporting.hhs.gov/>)** or
- By calling 1-800-FDA-1088

Please send other information or inquiries regarding e-cigarettes to:

- 1-877-CTP-1373 or
- **AskCTP@fda.hhs.gov** (**<mailto:AskCTP@fda.hhs.gov>**)

Adverse Event Reports for e-Cigarettes

We regularly receive voluntary reports¹ of adverse events involving e-cigarettes from consumers, health professionals and concerned members of the public. The adverse events described in these reports have included hospitalization for illnesses such as

- pneumonia,

- congestive heart failure,
- disorientation,
- seizure,
- hypotension, and
- other health problems.

Whether e-cigarettes caused these reported adverse events is unknown. Some of the adverse events could be related to a pre-existing medical condition or to other causes that were not reported to FDA. You can review the adverse event reports for e-cigarettes that were voluntarily reported to FDA from 6/22/2009 to 3/12/2014 at the **CTP FOIA Electronic Reading Room** (**//AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/AbouttheCenterforTobaccoProducts/ucm221165.htm**).

1. Under the Food, Drug and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act, FDA may accept voluntarily submitted information related to tobacco products, even if some of the information concerns tobacco products that are not yet regulated by FDA. (**back**)



FDA Warns of Health Risks Posed by E-Cigarettes

The Food and Drug Administration (FDA) has joined other health experts to warn consumers about potential health risks associated with electronic cigarettes.

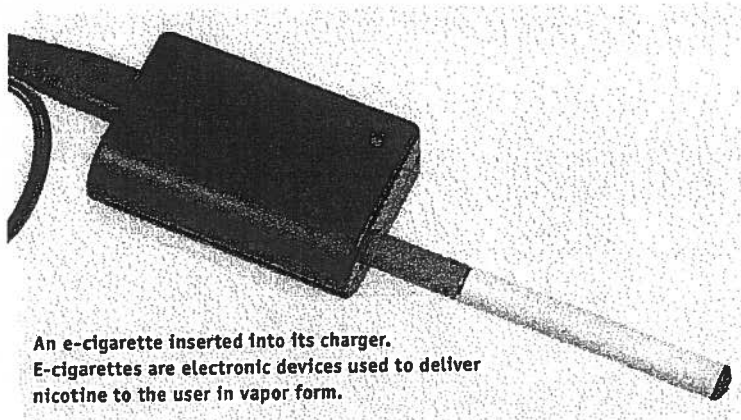
Also known as "e-cigarettes," electronic cigarettes are battery-operated devices designed to look like and to be used in the same manner as conventional cigarettes.

Sold online and in many shopping malls, the devices generally contain cartridges filled with nicotine, flavor, and other chemicals. They turn nicotine, which is highly addictive, and other chemicals into a vapor that is inhaled by the user.

"The FDA is concerned about the safety of these products and how they are marketed to the public," says Margaret A. Hamburg, M.D., commissioner of food and drugs.

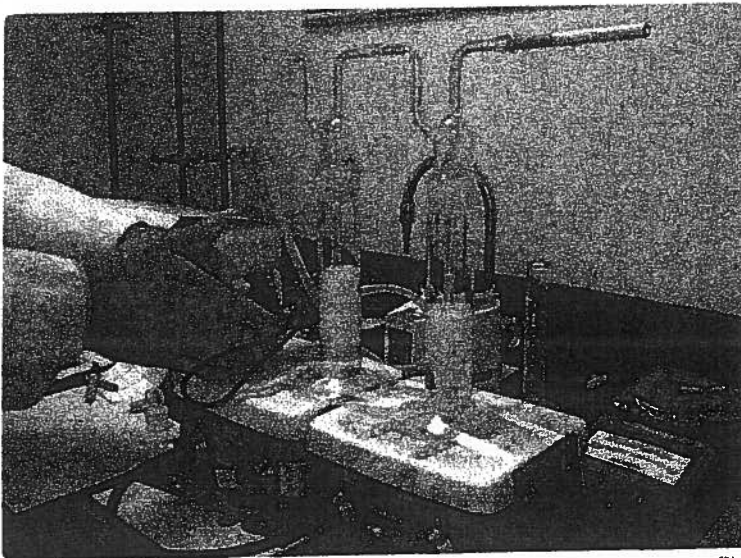
The agency is concerned that

- e-cigarettes can increase nicotine addiction among young people and may lead kids to try other tobacco products, including conventional cigarettes, which are known to cause disease and lead to premature death
- the products may contain ingredients that are known to be toxic to humans
- because clinical studies about the safety and efficacy of these products for their intended use have not been



An e-cigarette inserted into its charger. E-cigarettes are electronic devices used to deliver nicotine to the user in vapor form.

FDA



FDA

Air is drawn through an e-cigarette during a laboratory procedure that simulates a smoker taking a puff. The resulting vapor is tested.



submitted to FDA, consumers currently have no way of knowing

- whether e-cigarettes are safe for their intended use
- about what types or concentrations of potentially harmful chemicals, or what dose of nicotine they are inhaling when they use these products

The potential health risks posed by the use of e-cigarettes were addressed in a July 22, 2009, phone conference between Joshua M. Sharfstein, M.D., principal deputy commissioner of food and drugs; Jonathan Winickoff, M.D., chair of the American Academy of Pediatrics Tobacco Consortium; Jonathan Samet, M.D., director of the University of Southern California's Institute for Global Health; and Matthew T. McKenna, M.D., director of the Office on Smoking and Health at the national Centers for Disease Control and Prevention.

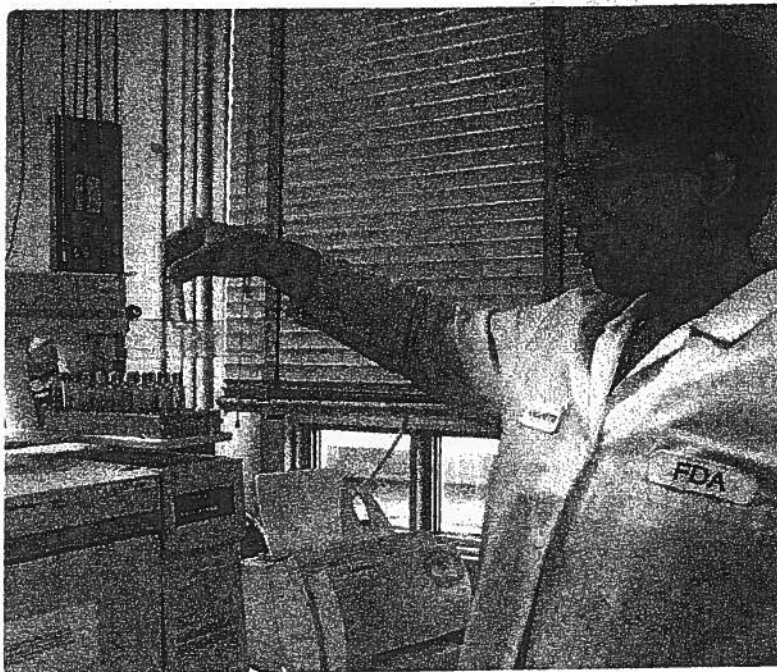
Conference participants stressed the importance of parents being aware of the health and marketing concerns associated with e-cigarettes. It was stated that parents may want to tell their children and teenagers that these products are not safe to use.

Of particular concern to parents is that e-cigarettes are sold without any legal age restrictions, and are available in different flavors (such as chocolate, strawberry and mint) which may appeal to young people.

In addition, the devices do not contain any health warnings comparable to FDA-approved nicotine replacement products or conventional cigarettes.

During the phone conference, which was shared with the news media, FDA announced findings from a laboratory analysis that indicates that electronic cigarettes expose users to harmful chemical ingredients.

FDA's Division of Pharmaceutical Analysis—part of the agency's Center for Drug Evaluation and Research—analyzed the ingredients in a small sample of cartridges from two leading brands of e-cigarette samples.



An FDA chemist uses a device set to the same temperature as an activated e-cigarette. This helps determine what might be inhaled by users of these products.

One sample was found to contain diethylene glycol, a toxic chemical used in antifreeze. Several othersamples were found to contain carcinogens, including nitrosamines.

Agency Actions

FDA has been examining and detaining shipments of e-cigarettes at the border and has found that the products it has examined thus far meet the definition of a combination drug device product under the Federal Food, Drug, and Cosmetic Act.

The agency has been challenged regarding its jurisdiction over certain e-cigarettes in a case currently pending in federal district court.

FDA is planning additional activities to address its concerns about electronic cigarettes.

Meanwhile, health care professionals and consumers may report seri-

ous adverse events or product quality problems with the use of e-cigarettes to FDA through the MedWatch program, either online at www.fda.gov/Safety/MedWatch/default.htm or by phone at 1-800-FDA-1088. **FDA**

This article appears on FDA's Consumer Updates page (www.fda.gov/ForConsumers/ConsumerUpdates/default.htm), which features the latest on all FDA-regulated products.

For More Information

FDA Press Release
www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm173222.htm

E-Cigarettes: FDA Web page
www.fda.gov/NewsEvents/PublicHealthFocus/ucm172906.htm



U.S. Food and Drug Administration

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Center for Drug Evaluation and Research

Division of Pharmaceutical Analysis

St. Louis, MO 63101

Tel. (314) 539-3869

Date: May 4, 2009

To: Michael Levy, Supervisor Regulatory Counsel, CDER, Office of Compliance, Division of New Drugs and Labeling Compliance

From: B.J. Westenberger, Deputy Director, CDER/OPS/OTR, Division of Pharmaceutical Analysis

Subject: Evaluation of e-cigarettes

Background: The Center for Drug Evaluation and Research through the Office of Compliance (OC) has requested that the Division of Pharmaceutical Analysis (DPA) evaluate two brands of electronic cigarettes (e-cigarettes) for nicotine content and other impurities. An e-cigarette is advertised as an alternative to smoked tobacco products. It is a battery-powered device that provides inhaled doses of nicotine by delivering a vaporized propylene glycol/nicotine mixture as shown in Figure 1. The Center is concerned that in addition to nicotine delivery, the vapor may also provide other potentially harmful volatile components. DPA was asked to quantitate the amount of nicotine present in each brand and to evaluate each brand for the presence of tobacco specific nitrosamines (TSNA), certain tobacco specific impurities, ethylene glycol (EG) and diethylene glycol (DEG).

Test Products: Njoy e-cigarette (Reference 1) with various cartridges

Smoking Everywhere Electronic Cigarette (Reference 2) with various cartridges

Nicotrol Inhaler, 10mg cartridge was used as a control for some test methods

Conclusions: Nicotine is present in both products. The Smoking Everywhere Electronic Cigarette cartridges listed as containing no nicotine in some cases had very low amounts of nicotine present. Tobacco specific nitrosamines and tobacco specific impurities were detected in both products at very low levels. DEG was identified in one cartridge, Smoking Everywhere 555 High. See Table 1 for results of analyses of entire cartridges after extraction.

A sparging apparatus (see figure in Attachment A) and headspace GC (HS-GC) analysis were utilized to simulate actual use of these products. With the sparging apparatus, nicotine was detected in cartridges claiming to contain nicotine and quantitated by LC-UV; cotinine was also found in some products by this procedure. Repeat testing of 3 different cartridges with the same label (menthol high) gave varying results from 26.8 to 43.2 mcg nicotine/100 mL puff. HS-GC detected nicotine in both products and β -Nicotyrine was detected in all Njoy cartridges (see Table 2).

Experimental: See Attachment A for further experimental details.

- Nicotine content was analyzed by HPLC-UV and GC-MS. Quantification was done by HPLC-UV using two different extractions: a methanol extraction, and a 10% acetonitrile/1% phosphoric acid in water extraction.
- Tobacco specific impurities and diethylene glycol were analyzed by GC-MS.
- Diethylene glycol presence was confirmed with proton NMR.
- Detection of nicotine and tobacco specific impurities during use of these products was estimated by simulating use temperatures and analyzing volatiles using head space GC-MS (HSGC-MS) and utilizing a sparging apparatus (see figure in attachment).

Results and Discussion:

Whole Cartridge: Nicotine content by HPLC-UV

Results, similar for both methanol extraction and 10% acetonitrile/1% phosphoric acid in water extractions, are shown in Table 1.

Whole Cartridge: Tobacco Specific Nitrosoamines by LC-MS/MS

The four major TSNAs include: N-nitrosonicotine (NNN), N-nitrosoanabasine (NAB), N-nitrosoanatabine (NAT) and 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK) were analyzed for using LC-MS/MS and the results are shown in Table 1.

Whole Cartridge: Tobacco Specific Impurities by GC-MS and GC-MS/MS

Nicotine was detected in both products in all cartridges including samples identified as containing no nicotine. Samples were screened for possible tobacco specific impurities: cotinine, nicotine-N-oxide, normicotine, anatabine, anabasine, pseudooxynicotine, myosmine, β -nicotyrine, and 1-methyl-3-nicotinoylpyrrolidine (MNP). Nicotine-N-oxide, normicotine, anatabine, pseudooxynicotine and MNP were not observed in any of the samples. Results from cotinine, anabasine, myosmine, and β -nicotyrine are shown in Table 1.

Whole Cartridge: Diethylene Glycol by GC-MS

Diethylene Glycol was detected in one sample (Smoking Everywhere 555 High cartridge) at approximately 1%.

Simulated Use: Nicotine and tobacco Specific Impurities by Head Space GC-MS (HSGC-MS) and sparging apparatus

HSGC is likely to be less sensitive than the GC-MS technique that takes advantage of injecting all of the soluble components and then volatilizing them at 280 °C; however, the head space analyzer can be set to a specific temperature to mimic what may be volatilized during use of the products.

The temperature of the heating element in each e-cigarette was determined by inserting a thermocouple and then activating the e-cigarette by drawing air through it. These temperatures ranged from 40 to 65°C. HSGC-MS analysis was conducted at 60°C to simulate the temperature that would be encountered during activation of an e-cigarette. Nicotine was detected in both products for all cartridges containing low, medium and high levels of nicotine but was not

observed in cartridges identified as containing no nicotine. Screening for the possible tobacco specific impurities cotinine, nicotine-N-oxide, normicotine, anabasine and myosmine was negative. β -Nicotyrine was detected in all Njoy cartridges but was not detected in the Smoking Everywhere cartridges. The sparging apparatus was used to quantify the amount of nicotine released during use of these electronic cigarettes (Table 2). Levels found were consistent with the labeling (low, medium and high); however, the cartridge labeled "no" still delivered some nicotine. The cartridges labeled "high" delivered more nicotine than the approved Nicotrol product. Repeat testing of 3 different cartridges with the same label (menthol high) gave varying results from 26.8 to 43.2 mcg nicotine/100 mL puff.

References:

- (1) <http://www.njoythefreedom.com/>
- (2) <http://www.smokingeverywhere.com/>
- (3) C.N. Man, L.H. Gam, S. Ismail, R. Lajis, R. Awang, J. Chromatogr. B 844 (2006) 322–327.
- (4) S. S. Yang et al., J. Chromatogr. A, 942 (2002) 33-39.
- (5) USP 31/NF 26, Official 12/1/08-4/30/09 NF Monographs: Diethylene Glycol Monoethyl Ether: Assay; pg 1126

06

Structure of an "Electronic Cigarette"

Cigarette body

The cigarette body is an integrated structure consisting of stainless steel shell, lithium ion battery assembly, smart chip and program controlled circuits, atomization chamber and cartridge and so on. In the front of it, there exists an operating mode indicator.

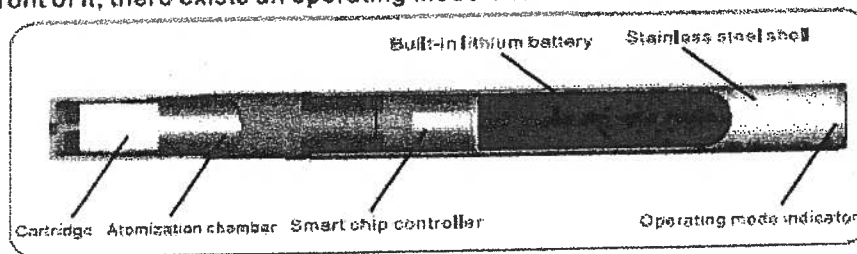


Figure 1: E-cigarette component diagram. Nicotine and/or other flavorants are housed in the white cartridge shown at the left.

Table 1. Results on analyses of whole cartridges

Sample	Tobacco specific nitrosamines (TSNA) ^A	mg nicotine/cartridge by HPLC-UV				Identification of possible tobacco specific impurities and DEG by GC-MS/MS ^B						
		10% ACN and 1% PA in water extraction	methanol extraction	DEG	Cotinine	Anabasine	Myosmine	β-nicotyrine				
Smoking Everywhere e-cigarettes	NAB	NAT	NNK	NNN	fiber absorbent	plug & wrapper	fiber absorbent	D	D	D	D	D
555 High					4.90	1.80	5.98	ND	D	ND	D	D
Cherry HIGH					4.88	0.86	5.50	ND	D	D	D	D
Tobacco Original MED	ND	ND	D	D	4.44	1.03	5.15	ND	D	D	D	D
Menthol HIGH					4.02	0.71	4.23	ND	D	D	D	D
Tobacco Original LOW	ND	ND	D	D	2.93	0.51	2.65	ND	D	D	D	D
Menthol MED					2.26	0.31	2.71	ND	D	D	D	D
Apple LOW	ND	ND	ND	ND	1.63	0.61	1.78	ND	D	D	D	D
Menthol LOW					1.42	0.30	1.57	ND	D	ND	D	D
Vanilla LOW	ND	ND	ND	ND	1.18	0.34	0.96	ND	D	D	D	D
Tobacco Original NO	ND	ND	ND	ND	0.04	0.00	0.03	ND	ND	ND	ND	ND
Vanilla NO					0.04	0.01	0.05	ND	ND	ND	ND	ND
Cherry NO					0.01	0.00	0.07	ND	ND	ND	ND	ND
Chocolate NO	ND	ND	ND	ND	0.01	0.00	0.03	ND	ND	ND	ND	ND
Apple NO	ND	ND	ND	ND	0.00	0.00	0.00	ND	ND	ND	ND	ND
Njoy e-cigarettes												
Menthol high	D	D	D	D	6.66	1.97	6.76	ND	D	D	D	D
Regular medium	D	D	D	D	4.09	1.58	4.31	ND	D	D	D	D
Menthol medium	D	D	D	D	3.98	1.46	4.77	ND	D	D	D	D
Regular low					3.35	1.56	5.16	ND	D	D	D	D
Control Sample – Nicotrol 10 mg cartridge Mfg. specification									(NMT 0.5%)		(NMT 0.5%)	(NMT 0.5%)

D= detected, ND= not detected NAB = N-nitrosanabasine (LOQ = 21 ppb); NAT = N-nitrosanatabine (LOQ = 21 ppb); NNK = 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone (LOQ = 75 ppb); NNN = N-nitrosomnicotine (LOQ = 24 ppb)

^A analyte was detected but at a level less than the limit-of-quantitation. Open boxes indicate the sample was not available for testing.

DEG = diethylene glycol

^B Limit of detection Cotinine 20 ppb. Anabasine 10 ppb; mysosmine 69 ppb; β-nicotyrine 170 ppb – present but at less than the level of the Nicotrol specification

Table 2. Results on simulated use of electronic cigarettes

Sample	Sparging Apparatus followed by LC-UV analysis		Head Space GC-MS @ 60 deg C*	
	mcg nicotine/100mL puff	mcg cotinine/100 ml puff (LOD ~0.03)	β -nicotyrine	nicotine
Smoking Everywhere e-cigarettes				
555 High	31.5	0.4		
Cherry HIGH			ND	D
Tobacco Original MED	15.7	trace	ND	D
Menthol HIGH				
Tobacco Original LOW				
Menthol MED			ND	D
Apple LOW			ND	D
Menthol LOW	9.9	ND	ND	D
Vanilla LOW			ND	D
Tobacco Original NO			ND	ND
Vanilla NO			ND	ND
Cherry NO			ND	ND
Chocolate NO			ND	ND
Apple NO	0.35	ND	ND	ND
Njoy e-cigarettes				
Menthol high	43.2, 34.9, 26.8	trace	D	D
Regular medium			D	D
Menthol medium	10.6	ND	D	D
Regular low				
Control (specs)				
Nicotrol 10mg cartridge	15.2			

DEG = diethylene glycol

D= detected, ND= not detected

* Presence of tobacco specific impurities cotinine, nicotine-N-oxide, normicotine, anabasine and myosmine was negative at 60 deg C. Open boxes indicate the sample was not tested.

Experimental Details:*Whole Cartridges: Detection and Quantitation of Nicotine by HPLC-UV*

Smokeless tobacco cartridges were extracted and analyzed using two different procedures:

- Methanol extraction and USP analytical procedure: cartridge components were weighed, extracted with methanol and reweighed. An aliquot of the methanol extract was diluted with mobile phase and analyzed by HPLC-UV following USP 31 p 2801 Nicotine Transdermal System Assay procedure.
- Extraction with [REDACTED] (b) (4) as described in NDA 20-714, Pharmacia & Upjohn method "Nicotine, Content Uniformity, Identification and Determination of Nicotine Related Substances in Nicotine Inhaler 10 mg" method NM-046-6 dated 1999-07-16

Whole Cartridges: Analysis of Tobacco Specific Nitrosamines by HPLC-MS/MS

Analysis was done using a variation of the method published by Wu, et al. using HPLC-MS/MS¹. As shown in Table 1, not all sample lots were available for analysis by LC-MS/MS as they were consumed in other testing. Smokeless tobacco cartridges were extracted using 100 mM ammonium acetate and analyzed for tobacco specific nitrosoamines (TSNAs). The four major TSNAs include: N-nitrosocotine (NNN), N-nitrosoanabasine (NAB), N-nitrosoanatabine (NAT) and 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK). While the published method is quite sensitive for the TSNAs (i.e. LOQ's of approximately 40 pg/mL or 40 parts per trillion), it should be noted that the extraction method used in that paper was for either finely ground tobacco or smoke captured on glass fiber filter pads. The matrix present in smokeless E-cigarette or NJoy cartridges is a spiked propylene glycol matrix supported on a fibrous material contained in a plastic housing (i.e. the inhaler component) as shown in Figure 1. The assumption was made that recovery of TSNAs from the E-cigarette cartridge assembly was as good as that published by Wu, et al., and quantitative.

For the extraction, the cartridge was removed from the inhaler unit/atomization chamber. The fibrous material was removed from the cartridge using a pair of tweezers and both the fibrous material and the white plastic housing were placed in an Erlenmeyer flask. The flask was weighed and the weight of the fibrous material and white plastic housing were recorded. 10 mL of 100 mM ammonium acetate and 100 µL of internal standard solution were added to the flask and the contents mixed on a flat-bed shaker for 30 minutes at ambient temperature. An aliquot of the solution was analyzed by HPLC-MS/MS.

TSNAs in the extract were quantified using deuterated internal standards. Two molecular reaction mechanisms (i.e. MRM's) were recorded for each TSNA: one for qualification and both for quantification. MRM's for each TSNA are shown in table below. The sum of the intensities of both molecular transitions was used to quantify each TSNA. TSNA content is reported as weight of TSNA per weight of nicotine/flavorant cartridge (ng/g).

MRM transitions for TSNAs

TSNA	Primary MRM	Qualifier MRM
NAB	192.1 to 162.1	192.1 to 133.1
NAT	190.1 to 160.2	190.1 to 106.1
NNK	208.1 to 122.1	208.1 to 106.0
NNN	178.1 to 148.1	178.1 to 120.1

¹ Wu, J., Joza, P., Sharifi, M., Rickett, W. Lauterbach, J. *Quantitative Method for the Analysis of Tobacco-Specific Nitrosamines in Cigarette Tobacco and Mainstream Cigarette Smoke by Use of Isotope Dilution Liquid Chromatography Tandem Mass Spectrometry*. Anal. Chem., 80, 2008, 1341-1345.

Whole Cartridges: Tobacco Specific Impurity Analysis by GC-MS and GC-MS/MS

An aliquot of each methanol extract prepared in the Detection and Quantitation of Nicotine by HPLC-UV analysis was transferred to a vial for GC-MS analysis. Samples were initially screened on an Agilent 6890 with a 5975 MSD operated in full scan mode using the method published by Man et al (Reference 3). Samples containing peaks of interest were then analyzed on a Varian 320 Triple Quad GC-MS in either single reaction monitoring mode (SRM) or multiple reaction monitoring mode (MRM) due to their increased sensitivity and selectivity. An Extracted Ion Chromatogram (EIC) looking for each impurity was obtained by individually extracting a main fragment ion for that impurity from the full scan chromatogram. Peak spectra were then compared to spectra from the NIST 05 Mass Spectral Library. All samples containing impurity peaks with spectral library matches to cotinine, anabasine, myosmine, and β -nicotyrine were then analyzed on a Varian 320 Triple Quad GC-MS in either single reaction monitoring mode (SRM) or multiple reaction monitoring mode (MRM). Identifications were based on retention time and mass spectra comparison to external standards.

Whole Cartridges: Diethylene Glycol

An aliquot of each methanol extract prepared in the Detection and Quantitation of Nicotine by HPLC-UV analysis was transferred to a vial for GC-MS analysis. Samples were screened on an Agilent 6890 with a 5975 MSD operated initially in full scan mode and later in SIM mode using the chromatographic parameters from a USP monograph procedure (Reference 5). Quantitation was performed using an external standard. The presence of diethylene glycol was confirmed in this sample by proton nuclear magnetic resonance spectroscopy by dissolving 10mg of the cartridge liquid in 500mg of D₂O and taking a spectrum on a 500 MHz NMR.

Simulated Use: Nicotine and Impurity Analysis by HSGC-MS

The cartridge contains a fiber plug within a cup. Both cup and fiber plug were placed in the same headspace vial for analysis. Compounds were identified by NIST library with greater than 90% match. Instrument parameters are detailed below.

CombiPal Headspace autosampler parameters:

Incubation: 60°C for 15 minutes, syringe: 2000mcL gas aliquot at 145°C,
Agitation: 250RPM, syringe fill and injection speed: 100mcL/s

Agilent 6890 Gas Chromatograph parameters (Reference 4):

Column: HP-5MS (5% diphenyl, 95%dimethyl), 15m, 0.25mm ID, 0.25 micron thickness

Temperature program: 40°C hold 3 min, 6°C/min to 300°C hold 3 min, runtime: 50 minutes

Splitless injection, injector port at 280°C, carrier gas: helium at 0.5mL/min

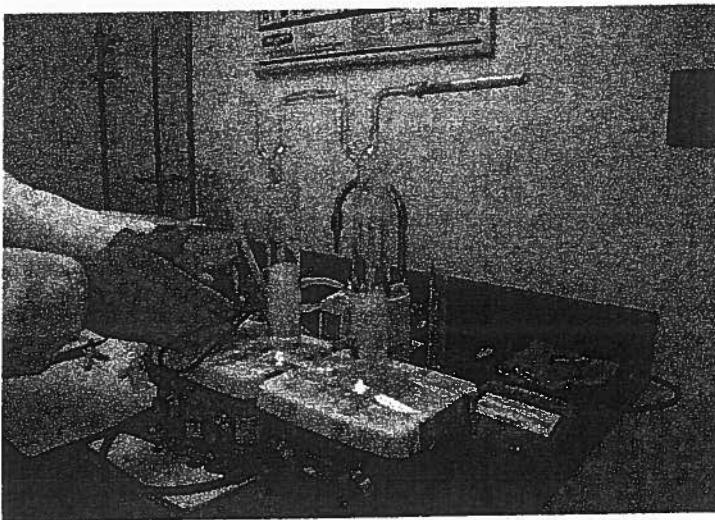
Agilent 5975B inert XL EI/CI MSD parameters:

Solvent delay: 1.2 min. voltage: 1705.9, low mass: 25.0, high mass: 350.0

MS quad at 150°C, MS source at 230°C, scan mode

Simulated Use: Sparging Apparatus: Determination of nicotine/100mL puff: trapping of nicotine and related compounds released from activation of e-cigarette

Trapping device consisted of a 150 ml gas washing bottle with sparger (see photo below). A magnetic stirring bar was added to the gas washing bottle along with 50 ml of extraction solution. Extraction solution was prepared by mixing 100 ml of acetonitrile, 11.5 g of phosphoric acid, and 800 ml of water. A draeger 100 cc hand pump was connected to the outlet of the gas washing bottle. The e-cigarette device with the selected cartridge type was connected to the inlet to the gas washing bottle via tygon tubing. The e-cigarette was butted directly up to the glass to avoid absorption. The magnet stirrer was turned on. At one minute intervals 100 cc of air were drawn through the e-cigarette into the gas washing bottle. The e-cigarette was observed to assure the LED lit indicating that the flow rate was sufficient to activate the heater in the e-cigarette. After an appropriate number of 100 cc puffs were trapped in the gas washing solution, the sample was allowed to mix for 10 minutes and the glass tubing in the gas washing bottle was rinsed with the trapping solution back into the gas washing bottle. The solution was mixed again and then sampled for analysis.



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FDA proposes to extend its tobacco authority to additional tobacco products, including e-cigarettes

As part of its implementation of the Family Smoking Prevention and Tobacco Control Act signed by the President in 2009, the U.S. Food and Drug Administration today proposed a new rule that would extend the agency's tobacco authority to cover additional tobacco products.

Products that would be "deemed" to be subject to FDA regulation are those that meet the statutory definition of a tobacco product, including currently unregulated marketed products, such as electronic cigarettes (e-cigarettes), cigars, pipe tobacco, nicotine gels, waterpipe (or hookah) tobacco, and dissolvables not already under the FDA's authority. The FDA currently regulates cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco.

"This proposed rule is the latest step in our efforts to make the next generation tobacco-free," said HHS Secretary Kathleen Sebelius.

Consistent with currently regulated tobacco products, under the proposed rule, makers of newly deemed tobacco products would, among other requirements:

- Register with the FDA and report product and ingredient listings;
- Only market new tobacco products after FDA review;

- Only make direct and implied claims of reduced risk if the FDA confirms that scientific evidence supports the claim and that marketing the product will benefit public health as a whole; and
- Not distribute free samples.

In addition, under the proposed rule, the following provisions would apply to newly "deemed" tobacco products:

- Minimum age and identification restrictions to prevent sales to underage youth;
- Requirements to include health warnings; and
- Prohibition of vending machine sales, unless in a facility that never admits youth.

"Tobacco remains the leading cause of death and disease in this country. This is an important moment for consumer protection and a significant proposal that if finalized as written would bring FDA oversight to many new tobacco products," said FDA Commissioner Margaret A. Hamburg, M.D. "Science-based product regulation is a powerful form of consumer protection that can help reduce the public health burden of tobacco use on the American public, including youth."

"Tobacco-related disease and death is one of the most critical public health challenges before the FDA," said Mitch Zeller, director of the FDA's Center for Tobacco Products. "The proposed rule would give the FDA additional tools to protect the public health in today's rapidly evolving tobacco marketplace, including the review of new tobacco products and their health-related claims."

The FDA proposes different compliance dates for various provisions so that all regulated entities, including small businesses, will have adequate time to comply with the requirements of the proposed rule.

Products that are marketed for therapeutic purposes will continue to be regulated as medical products under the FDA's existing drug and device authorities in the Food, Drug & Cosmetic Act.

The proposed rule will be available for public comment for 75 days. While all comments, data, research, and other information submitted to the docket will be considered, the FDA is requesting comments in certain areas, including:

- The FDA recognizes that different tobacco products may have the potential for varying effects on public health and is proposing two options for the categories of cigars that would be covered by this rule. The FDA specifically seeks comment on whether all cigars should be subject to deeming, and which other provisions of the proposed rule may be appropriate or not appropriate for different kinds of cigars.
- The FDA seeks answers to the many public health questions posed by products, such as e-

cigarettes, that do not involve the burning of tobacco and inhalation of its smoke, as the agency develops an appropriate level of regulatory oversight for these products. The FDA seeks comment in this proposed rule as to how such products should be regulated.

For more information:

- Proposed rule: **Tobacco Products Deemed to be Subject to the Food, Drug and Cosmetic Act (Deeming)** (<https://federalregister.gov/a/2014-09491>) 
- FDA: **Extending Authorities to Additional Tobacco Products** ([/TobaccoProducts/Labeling/ucm388395.htm](http://TobaccoProducts/Labeling/ucm388395.htm))
- Consumer Update: **Recognize Tobacco in Its Many Forms** ([/ForConsumers/ConsumerUpdates/ucm392735.htm](http://ForConsumers/ConsumerUpdates/ucm392735.htm))
- FDA Voice Blog: **Proposed Rule Would Expand FDA's Tobacco Control Authority** (<http://blogs.fda.gov/fdavoiced/index.php/2014/04/proposed-rule-would-expand-fdas-tobacco-control-authority/>)
- En Espanol: **La FDA propone ampliar su autoridad para regular otros productos de tabaco, incluyendo los cigarros electrónicos** ([/NewsEvents/Newsroom/ComunicadosdePrensa/ucm394669.htm](http://NewsEvents/Newsroom/ComunicadosdePrensa/ucm394669.htm))

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

###

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Issue Snapshot on Deeming: Regulating Additional Tobacco Products

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), signed by the President in 2009, created the FDA Center for Tobacco Products and gave FDA powerful tools to protect the public's health through our oversight of the manufacture, distribution, and marketing of tobacco products. Under the law, FDA currently regulates cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco products. The law also gave FDA the ability to regulate additional tobacco products, commonly referred to as "deeming" them through rulemaking. The proposed rule would include the following products under FDA's authority: electronic cigarettes (e-cigarettes), cigars, pipe tobacco, waterpipe (hookah) tobacco, and novel products like nicotine gels and dissolvables not already under FDA's authority. FDA's proposed rule also would include tobacco product components or parts that are used in the consumption of a tobacco product, like e-cigarette cartridges. It would not include tobacco product accessories, like cigar cases.

WHY THE DEEMING PROPOSED RULE IS SO IMPORTANT FOR PUBLIC HEALTH

With the release of the 50th Anniversary Surgeon General's Report on Smoking and Health, we now know that the annual death toll from tobacco-attributable disease has risen to more than 480,000. At this rate, there will be more than 17 million deaths from tobacco use between now and mid-century. Additionally, youth use of certain unregulated tobacco products, such as e-cigarettes and cigars, is on the rise. FDA oversight of tobacco products can provide important information about proposed deemed tobacco products and help limit youth exposure to these products. The proposed rule would also enable FDA to explore whether different products pose different levels of risk and help the Agency develop policies to improve public health.

HIGHLIGHTS OF THE DEEMING PROPOSED RULE

Consistent with currently regulated tobacco products, under the proposed rule, makers of newly deemed tobacco products would, among other requirements:

- Register with FDA and report product and ingredient listings
- Only market new tobacco products after FDA review
- Only make claims of reduced risk if FDA confirms that scientific evidence supports the claim and that marketing the product will benefit public health as a whole
- Not distribute free samples

In addition, under the proposed rule, the following items would apply to newly deemed covered tobacco products:

- Minimum age and identification restrictions to prevent sales to underage youth
- Requirements to include health warnings
- Prohibition of vending machine sales, unless in a facility that never admits youth

The term "covered tobacco products" is defined here as those products deemed to be subject to the Food, Drug & Cosmetic Act under section 1100.2 of title 21 of the Code of Federal Regulations (CFR), other than a component or part that does not contain tobacco or nicotine.



EXHIBIT 4

Chicago bans indoor electronic cigarette smoking

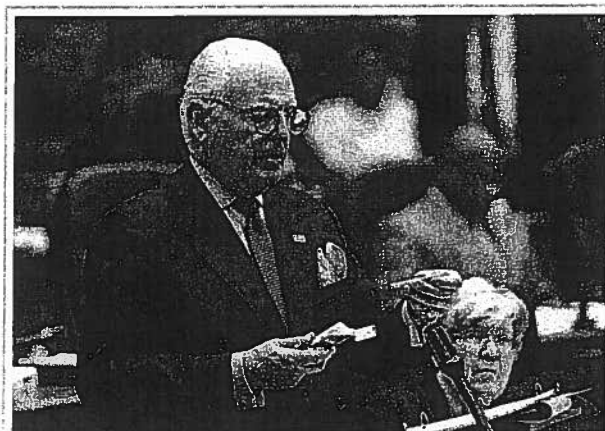
January 15, 2014 | By John Byrne | Clout Street

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E-cigarettes will join regular smokes and other tobacco products as forbidden in most indoor public places in Chicago after aldermen today passed a measure backed by Mayor Rahm Emanuel to restrict where electronic cigarettes can be used and how they can be sold.

The ordinance, which passed 45-4 after opponents took one last chance to voice their displeasure, will prohibit people from using e-cigarettes in restaurants, bars and most other indoor public places in the city. The measure also will require retailers to sell e-cigarettes from behind the counter so it's harder for minors to get their hands on them.



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Emanuel has made tobacco regulations a recent focus, working to frame the discussion over cigarette sales as a question of how willing elected officials are to protect children from getting lured into addiction at a young age.

At the last City Council meeting, aldermen voted to restrict sales of menthol cigarettes near Chicago schools. Emanuel delivered a short speech from the dais positioning himself as a bulwark against the evils of Big Tobacco. Emanuel also increased the city's cigarette tax as part of his 2014 budget.

On Wednesday, the mayor used the passage of the e-cigarette regulations as a chance to again lay out his anti-tobacco bona fides, saying Chicago can't wait for the Food and Drug Administration to take a position on the safety of the products.

"Having worked with the FDA, having encouraged them to take steps to protect individuals and children, they are usually an agency that leads from behind," Emanuel said. "And when it comes to the city of Chicago, when it comes to the people of the city of Chicago, when it comes to the children of the city of Chicago, I do not believe we should wait."

But Ald. Brendan Reilly, 42nd, a smoker, continued to oppose the indoor ban on e-cigarettes. Reilly, who said he's using e-cigarettes to help himself quit, likened e-cigarettes to needle exchanges for heroin addicts and said they help reduce the harm smokers suffer by offering a product safer than conventional smokes. "We're talking about treating two different products like they're one, like they're combustible cigarettes," Reilly said.

And Ald. Rey Colon, 35th, said he resents how people who oppose greater restrictions on e-smoking have been accused of not having children's best interests at heart. "I hate to keep using, I keep thinking of that movie 'My Cousin Vinny' – 'the youths, the youths.' We keep using the children as an excuse to pass any ordinance we want to pass, because who can deny the children?" Colon said.

In other action: Aldermen approved \$13.8 million in lawsuit settlements. Nanny Jennifer Anton was pushing a stroller carrying a 20-month-old girl and shoved the child out of harm's way before drunken city worker Dwight Washington crashed his city pickup truck into a crowd on a Gold Coast sidewalk. Anton will receive \$7.4 million for severe injuries she suffered in the May 2011 incident. Separately, Larry Gillard will get nearly \$6.4 million for a wrongful conviction in a 1981 rape case.

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E-cigarettes: Healthy tool or gateway device?

By Jen Christensen, CNN

updated 12:46 PM EST, Thu February 6, 2014

CNN.com

E-cigarettes: Healthy tool or gateway device?

Are e-cigarettes bad for your health?

(CNN) -- If the tiny sample of smokers in a new study in the British journal *Lancet* are any indication, electronic cigarettes might be slightly more effective than nicotine patches in helping people quit smoking.

Great, right? Except another new study from the Centers for Disease Control and Prevention suggests more children and teens are trying them.

The implications of both these studies means electronic cigarettes have been getting a lot of attention lately. Just what e-cigarettes are and what role they should play in helping people quit smoking depends very much on who you speak with about this topic.

Smoking is still the leading cause of avoidable death in the United States. The devices are not one of the FDA-approved methods to help people quit, but many people are using them this way. A growing number of scientists are studying them to see whether they may be a way to end an epidemic.



New cigarette trend 'smokeless'



E-cigarette sales on the rise

The topic,

though, remains as polarizing a health issue as sex education or diet sodas.

An e-what?

The e-cigarette was actually developed by a pharmacist in China.

The pharmacist, Hon Lik, was a three-pack-a-day smoker. That was nothing unusual -- more than 300 million people in China are regular smokers. But when Lik's father, who was also a heavy smoker, died of lung cancer, Lik decided he had to come up with an alternative that wouldn't kill him.

Most scientists believe nicotine itself, while highly addictive, is not what causes cancer for smokers or for the people around them who breathe their second-hand smoke. Instead, it's the toxic chemicals that are created when tobacco and filler products burn that are

dangerous.

If there was a way to get nicotine addicts their fix without the burn, you just might avoid the health problems. Nicotine then becomes as harmless as any other addictive substance, such as caffeine, some experts say.

So Lik developed an e-cigarette -- a device that uses a small battery to atomize a pure liquid solution of nicotine. Nothing is burned. There is no ash. There is no smoke. There is nicotine, and then there is flavoring added for taste.

Essentially the person using these inhales a kind of vapor that looks like fog from a fog machine. A recent review of all the scientific research done on e-cigarettes by Drexel University professor Igor Burstyn concludes "current data do not indicate that exposures to vapors from contaminants in electronic cigarettes warrant a concern."

In plain language, Burstyn concludes: "It's about as harmless as you can get."

"I wouldn't worry at all if someone was smoking one of these by my kids," Burstyn said. "From a pure health perspective, these are not as bad as a cigarette."

E-cigarettes came to the U.S. market around 2009. The CDC now estimates about one in five American smokers have tried an e-cigarette -- that's about 6% of all adults.

There are e-cigarette stores, but now you can also buy them online or in convenience stores. Some look like regular cigarettes; some look like pens or thumb drives.

First you buy a starter kit, which costs between \$40 and \$130. In the kit is the e-cigarette, a charger and a few cartridges. The cartridges typically last as long as a 20-pack of cigarettes and sell for around \$10. You can also buy a bottle of e-liquid to refill the cartridge yourself.

The anti-e-cigarette camp

Critics point out e-cigarettes come in kid-friendly flavors such as gummy bear, atomic fireball candy and cookies and cream. It makes them worry that e-cigarettes will become a gateway to encourage kids to develop a lifelong nicotine addiction -- or worse, try the real thing.

Only about 20 states specifically forbid the sale of e-cigarettes to children.

Tobacco use has been on the decline with kids; it's about half what it was in the mid-1990s. But the latest CDC study shows a growing number of middle and high school students have tried e-cigarettes.

One in 10 high school students surveyed said they had tried e-cigarettes last year. That's double the number from 2011. One high school in Connecticut banned them after the principal said administrators dealt with at least one incident involving e-cigarettes every day.

CDC director Tom Frieden characterized this trend as "deeply troubling."

But as far as risky behavior goes, it's still a tiny fraction of students. The survey showed about 3% of these kids said they had used one in the last 30 days. By contrast, 39% of students said they drank some amount of alcohol in the past 30 days, 22% binge drank and 24% rode with a driver who had been drinking.

The real problem is that 88% of adult smokers who smoke daily said they started when they were kids, according to the CDC. Kids who start down the path to using e-cigarettes may stick with them for life.

"So much is unknown about them and what the long-term complications could be with their use," said the American Lung Association's Erika Sward. "Bottom line, we don't know what the consequences of using them are, and we are very troubled that kids would find them attractive."

E-cigarettes are unregulated in the United States; no laws make manufacturers tell you what you are actually inhaling. The unknown is one of the many qualities of e-cigarettes that the American Lung Association doesn't like.

It's "a complete unregulated Wild West," Sward said. She wants the FDA to move quickly with regulatory oversight, which she says would make manufacturers disclose what the actual ingredients are in each of the 250 or so brands available.

In 2009, a FDA test on a small number of e-cigarette samples found "detectable levels of known carcinogens and toxic chemicals to which users could potentially be exposed." They found diethylene glycol in one cartridge at a 1% level; this is an ingredient used in antifreeze and can be toxic to humans in large quantities. Diethylene glycol is also found in some dental products and in some pharmaceuticals.

After that study, the FDA banned the sale of e-cigarettes. They warned e-cigarette smokers that they were inhaling "toxic" and "harmful" chemicals. However, in 2010, a court ruled that "the FDA had cited no evidence to show that electronic cigarettes harmed anyone," and stores could go on selling them.

The early e-adopters

On the other side of the debate are the passionate supporters of e-cigarettes. Many who use them say it is the first thing that has helped them stop using cigarettes -- something more than 90% of smokers fail to do with any of the existing FDA-approved methods. There are blogs and message boards dedicated to them. And there are countless impassioned testimonials from the people who use them.

Florida resident Craig Lashley says they've changed his life.

"I got tired of being like that little kid in 'Peanuts' who had the cloud of smoke following him all the time," Lashley said. "I didn't like the way I smelled when I smoked, and I didn't like what smoking said about me, especially to kids."

He discovered the e-cigarette about a year ago and hasn't smoked a regular cigarette since.

He says he smells better, feels better and spends a lot less -- about \$10 a week on e-cigarettes. He used to spend about \$45 a week on regular cigarettes.

"I like the feel of blowing smoke," Lashley said. "It seems to me like (e-cigarettes are) a healthier alternative."

A growing number of respected physicians and scientists agree, and they say these products could end a major health problem.

"Electronic cigarettes and other nicotine-containing devices offer massive potential to improve public health, by providing smokers with a much safer alternative to tobacco," the Royal College of Physicians says. "They need to be widely available and affordable to smokers."

The latest study, published in the British journal the Lancet, examined whether people who used them as an alternative to smoking would abstain from using regular cigarettes.

The New Zealand authors studied the behavior of 657 people who were trying to quit. One group got nicotine patches, another got nicotine e-cigarettes and others got placebo e-cigarettes without the nicotine.

Over a period of six months, only a tiny fraction of the people in the study actually quit smoking.

People using the nicotine e-cigarettes quit at a slightly better rate compared with those using the patch, though. Some 7.3% using the e-cigarettes abstained from smoking traditional cigarettes compared with the 5.8% who stopped with the patch. About 4.1% stopped with just the placebo e-cigarettes.

It was such a small number of people who quit that the authors concluded "more research is urgently needed to clearly establish their overall benefits and harms at both individual and population levels."

Dr. Michael Siegel, a physician who has spent the past couple decades working on tobacco control initiatives, has been surprised by the negative reaction to e-cigarettes from so many people in the public health sector. Siegel says the studies he's done have shown e-cigarettes are a help.

"True we don't know the long-term health effect of e-cigarettes, but there's a very good likelihood that smokers are going to get lung cancer if they don't quit smoking," he said. "If they can switch to these and quit smoking traditional cigarettes, why condemn them?"

Siegel theorizes the e-cigarettes might look too much like smoking.

"It's ironic the very thing that makes them so effective ... drives the anti-smoking groups crazy. But what makes them so effective is it mimics the physical behaviors smokers have, which is something the patch can't do."

Siegel does believe there is an urgent need for more regulations.

Ray Story, founder of the Tobacco Vapor Electronic Cigarette Association, agrees. He says his association has also pushed for age verification legislation.

"When you have these companies trying to promote these as something they are not, and you have stores that sell them in the candy aisle, you are going to have a problem," Story said. "If they are officially categorized as a tobacco product, you get an automatic age verification put in place.

"Nicotine is addictive, and we want the federal government to create guidelines and a structure that will confine these to being sold as adult products."

Lashley says no matter what the debate, he will continue to spread the e-cigarette gospel to his fellow adults.

So far, his co-workers have been receptive to the idea. He used to be the only one with an e-cigarette on smoke breaks. Now he says he's got more than a dozen colleagues doing the same.

One colleague, though, complained about it.

"He said 'I'm sick of all these people smoking electronic cigarettes,'" Lashley said. "When I asked him why he said. 'Simple, now I can't bum any off of them.' "

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CORRECTION: This story was updated on March 26, 2014, to state that small amounts of cadmium, nickel, and lead have been detected not only in e-cigarette vapor but also in tobacco cigarette smoke.

Volume 92 Issue 10 | pp. 32-33
Issue Date: March 10, 2014

Controversy Clouds E-Cigarettes

Rising popularity of electronic cigarettes prompts debate over health impacts for users and the public

By Deirdre Lockwood

Department: Science & Technology | Collection: Life Sciences
News Channels: Biological SCENE
Keywords: health, smoking, electronic cigarettes, e-cigarettes, tobacco

(+)Enlarge



Credit: Newscom

On a recent afternoon in Seattle's University District, a steady stream of customers—mostly young men—filtered in and out of a small, recently opened shop called E Cig 'N Vape. It's one of a chain of six Washington state stores that sells supplies for smoking electronic cigarettes, or e-cigarettes. The battery-powered devices deliver an inhalable vapor, with or without nicotine, in a variety of flavors.

Pete Knutson, a 32-year-old University of Washington student who works at the shop, told a customer about some of the 60 flavors of e-liquid, or e-juice, the store offers. Key lime pie "tastes like key lime going out with a kind of a graham cracker crust," he said; black honey tobacco, one of the most popular flavors, is "nice and earthy. It's good for people who are transitioning from smoking—they don't quite like fruit, but they don't want to taste tobacco."

In addition to flavoring agents, the e-liquids contain an aqueous solution of glycerol or propylene glycol, which turns into an opaque vapor when heated. E-liquids come in five different levels of nicotine, ranging from 0 mg to 24 mg in 1 mL of juice.

Similar to about 90% of the store's customers, Knutson smoked tobacco cigarettes for years before switching to smoking e-cigarettes—often called vaping—two years ago. Taking a drag from a reusable e-cigarette, he let out a cloud of a flavor called hypnotic. It smelled like cotton candy.

Nathan Pierce, a 19-year-old customer who attends North Seattle Community College, sat in a chair and puffed on his e-cigarette. Pierce had smoked tobacco occasionally, enjoying the nicotine buzz but not how it made him feel and smell afterward. So he bought a reusable e-cigarette a month and a half ago. "It's nice to be able to enjoy different flavors and choose how much nicotine I'm putting in my body," he said.

E-cigarette use is on the rise in the U.S., with projected sales of \$1.5 billion in 2014. Like Knutson, many start using the devices because they seem like a safer alternative to tobacco cigarettes, with the added draw that they can still be enjoyed in public in many places. Some also use them to aid in quitting smoking by reducing their nicotine intake.

This growth in use has also fueled a debate over the health risks of e-cigarettes. Some researchers project that a widespread switch to the devices by current smokers could reduce the number of smoking-related deaths. But they and others also worry about e-cigarettes' acute and secondhand health risks, as well as a lack of regulation of the devices. Additionally, some public health advocates say that e-cigarettes pose a risk of remystifying smoking, a habit that has been on the decline in the U.S. since the 1960s.

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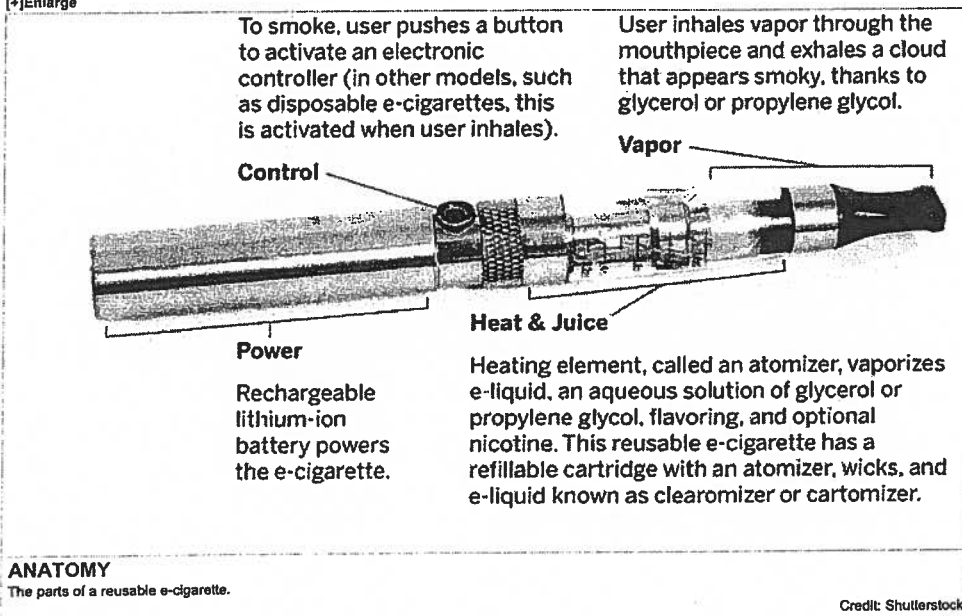
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Because of these concerns, several states and more than 100 counties and cities in the U.S., including New York City and Chicago, have banned the use of e-cigarettes in spaces where tobacco smoking is prohibited. Many other states prohibit their use in specific locales such as schools, workplaces, and corrections facilities. In 2011, the Food & Drug Administration announced its intention to regulate e-cigarettes as tobacco products; the agency's proposed plan is anticipated soon.

Compared with tobacco products, e-cigarettes are a safer option for smokers; they don't deliver many of the harmful by-products of tobacco combustion, says Maciej L. Goniewicz, a toxicologist at Roswell Park Cancer Institute, in Buffalo. Nicotine is addictive and can increase heart rate, but it poses lower risk than the carcinogenic compounds in tobacco smoke, he says. The glycerol and propylene glycol in e-liquid are generally recognized as safe by FDA.

"But there's no reason for experimenting with this product if you're not already smoking tobacco cigarettes," he adds. Little research has been done on e-cigarettes' acute health risks, and their danger, especially for long-term use, is unknown. As the devices are unregulated, the quality control of the more than 250 brands currently on the market is uncertain.

[*]Enlarge



To look inside, Goniewicz and colleagues recently enlisted a robotic smoking machine to take puffs of 12 different brands of e-cigarettes. Using chromatography and mass spectrometry, the team analyzed four types of potentially harmful compounds in the vapor (*Tob. Control* 2014, DOI: 10.1136/tobaccocontrol-2012-050859).

The researchers found small amounts of six toxic substances that are also found in tobacco cigarette smoke at 9 to 450 times as great a level as what is found in e-cigarette vapor. The substances include three carbonyl compounds: formaldehyde, a carcinogen, as well as acetaldehyde and acrolein. The team also found the volatile organic compound toluene and traces of two carcinogenic nitrosamines.

Additionally, they found small amounts of cadmium, nickel, and lead in the vapor—less than 1 µg per 150 puffs—that are also present in tobacco cigarette smoke. Another research team has also found metal particles in e-cigarette vapor (*PLoS One* 2013, DOI: 0.1371/journal.pone.0057987).

Inhaling particles containing metals and other compounds can trigger lung and throat inflammation. But predicting the risks for the average e-cigarette user is challenging, Goniewicz notes, because e-cigarette design variation and how deeply a user inhales affect exposure. According to Goniewicz, the larger, unanswered question is, "What will happen after many years of vaping? To see some of the long-term effects we just need time."

Bystanders are exposed to nicotine when others vape near them but not necessarily to other toxicants found in e-cigarette vapor, Goniewicz and other groups have found (*Nicotine Tob. Res.* 2013, DOI: 10.1093/ntr/ntt203). Nicotine from the vapor is also deposited on surfaces, according to data the group presented at last month's meeting of the Society for Research on Nicotine & Tobacco. Nicotine residue can react with other compounds in air to form carcinogenic nitrosamines. "Parents using e-cigarettes around small kids should be aware of these findings," Goniewicz says.

To address these risks, Stanton A. Glantz, a medical researcher at the University of California, San Francisco, thinks communities should integrate bans on e-cigarettes into clean indoor air legislation. He adds that smoke-free environments are a strong incentive to help people quit smoking.

Glantz is also troubled by evidence that minors are adopting e-cigarettes, potentially leading to nicotine addiction and tobacco use. The proportion of U.S. high school students who said they had tried e-cigarettes more than doubled from 2011 to 2012, a jump from 4.7% to 10%, according to a survey by the Centers for Disease Control & Prevention. About 76% of middle and high school students who said they used them in the past month had also used tobacco within the same period. So far, at least nine states

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have outlawed the sale of the devices to minors.

Both Glantz and Goniewicz say FDA should adopt quality-control standards for e-cigarettes to protect consumers. Glantz also thinks the agency should crack down on claims by e-cigarette companies that the devices help users quit smoking because this has not been conclusively demonstrated. FDA-approved nicotine replacement therapies, including patches, gum, and inhalers, are options with proven track records.

Back at E Cig 'N Vape, Pierce said he tries to keep up on new information about the health risks of e-cigarettes. Knutson thinks switching to them has been better for both his health and his budget. "Two years ago, I wouldn't have been able to walk up the hill over there," he said, pointing out into the rain. "Now I can jog up it."

"We see some potential for smokers and some dangers, including experimentation among kids," Goniewicz notes. "FDA must look at the whole public health impact of the product."

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Comments

yeh (March 11, 2014 2:24 PM)

You should take a look at the National Cancer Institute's recent paper saying that second-hand smoke concerns have no scientific foundations....

» Reply

yeah.... (March 24, 2014 10:43 AM)

You mean the article in which they state that there is no safe exposure level for second hand smoke, and that it contains harmful chemicals that cause cancer?

<http://www.cancer.gov/cancertopics/factsheet/Tobacco/ETS>

» Reply

C. Douglas (March 24, 2014 11:36 PM)

That statement couldn't be more ludicrous. The National Cancer Institute agrees 100% with the U.S. Surgeon General that secondhand smoke is the fourth leading cause of death in the U.S., responsible for about 42,000 deaths annually.

» Reply

Diane Jarzebinski (March 11, 2014 8:32 PM)

I think that they are better then cigs I have used my e CIG over six months now and like them I think they should not allow minors use them at all I think that part needs regulated a;

» Reply

www.UpstateVapesSC.com (March 12, 2014 8:59 AM)

I run www.UpstateVapesSC.com and I believe that using electronic cigarettes will save millions of lives. Numerous studies show that the e-liquid based vape is hundreds of times healthier then smoking.

» Reply

happy e-vapor (August 29, 2014 10:10 AM)

I was a smoker for over 40 years and made a conscious decision on May 22, 2014 to try the "vape"

I have not smoked not even 1 cigarette since. I don't cough, choke, wheeze, feel exhausted all the time... Everything in life has consequences, risks, hazards, side effects...

E-cigs, vaping, are in my humble opinion the best alternative. I am still courteous with my vaping like I was with my smoking.. No smoking inside, no smoking around others or in public places within 50 feet of an entrance.

There will always be someone somewhere to say that something is "bad" "Unhealthy" "harmful" etc... give it a rest people, E-cigs are no more harmful than waking up, getting out of bed and stepping outside to inhale our ever so lovely polluted air every morning. So long as everyone acts responsibly, which as adults we should regardless, then you should silence yourselves.

As for the minors.. we all know, we were ALL minors, where there is a will there is a way and all the outcry and uprising over controlling this and that.. some are still going to find a way. I don't condone, nor do I approve of underage consumption be it nicotine or alcohol... but it is going to happen and those who have their heads in the sand are more irresponsible than the minors who are "testing the waters"

Stepping off the soap box now

» Reply

Justthefacts (March 12, 2014 11:49 AM)

One of the biggest problems that plagues the e cig industry is a lack of internal regulation and quality control. There are plenty of

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THE SACRAMENTO BEE 4 DAYS AGO

E-cigarettes face restrictions as cities update smoking ordinances

Electronic cigarettes, touted as a smokeless alternative to regular cigarettes, are coming under increased scrutiny as cities and counties consider applying the same restrictions to e-cigarettes as to their tobacco counterparts.

At a workshop last week, the Rancho Cordova City Council was unanimous in directing staff members to treat e-cigarettes like regular cigarettes as they draft amendments to city code sections governing smoking.

Kelly Stachowicz, Davis' deputy city manager, said she was preparing a staff report on the same topic scheduled for City Council discussion Tuesday, although no action will be taken at that meeting.

"Our no-smoking ordinance has been in effect for a long while, but technology has surpassed the ordinance," she said. "We're trying to see if we need to catch up or amend the ordinance."

Electronic cigarettes typically use battery-powered heat to vaporize a liquid solution held in the mouthpiece of the device. Under state law, it is illegal to sell or give e-cigarettes to minors, but the law does not extend other smoking prohibitions to the devices.

Although some studies have indicated that e-cigarettes can be effective in helping people quit smoking or reduce their tobacco use, the U.S. Food and Drug Administration has not declared them an effective cessation product, said Lindsey Freitas, policy manager for the American Lung Association in California. E-cigarettes are not regulated by the FDA.

The American Lung Association in California advocates treating e-cigarettes as tobacco products. "We're really concerned that we just don't know what is in them," Freitas said.

The Los Angeles City Council voted last week to restrict e-cigarette use where tobacco smoking is restricted, including restaurants, parks, bars, nightclubs, beaches and workplaces. Similar measures have been approved in a number of Bay Area cities, including San Francisco, Hayward, Walnut Creek and Union City.

Representatives of the cities of Roseville and Folsom said e-cigarettes are on their radar, as well, though no decisions have been made.

"Our city attorney tells me that he's just started looking at our existing smoking ordinance, adopted in 1994, and considering incorporating e-cigarette restrictions," said Sue Ryan, spokeswoman for the city of Folsom. She said the City Council likely will take up the matter within the next couple of months.

Regulation of e-cigarettes also was mentioned during a February meeting of Sacramento's Law and Legislation Committee in discussing a possible smoking ban in outdoor dining areas, said city spokeswoman Amy Williams. "However, no direction was given, and we don't foresee it coming forward anytime soon," she said.

Because they don't burn, e-cigarettes have been promoted as having fewer secondhand effects, but studies have shown that the vapor contains carcinogens and toxic chemicals, as well as nicotine, an element of tobacco that is highly addictive, said Rancho Cordova City Attorney Adam Lindgren. When the smoker exhales those vapors, they affect people around them, he said, likening the vapors to secondhand smoke.

Rancho Cordova Councilman David Sander said that although there is some evidence that e-cigarettes may help people quit smoking, there also is evidence that they may entice kids to start smoking.

Freitas, of the American Lung Association, said many civic leaders have expressed particular concern that e-cigarettes that come in flavors like Cap'n Crunch and Gummy Bears are an enticement to youths.

Kate Cook, an attorney who researched e-cigarettes for the Rancho Cordova City Council, said most e-cigarettes come from China, and they are not all the same. Some might contain more carcinogens than others, and metal pieces have been found in some.

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The comments I received (from chamber members) is that it has become culturally unacceptable to smoke

From a regulatory perspective, Lindgren said, restricting their use could be supported for public health and welfare reasons.

SOURCE: The Sacramento Bee
4 DAYS AGO

Attal Sadiq, owner of Gaga Smoke Shop in Rancho Cordova, said he attended the council workshop primarily to gather information.

"Sixty-five percent of what we sell doesn't have nicotine," he told the council. Of the customers buying e-cigarettes that do contain nicotine, he said, about 95 percent are doing so to quit smoking.

Diann Rogers, president and CEO of the Rancho Cordova Chamber of Commerce, said she found most businesses in the city were doing a "stellar job of self-regulating." Most, she said, are treating e-cigarettes as regular cigarettes.

"The comments I received (from chamber members) is that it has become culturally unacceptable to smoke," Rogers said. "The gist is, they would like to treat e-cigarettes the same as tobacco."

The public will have plenty of opportunity to weigh in on any proposed changes in Rancho Cordova's smoking ordinance. Once completed, the proposed ordinance will be the subject of two hearings before the City Council, Lindgren said.

Freitas said more than 45 communities in California have included e-cigarette regulations in their smoking ordinances. Fifty-nine include e-cigarettes in their tobacco retailer license programs, meaning those who want to sell e-cigarettes must obtain a license. Also, 55 jurisdictions have included e-cigarettes in smoking provisions that apply to housing complexes, she said.

But Freitas said federal action is needed to determine the safety of e-cigarettes. "We just want to reiterate that it is really important for the FDA to assert its authority over e-cigarettes," she said, "so we can get some clarity of what is actually in them."

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Barry Smith, Electric Cigarette Lounge owner, calls e-cigarettes "miraculous," saying they help smokers get their nicotine fix without the fatal side effects of cigarettes.

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E-cigarettes face restrictions as cities update smoking ordinances

By Cathy Locke

clocke@sacbee.com

Published: Monday, Mar. 10, 2014 - 10:07 pm

Last Modified: Thursday, Mar. 13, 2014 - 9:24 am

The electronic cigarettes flooding the U.S. market don't technically emit smoke, but many cities have decided they're not much different from ordinary cigarettes.

Last week, Rancho Cordova became the latest local government to pursue restrictions on e-cigarettes; the City Council directed staff members to treat them like regular smokes when they draft amendments to city code sections governing smoking. The Los Angeles City Council also voted last week to restrict e-cigarette use where tobacco smoking is restricted, including restaurants, parks, bars, nightclubs, beaches and workplaces. Similar measures have been approved in a number of Bay Area cities, along with New York and Chicago.

The Davis City Council is scheduled to discuss e-cigarettes tonight.

Representatives of the cities of Roseville and Folsom said e-cigarettes are on their radar, too, though no decisions have been made.

"Our city attorney tells me that he's just started looking at our existing smoking ordinance, adopted in 1994, and considering incorporating e-cigarette restrictions," said Sue Ryan, spokeswoman for the city of Folsom. She said the City Council likely will take up the matter within the next couple of months.

Sales of e-cigarettes have skyrocketed in recent years. Big tobacco companies have been getting into the business, and ads for e-cigarettes are now appearing on television, a space where traditional smokes have been banned for more than 40 years. The fast evolution of the market has left governments racing to keep pace.

"Our no-smoking ordinance has been in effect for a long while, but technology has surpassed the ordinance," said Kelly Stachowicz, Davis' deputy city manager. "We're trying to see if we need to patch up or amend the ordinance."

On a federal level, the U.S. Food and Drug Administration is expected to propose regulations

governing the e-cigarette industry. The European Parliament took action last month, adopting measures to ban e-cigarette advertising and require health warnings.

Electronic cigarettes typically use battery-powered heat to vaporize a liquid solution containing nicotine that is held in the mouthpiece of the device. Under state law, it is illegal to sell or give e-cigarettes to minors, but the law does not extend other smoking prohibitions to the devices.

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Kate Cook, an attorney who researched e-cigarettes for the Rancho Cordova City Council, said most e-cigarettes come from China and that they are not all the same. Some might contain more carcinogens than others, and metal pieces have been found in some.

From a regulatory perspective, Lindgren said, restricting their use could be supported for public health and welfare reasons.

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"The comments I received (from chamber members) is that it has become culturally unacceptable to smoke," Rogers said. "The gist is, they would like to treat e-cigarettes the same as tobacco."

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Regulation of e-cigarettes also was mentioned during a February meeting of the city of Sacramento's Law and Legislation Committee in discussing a possible smoking ban in outdoor dining areas, said city spokeswoman Amy Williams. "However, no direction was given, and we don't foresee it coming forward anytime soon," she said.

Freitas said federal action is needed to determine the safety of e-cigarettes. "We just want to reiterate that it is really important for the FDA to assert its authority over e-cigarettes," she said, "so we can get some clarity of what is actually in them."

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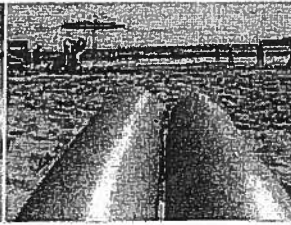
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[Subscribe](#) [RSS](#)**Chris Hickman**

204 days ago

I thought smoking ordinances were concerned with tobacco products and well, you know, SMOKE.

E-cigarettes contain nor produce either. There is no science whatsoever behind these nanny laws. But don't let logic get in the way of legislation. This is California after all.

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**bri james**

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I'm not a smoker, never have been, but there is no smoke from these, and I know people using them at this time, trying to quit smoking. I was standing near someone today using one, and there was no smoke, and no smell I see nothing wrong with them.

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**Bruce Miller**

204 days ago

I think it has more to do with control and the belief someone is getting around the rules.

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BUSINESS DAY

Selling a Poison by the Barrel: Liquid Nicotine for E-Cigarettes

By MATT RICHTEL MARCH 23, 2014

A dangerous new form of a powerful stimulant is hitting markets nationwide, for sale by the vial, the gallon and even the barrel.

The drug is nicotine, in its potent, liquid form — extracted from tobacco and tintured with a cocktail of flavorings, colorings and assorted chemicals to feed the fast-growing electronic cigarette industry.

These “e-liquids,” the key ingredients in e-cigarettes, are powerful neurotoxins. Tiny amounts, whether ingested or absorbed through the skin, can cause vomiting and seizures and even be lethal. A teaspoon of even highly diluted e-liquid can kill a small child.

But, like e-cigarettes, e-liquids are not regulated by federal authorities. They are mixed on factory floors and in the back rooms of shops, and sold legally in stores and online in small bottles that are kept casually around the house for regular refilling of e-cigarettes.

Evidence of the potential dangers is already emerging. Toxicologists warn that e-liquids pose a significant risk to public health, particularly to children, who may be drawn to their bright colors and fragrant flavorings like cherry, chocolate and bubble gum.

“It’s not a matter of if a child will be seriously poisoned or killed,” said Lee Cantrell, director of the San Diego division of the California Poison Control System and a professor of pharmacy at the University of California, San Francisco. “It’s a matter of when.”

Reports of accidental poisonings, notably among children, are soaring. Since 2011, there appears to have been one death in the United States, a suicide by an adult who injected nicotine. But less serious cases have led to a surge in calls to poison control centers. Nationwide, the number of cases linked to e-liquids jumped to 1,351 in 2013, a 300 percent increase from 2012, and the number is on pace to double this year, according to information from the National Poison Data System. Of the cases in 2013, 365 were referred to hospitals, triple the previous year's number.

Examples come from across the country. Last month, a 2-year-old girl in Oklahoma City drank a small bottle of a parent's nicotine liquid, started vomiting and was rushed to an emergency room.

That case and age group is considered typical. Of the 74 e-cigarette and nicotine poisoning cases called into Minnesota poison control in 2013, 29 involved children age 2 and under. In Oklahoma, all but two of the 25 cases in the first two months of this year involved children age 4 and under.

In terms of the immediate poison risk, e-liquids are far more dangerous than tobacco, because the liquid is absorbed more quickly, even in diluted concentrations.

"This is one of the most potent naturally occurring toxins we have," Mr. Cantrell said of nicotine. But e-liquids are now available almost everywhere. "It is sold all over the place. It is ubiquitous in society."

The surge in poisonings reflects not only the growth of e-cigarettes but also a shift in technology. Initially, many e-cigarettes were disposable devices that looked like conventional cigarettes. Increasingly, however, they are larger, reusable gadgets that can be refilled with liquid, generally a combination of nicotine, flavorings and solvents. In Kentucky, where about 40 percent of cases involved adults, one woman was admitted to the hospital with cardiac problems after her e-cigarette broke in her bed, spilling the e-liquid, which was then absorbed through her skin.

The problems with adults, like those with children, owe to carelessness and lack of understanding of the risks. In the cases of exposure in children, "a lot of parents didn't realize it was toxic until the kid started vomiting," said Ashley Webb, director of the Kentucky Regional Poison Control Center at Kosair Children's Hospital.

The increased use of liquid nicotine has, in effect, created a new kind of recreational drug category, and a controversial one. For advocates of e-cigarettes, liquid nicotine represents the fuel of a technology that might prompt people to quit smoking, and there is anecdotal evidence that is happening. But there are no long-term studies about whether e-cigarettes will be better than nicotine gum or patches at helping people quit. Nor are there studies about the long-term effects of inhaling vaporized nicotine.

Unlike nicotine gums and patches, e-cigarettes and their ingredients are not regulated. The Food and Drug Administration has said it plans to regulate e-cigarettes but has not disclosed how it will approach the issue. Many e-cigarette companies hope there will be limited regulation.

"It's the wild, wild west right now," said Chip Paul, chief executive officer of Palm Beach Vapors, a company based in Tulsa, Okla., that operates 13 e-cigarette franchises nationwide and plans to open 50 more this year. "Everybody fears F.D.A. regulation, but honestly, we kind of welcome some kind of rules and regulations around this liquid."

Mr. Paul estimated that this year in the United States there will be sales of one million to two million liters of liquid used to refill e-cigarettes, and it is widely available on the Internet. Liquid Nicotine Wholesalers, based in Peoria, Ariz., charges \$110 for a liter with 10 percent nicotine concentration. The company says on its website that it also offers a 55 gallon size. Vaporworld.biz sells a gallon at 10 percent concentrations for \$195.

Mr. Paul said he was worried that some manufacturers outside the United States — China is a major center of e-cigarette production — were not always delivering the concentrations and purity of nicotine they promise. Some retailers, Mr. Paul said, "are selling liquid and they don't have a clue what is in it."

Cynthia Cabrera, executive director of Smoke Free Alternatives Trade Association, said she would also favor regulations, including those that would include childproof bottles and warning labels, and also manufacturing standards. But she said many companies already were doing that voluntarily, and that parents also needed to take some responsibility.

"You wouldn't leave a bottle of Ajax out," she said. Advocates of e-cigarettes sometimes draw comparisons between nicotine and caffeine, characterizing both

as recreational stimulants that carry few risks. But that argument is not established by science, and many health advocates take issue with the comparison.

"There's no risk to a barista no matter how much caffeine they spill on themselves," said Dr. Neal L. Benowitz, a professor at the University of California, San Francisco, who specializes in nicotine research. "Nicotine is different."

Without proper precautions, like wearing gloves while mixing e-liquids, these products "represents a serious workplace hazard," he said.

The nicotine levels in e-liquids varies. Most range between 1.8 percent and 2.4 percent, concentrations that can cause sickness, but rarely death, in children. But higher concentrations, like 10 percent or even 7.2 percent, are widely available on the Internet. A lethal dose at such levels would take "less than a tablespoon," according to Dr. Cantrell, from the poison control system in California. "Not just a kid. One tablespoon could kill an adult," he said.

A version of this article appears in print on March 24, 2014, on page A1 of the New York edition with the headline: Selling a Poison by the Barrel: Liquid Nicotine for E-Cigarettes.

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ORANGE COUNTY REGISTER

PRICE: \$1 • TUESDAY, MARCH 25, 2014 • OCREGISTER.COM

E-cigarette industry fumes over news report

New York Times notes rise
in poisonings from
ingesting liquid nicotine.

Vinh Nguyen gives his customers at Vapor Bombz every warning there is about electronic cigarettes and the liquid nicotine that fuels them.



**LANDON
HALL**
STAFF
WRITER

Show me ID. Mind the labels and the dosage. Got kids? Try a resistant cap, or the vial in shrink-wrapped plastic. Keep vials out of reach, out of sight. But once money changes hands and customers leave his shop, however, it's up to them to be responsible with what is, after all, a toxic product.

"We tell them this stuff is poisonous," says Nguyen, 30, who co-owns the shop with his brother, Steve. "We do everything we can to protect the consumer, but at the end of the day, you leave a loaded gun on the floor, and your child gets hold of it, it's not going to be the gunmaker's responsibility."

SEE NICOTINE • PAGE 11

NICOTINE

FROM PAGE 1

ity."

The vaping industry, which has grown quickly in Southern California in the past few years, went into a defensive crouch Monday, defending itself against a New York Times article that highlighted a trend of rising calls to poison-control centers linked to e-liquids, the term used for the substance that's combusted inside e-cigarettes. Across the nation, the number of such calls rose three-fold from 2012 to 2013, to 1,351.

Many have been sickened, but the only recent death, the article says, appears to have come in 2011, when a man injected himself with nicotine.

E-cigarettes and liquid, also called "juice," have been hailed by proponents as a way for addicted smokers to get their nicotine fix without sucking in the thousands of carcinogens found in traditional cigarettes.

The liquid normally is a mixture of water, flavoring and propylene glycol, a compound that allows the juice to atomize at a relatively low temperature. When it burns, it delivers a hit of nicotine through a mouthpiece. If a user fills up a 4.5-milliliter tank with juice that's 1.8 percent nicotine, and makes it last all day, he'll inhale roughly 80 milligrams of nicotine, or the same amount that's in about 10 cigarettes.

In its purest form, nico-

tine, which is extracted from the tobacco plant, can be toxic to the touch. But the product juice-makers buy, often in jugs or barrels, already is diluted to about 10 percent. If enough gets absorbed through the skin, from a broken vial, for instance, it could make a person nauseated.

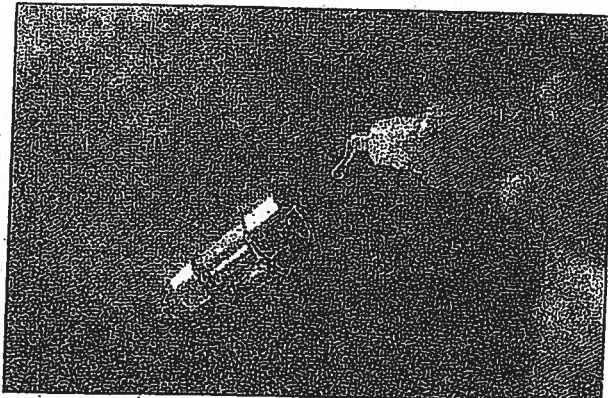
The real danger, though - and the thrust of the New York Times story - is the possibility that children could happen upon a vial of juice and ingest it.

"These fluids come in flavors that are attractive for kids," said Dr. Helene Calvet, deputy county health officer for Orange County's Health Care Agency. "If a kid gets hold of this and sucks down even a small amount, it could be pretty dangerous."

Nicotine would be potentially fatal for an adult who ingests 0.5 to 1.0 milligrams per kilogram of body weight. But for children, that threshold could be as low as 0.1 mg per kilo, says Dr. Chesda Eng, a smoking-cessation specialist with St. Joseph Heritage Medical Group in Garden Grove. If a child ingests "maybe a teaspoon, that can be lethal."

Some e-cig proponents took serious issue with The Times' reporting: nicotine levels in most juicers "range between 1.8 percent (18 mg per ml) and 2.4 percent, concentrations that can cause sickness, but rarely death, in children. But higher concentrations, like 10 percent or even 7.2 percent, are widely available on the Internet."

Vapor Bombz and many other stores carry vials with concentrations to 1.8



CINDY YAMANAKA, STAFF PHOTOGRAPHER

E-liquid for an electronic cigarette is dripped in a pro tank at Vapor Bombz in Anaheim.

LOCAL LAWS

Cities: Seal Beach was the first local city to regulate e-cigarettes and restricts smoke shops to commercial zones and prohibits smoking lounges. Aliso Viejo and Laguna Niguel city councils are drafting regulations on e-cigarette use. Aliso Viejo is looking at prohibiting e-cigarette use near schools, churches and parks. Buena Park banned smoking, including e-cigarettes in recreational areas.

School districts: All Orange County school districts have tobacco-free policies, though not all mention e-cigarettes. Some districts, such as Huntington Beach City, Orange and Capistrano changed policies to include e-cigarettes.

Colleges: The University of California prohibits use of all nicotine products indoors and outdoors at all campuses. Also: Los Angeles, Long Beach, Lakewood and Seal Beach regulate e-cigarette sales.

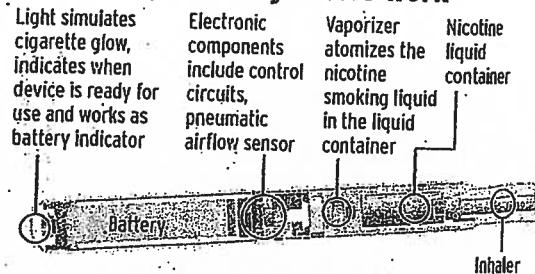
- ELYSSE JAMES, staff writer

percent, but no higher. "We feel that it is unnecessary to be that high in the first place," said Nguyen, who is a co-partner of an Anaheim juice-maker, Epic Juice. A vial that's 2.4 percent would mostly be used by a long-term smoker trying to

maintain his fix until he can reduce the dosage.

The Times noted that Minnesota's poison-control center received 74 calls in 2013 related to poisoning cases from e-cigs or nicotine. Of those, 29 were children 2 and under. But an e-

How e-cigarettes work



Nicotine levels compared

Electronic	Equivalent	Traditional
One e-cigarette	100 Puffs per cigarette	6-7 cigarettes
6-24 mg. E-cigarette with 24 mg of nicotine	Nicotine level Nicotine per puff 0.16 mg/puff	0.6-2.4 mg. Cigarette with 1.8 mg of nicotine 0.36 mg/puff

Sources: E-Cig, Winston-Salem Journal

McCLATCHY TRIBUNE

cigarette group, Consumer Advocates for Smoke-free Alternatives Association, noted that same center received 35 calls about nicotine-replacement therapy products.

"E-cigarettes have proven to be a way of quitting for lots and lots of people who tried every other way and failed at them, so that alone means that they are saving peoples' lives," said Carl V. Phillips, a tobacco researcher and the group's scientific director, based in Nashua, N.H. "A lot of them have the potential to quit smoking next week if they try it, and they won't if they're being convinced that they're just as bad as smoking, or if they're con-

vinced that it's a dire hazard to their children if they even have them around."

E-cigarette users, manufacturers and local governments forced to come up with patchwork solutions are all hoping the Food and Drug Administration will issue some kind of guidance on e-cigarettes and liquids soon. The FDA has the authority to regulate the devices and juices, along with other tobacco products, but the agency is waiting on the Office of Budget and Management to review the "deeming rule" before it acts.

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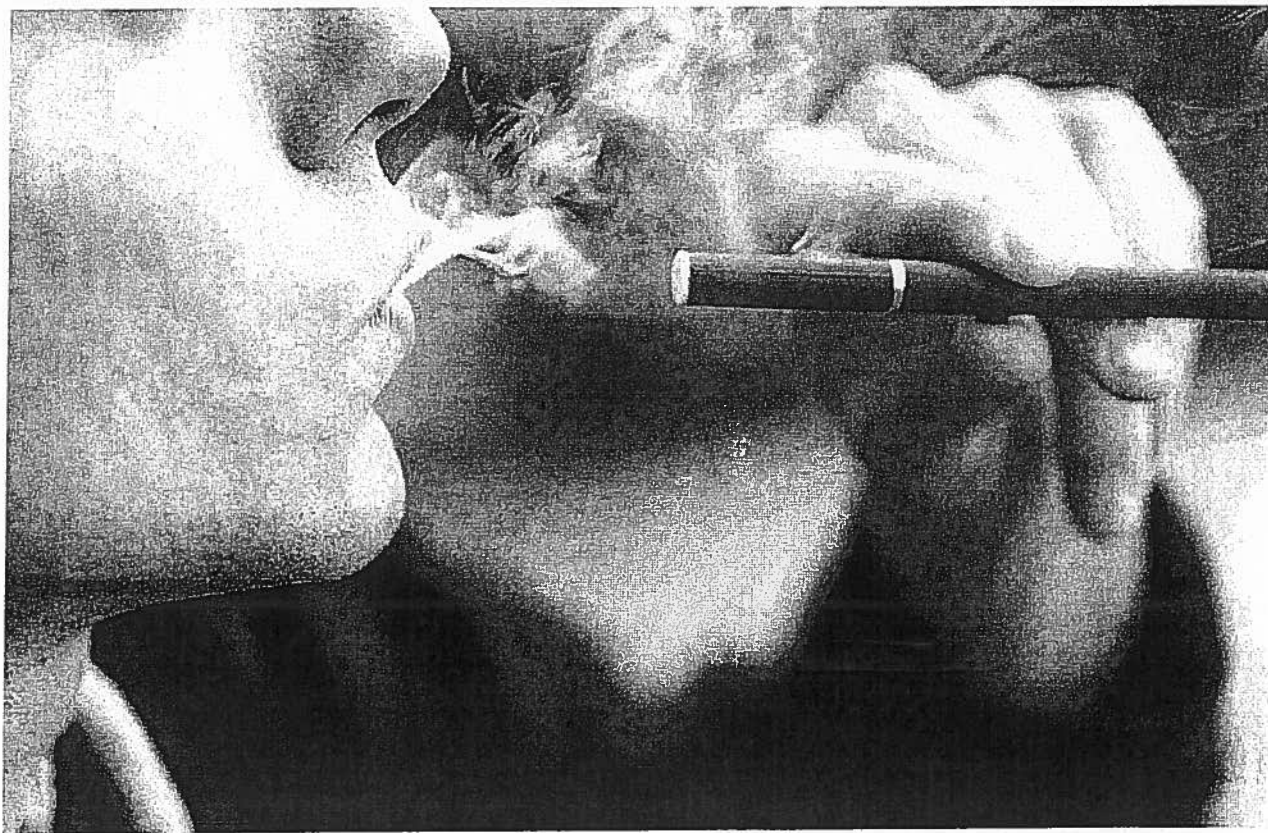
SPORTS

Patriots have Way

DAILY DOSE

Do e-cigarettes help smokers quit?

By Deborah Kotz | GLOBE STAFF MARCH 31, 2014



ISTOCK

Electronic cigarettes are certainly trendy — look no further than the Vapefest in the nation's capital last week — but whether inhaling nicotine vapors actually helps smokers quit traditional cigarettes remains a subject of fierce debate.

A new study is bound to add fuel to the fire. Researchers followed nearly 1,000 smokers for a year and found that those who used e-cigarettes were no more likely to quit smoking or reduce their dependence on tobacco cigarettes than those who weren't using the products at the beginning of the study. About 14 percent of those who didn't use e-cigarettes quit smoking compared to 10 percent of those used the products.

CONTINUE READING BELOW ▼

But the research, published last Monday in the journal JAMA Internal Medicine, raises more questions than it answers because only 88 of the 949 smokers in the study reported using e-cigarettes.

That small sample size makes it difficult to draw firm conclusions, admits study leader Dr. Pamela Ling, an associate professor of medicine at University of California, San Francisco. "We also looked at a broad population of smokers," she said, "not just those who were specifically interested in quitting."

In fact, only 8 percent of e-cigarette users reported that they were trying to quit when they were surveyed, and only 40 percent had any intention of quitting in the next six months.

"This means that we actually know for a fact that the majority of e-cigarette users in this study were not using these products as part of a quit attempt," Dr. Michael Siegel, a tobacco control researcher at Boston University School of Public Health, wrote in a post on his blog. "Rather, it is a deliberate attempt on the part of the investigators to misuse data."

Setting those fighting words aside, the study highlights the lack of evidence to determine whether e-cigarettes are a good smoking cessation aid — even though some smokers swear by them for helping them ease off their habit.

Only one clinical trial compared e-cigarettes with nicotine patches to help smokers quit, Ling said, and it found that both were about equally effective — or rather, equally ineffective since neither worked particularly well. Only 5 to 7 percent of the smokers in the study were able to completely stop lighting up regardless of which method they used.

“Although there are no data showing that e-cigarette use helps with cessation, there is potential harm,” wrote Dr. Mitchell Katz, the deputy editor of JAMA Internal Medicine in an editorial that accompanied the new study.

The products — which contain nicotine in liquid form mixed with flavorings, colorings, and various chemicals — remain unregulated, though the US Food and Drug Administration might move this year to put them under the same rules as other tobacco products. Even more concerning are recent modifications that have turned once disposable e-cigarettes into larger, reusable gadgets that users fill with highly potent liquid nicotine. Such handling can be very hazardous since liquid nicotine can be toxic if applied to the skin or ingested, according to an [article in The New York Times](#).

Last year, the American Association of Poison Control Centers received 1,414 calls regarding accidental exposures and poisoning linked to liquid nicotine or e-cigarette devices — a 300 percent increase from 2012. Poison control centers have already received 651 calls through March 24 of this year and urged parents last week to keep the devices and liquid nicotine away from children. Whether vaping poses health risks remains unknown, though that hasn’t stopped e-cigarette makers from proclaiming that the product provides the “freedom to have a cigarette without the guilt,” as actress Jenny McCarthy states on the [blu eCigs website](#).

In a study published earlier this month, Ling and her colleagues reviewed 59 websites selling e-cigarette products and found that 95 percent of them made health-related claims: more than half claimed the product helped with smoking cessation, and three-quarters claimed the product does not produce secondhand smoke. (It does, though, produce vapor that others can inhale and which may pose health risks to bystanders.)

Some manufacturers claimed on websites that their products were toxin free and didn’t contain the kinds of cancer-causing chemicals found in tar-ridden cigarettes. That’s something that requires more study to determine.

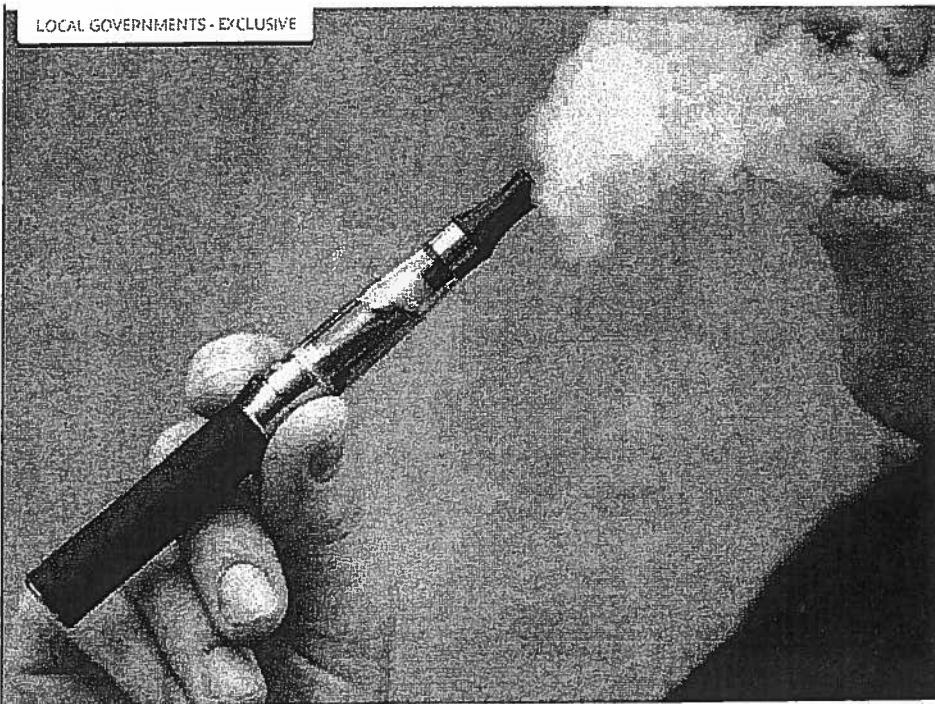
“Right now, we have an unusual situation with a product allowed on the market that’s making health and smoking cessation claims,” Ling said, “and manufacturers shouldn’t be allowed to make those claims without the science to support them.”

Deborah Kotz can be reached at dkotz@globe.com. Follow her on Twitter [@debkotz2](#).

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LOCAL GOVERNMENTS - EXCLUSIVE



New Fears Push More California e-Cigarette Bans

POSTED BY: CAL WATCHDOG APRIL 1, 2014

By James Poulos.

Southern California's thriving e-cigarette industry faces a big new problem: nationwide, their products are becoming a hot new focal point of public health worries.

In the latest report casting "vapes" in a negative light, the New York Times called the nicotine solution found in e-cigs "poison by the barrel." That has producers and retailers in a "defensive crouch," according to the Riverside Press-Enterprise. The most sensational danger posed by nicotine "juice" is its potential to kill children who consume even a teaspoon.

That alarming piece of data presupposes a nicotine concentration level that not all vials of juice contain. For anti-vape advocates, however, the Times report is an aid in turning public opinion firmly against permissive e-cig laws.

California's robust market for vapes makes the state a critical test case for the advancement of new prohibitions. Relying in large part on health fears surrounding the safety of children, advocates have

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already made substantial gains on the West Coast.

In Los Angeles, City Council President Herb Wesson delivered an impassioned address during the floor debate, testifying that his desire to "be cool" as a young man led to a lifelong addiction to tobacco cigarettes that would probably end his life.

The city extended its sweeping tobacco cigarette ban to vapes, ~~per~~ prohibiting their use in "vaping lounges," but rejected an exemption that would permit vaping in bars or nightclubs with a 21-and-over policy.

Crackdown

In the wake of the action by Los Angeles, other California municipalities are considering a crackdown of their own. The Long Beach city council voted to ban vaping even inside places where e-cigs are sold, prompting an outcry from industry business people. One distributor objected that half of the juice sold in South Orange County is actually nicotine-free, the OC Weekly reported.

Frustration is mounting over officials' tendency to ban now and ask questions later. As the current director of the U.S. Centers for Disease Control and Prevention told the Times, "I think the precautionary principle — better safe than sorry — rules here."

Judging by developments in California, municipalities agree. "If you watch the city council meeting," the Long Beach vape distributor told the Weekly, "some of the members said they don't have enough information to make a proper decision, but they decided to go with the original ordinance anyway."

The precautionary principle may well take hold among some citizens as well.

Elsewhere in the state, the Santa Cruz city council is now set to consider whether to become the 46th California community to add e-cigs to their tobacco smoking ordinances, according to KSBW. While city officials worry that failing to crack down will permit confusion and disorder to take hold, residents find themselves even less informed than would-be regulators. KSBW illustrates the point by citing one restaurateur's support for a ban "because of the unknown effects of e-cigarettes."

While local governments often look to Washington, D.C., for strong guidance and information about which substances to ban or regulate, federal data on e-cigarettes is still lacking. That has led lawmakers in at least ten states to treat e-cigs like tobacco cigarettes, or ban their sales to minors, with still others considering industry-specific taxes and tougher regulations for online commerce.

Permissive

The case for more permissive e-cig regulations, meanwhile, now centers on a few key arguments. Proponents point to the absence of harms equivalent to secondhand tobacco smoke, the lack of adverse findings by the Food and Drug Administration, and the inspirational power of e-cigs to draw smokers away from cigarettes' lethal carcinogens. Nationwide, libertarian organizations are turning their attention to increasing public awareness of these attributes.

New developments suggest that the tide of regulatory opposition is now leading vapers to organize and push back. Confronting an e-cig ban in the San Diego County town of Encinitas, the Consumer Advocates for Smoke-Free Alternatives Association created a tip sheet, complete with talking points and city council contact information.

As the need for a better public image grows clear, a confrontational attitude to e-cig crackdowns is increasingly discouraged. In its recommendations, CASAA urged vapers who attend the Encinitas hearing to refrain from smoking e-cigarettes.

It remains to be seen whether the e-cig movement's turn to better public relations is enough to keep California vapers in the regulatory clear.

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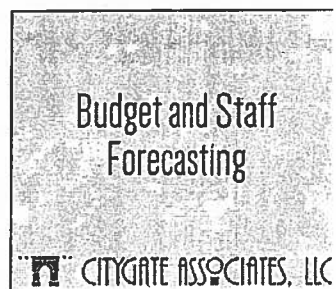
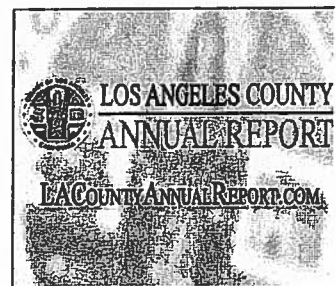
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Date: Apr 2, 2014; Section: Front Page; Page: News 1

Aplume of confusion for e-cig smokers

Cities are all over the map in allowing the devices in public places.

BY TOMOYA SHIMURA and JOHN WILKINSON

STAFF WRITERS

LAGUNA HILLS › Zach Rowe browses a list of liquid nicotine flavors at e-cig Gallery, the slightly fruity smell of nicotine vapor surrounding him.

Rowe is eager to try out a new flavor in his silver SmokTech e-cig on his way back to his Laguna Hills home. However, he'd be hard-pressed to take the same pull of his e-cig at public playgrounds in Buena Park. Or restaurants in Seal Beach. Or, soon, at city parks in Laguna Niguel.

Pop over to the Great Park in Irvine, though, or down to the beach in Laguna? Light 'em up.

Amid the growing popularity of ecigarettes – sales topped \$1.6 billion in 2013, according to Thomas Kiklas of the Tobacco Vapor Electronic Cigarette Association, which represents ecigarette manufacturers and distributors – smokers are facing more regulation, exposing a clash of ideology between "vapers," as they refer to themselves, and those who believe the devices' vapors might be harmful.

A handful of cities in Orange County already have taken sides on the batterypowered devices that vaporize nicotine-infused liquid, despite a lack of clarity about the health effects. Most, however, are taking a wait-and-see approach.

"A lot of cities are debating and discussing what their roles should be in regulating e-cig," said Steve Greyschok, spokesman for the Association of California Cities-Orange County. "In general, there's a desire to understand the health effects as well as the cities' responsibility in regulating ecig businesses. ... More time is needed to study the issue."

EXISTING REGULATIONS

Statewide, about 100 cities have ordinances regulating e-cigarettes, said Eva Spiegel, director of communications for the League of California Cities, an association of city officials. The most common move cities are making is adding e-cigarette language to smoking bans already on the books.

That was the approach taken in early March by the Los Angeles City Council, which prohibited e-cigarettes in public areas, including restaurants and bars, where state law bans smoking.

Also in March, Long Beach city officials classified e-cigs as tobacco products, prohibiting their use in enclosed workplaces or public parks, among other public spaces.

Seal Beach, the first Orange County city to regulate e-cigarettes, adopted comprehensive ordinances in February and March. As in Los Angeles, e-cigarette use is prohibited where state law bans smoking.

The city treats the sale and use of e-cigarettes the same way it does tobacco products. E-cigarette shops are able to operate only in commercial zones, and smoking lounges of any kind are prohibited.

The city created the ordinances after receiving requests to open e-cigarette businesses in town, Community Development Director Jim Basham said.

"We didn't have sufficient provisions in our municipal code to address this growing trend," he said.

The Buena Park City Council in March voted to ban smoking, including ecigarettes, in recreational areas, after the American Lung Association and American Cancer Society suggested the change, City Clerk Shalice Tilton said. San Clemente and Laguna Niguel are evaluating similar measures.

Mission Viejo has interpreted existing municipal and zoning codes to include e-cigarettes under smoking, though the codes don't specify e-cigarettes, according to City Clerk Karen Hamman and Community Development Director Elaine Lister.

Advocates of e-cigarettes are frustrated by opponents' attempts to lump ecigarettes in with tobacco products, saying they are less harmful.

"I think it's unfortunate that the industry is being villainized," said David McElroy, 31, who tried to open MetaVape e-cigarette lounge in Aliso Viejo.

WAIT AND SEE

The majority of Orange County cities are observing from the sidelines, paying attention to news headlines and medical research.

"We are keeping an eye open for what other cities do, but we do not anticipate any changes in the near future," Brea City Clerk Cheryl Balz said.

The League of California Cities has not taken a stance on e-cigarettes, Spiegel said, though the organization's board is scheduled to take up the issue April 24.

Part of the reason some cities prefer to hold off is they haven't run into any issues, and the jury is still out on health effects of e-cigarettes.

Irvine and Laguna Beach are waiting, for now.

The majority of the Irvine council late last month said not enough information is available about e-cigarettes and their effects, and a ban would threaten individual liberties.

"I have confidence in individuals and their ability to make their own choices," Irvine Councilman Jeff Lalloway said.

HEALTH EFFECTS

UNCLEAR

E-cig supporters cite anecdotal evidence suggesting they help people quit smoking tobacco products, though the World Health Organization stated last year that hasn't been scientifically proven.

A 2013 study published in the Nicotine and Tobacco Research journal – cited by Aliso Viejo in its study of the issue – states secondhand concentration of nicotine is 10 times less in e-cigarette vapor than in smoke from a traditional cigarette.

Opponents are quick to point out the lack of regulations in manufacturing ecigarettes and the liquid nicotine used in them. The Food and Drug Administration said it intends to regulate e-cigarettes as it does tobacco products, but hasn't provided a timeline for the effort.

Albert Armijo, director of planning services at Aliso Viejo, researched health effects of e-cigarettes for the City Council and recommended rejection of McElroy's application. The council denied it, saying it was too close to child care facilities.

"The City Council recognized there are people helped by e-cigarettes, but the situation is that there are no regulations governing materials that go into these products," Armijo said.

McElroy's application also prompted the council to ask for a zoning code change that would ban smoking lounges near "sensitive land uses," such as schools, churches, parks and child care centers.

"Right now, health impacts (of e-cigarettes) are a little unknown," Aliso Viejo Mayor Phillip Tsunoda said after voting against Meta-Vape. "But in my opinion, I'd rather be safe than sorry."

So where does that leave Rowe?

"Even if they put a regulation on it, I'll still do it wherever the hell I want to do it," he said. "I think it should be up to the person vaping because it doesn't really affect anybody else. It doesn't stink, it doesn't really bother anybody else, as long as you are going about it kind of smart."

Staff writers Elysse James and Kim Pierceall contributed to this report.

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FDA to begin regulating e-cigarettes

The Food and Drug Administration will propose its first regulations for electronic cigarettes, including requiring health warnings and banning sales to minors.

April 23, 2014 | By Lalita Clozel

WASHINGTON — The Food and Drug Administration plans to begin regulating electronic cigarettes for the first time, banning sales to minors and requiring manufacturers to put health warnings on the nicotine-delivering devices that have become a multibillion-dollar industry, according to officials who described the agency's proposal.

But the agency will stop short of steps that many public health advocates and some members of Congress have called for, including restrictions on television advertisements and flavorings, such as pumpkin spice or chocolate, that may target younger consumers, officials said. The agency plans to announce the new rule Thursday.

Regulators do not yet have scientific evidence for a rule on flavorings, but the subject is still being researched, Mitchell Zeller, director of the FDA's Center for Tobacco Products, told reporters.

"There are far more questions than answers," he said, adding that the new regulation would provide a "framework" for additional rules in the future.

Even without restrictions on advertising or flavorings, the new rule represents a "significant step in the agency's ability to regulate tobacco products," Zeller said. "I call the market for e-cigarettes the wild, wild West in the absence of regulations."

The proposed rule, which must go through a public comment process and overcome potential legal challenges before becoming final, would impose restrictions on other tobacco-related products as well, including nicotine gels and pipe tobacco.

Companies would have to register the products and their ingredients with the FDA, but would have two years to do so.

In the interim, they could continue selling their existing devices and introduce new products without regulators' approval. The new health warning labels would caution users against the danger of becoming addicted to nicotine.

E-cigarettes come in several forms, but all heat liquid nicotine into a vapor that can be inhaled and that gives use of the devices its popular term, "vaping."

The FDA has been trying to regulate the devices for at least five years. In 2009, the agency sought to impose restrictions on them as medical devices designed to deliver nicotine, a chemical compound that is addictive.

After a federal court struck down that effort the next year, the agency switched grounds and declared that it could issue rules for the devices under the authority Congress gave it to regulate tobacco products.

Regulating the devices raises more complex issues than rules for traditional cigarettes because the health impact of e-cigarettes is unclear.

Supporters say they could be beneficial by allowing users to get nicotine without the exposure to tar and other carcinogens found in cigarette smoke. They have touted the devices as an effective way for some of the country's roughly 42 million smokers to quit.

Opponents say that the devices inevitably will lead to more nicotine addiction, that the health risks of long-term use are unknown and that widespread use of e-cigarettes, especially by minors, will lead to increases in smoking.

"Definitive data" on the health impact of vaping do not exist, an FDA official, Priscilla Callahan-Lyon, wrote recently in a medical journal in which she reviewed studies of the devices.

The agency spent years amassing data before declaring in the mid-1990s that nicotine in the amounts delivered by cigarettes was an addictive drug.

While the debate over the health effects of vaping has continued, sales of the devices have rocketed, reaching more than \$1.5 billion in 2012.

A September 2013 study by the Centers for Disease Control and Prevention found the percentage of high school students who had tried e-cigarettes had more than doubled within a year, from 4.7% in 2011 to 10% in 2012.

The growth in use of e-cigarettes has caused some cities, including Los Angeles, Chicago and New York, to ban or restrict their use in parks, workplaces and other public places. More than half the states already ban sales to minors.

In addition to concern about the effect on users, opponents of the devices have warned about secondary risks, particularly from the liquid nicotine that consumers can buy to refill some devices.

In the last few years, poison centers across the country have reported a sharp increase in nicotine poisoning, particularly of small children. Even small amounts of nicotine can cause nausea and vomiting if swallowed by an adult, and can be potentially deadly for a small child.

9/30/2014

FDA to begin regulating e-cigarettes - Los Angeles Times

The CDC reported this month that calls had increased from just one in September 2010 to 215 this February, with more than half of the calls involving children under 5.

A group of Democrats in Congress, including Rep. Henry A. Waxman (D-Beverly Hills) and Sen. Richard J. Durbin (D-Ill.), released a report this month that accused the makers of e-cigarettes of aggressively targeting minors with marketing tactics that would be illegal if used for traditional cigarettes.

The report singled out kid-friendly flavorings, which are banned by law for traditional cigarettes, and the sponsorship of popular entertainment events such as the Coachella Valley Music and Arts Festival.

"With over a million youth now using e-cigarettes, FDA needs to act without further delay to stop the companies from marketing their addictive products to children," said Waxman, who has led efforts in Congress for decades to limit tobacco use.

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FDA TO PROPOSE NEW RULES FOR E-CIGARETTES

Regulations, which also cover pipe tobacco and cigars, ban sales to minors.

BY SABRINA TAVERNISE
THE NEW YORK TIMES

WASHINGTON • The Food and Drug Administration will propose sweeping new rules today that for the first time would extend its regulatory authority from cigarettes to electronic cigarettes, popular nicotine delivery devices that have grown into a multibillion-dollar business with virtually no federal oversight or protections for U.S. consumers.

The regulatory bite

print, with broad implications for public health, the tobacco industry and the nation's 42 million smokers, would also cover pipe tobacco and cigars, tobacco products that have long slid under the regulatory radar and whose use has risen sharply in recent years. The new regulations would ban the sale of e-cigarettes, cigars and pipe tobacco to Americans under 18, and would require that people buying them show photo identification to prove their age, measures already mandated in a number of states.

Once finalized, the regulations will establish oversight of what has been a market free-for-all of products, including vials of liquid nicotine of varying

REGISTERING WITH THE FDA

Perhaps the biggest proposed change would require producers of cigars and e-cigarettes to register with the FDA, provide the agency with a detailed accounting of their products' ingredients and disclose their manufacturing processes and scientific data. Producers would also be subject to FDA inspections.

quality and unknown provenance. It has taken the agency four years since Congress passed a major tobacco-control law in 2009 to get to this stage, and federal officials and advocates say it will take at least another year for the rules to take effect — and possibly significantly longer if affected companies sue to block them.

"If it takes more than a year to finalize this rule, the FDA isn't doing its job,"

groups, descended on Washington in November, and reported holding nearly 50 meetings with congressional officials to help them "learn more about the negative impact inappropriate regulation could have on this nascent industry," the group said in a statement.

The industry has several trade associations, and a number of them have met with Obama administration officials about the regulations over the past several months, according to public records and industry group statements.

FDA officials gave journalists an outline of the new rules Wednesday, but reiterated that they not talk to industry or public health groups until after today's

formal release of the document.

The agency said the 2009 law gave it the power to prohibit sales to minors of all tobacco products that it has authority over, which now will include e-cigarettes and cigars. A spokeswoman said the move did not reflect a finding about the safety of these products.

But the new blueprint was also notable for what it did not contain: any proposal to ban flavors in e-cigarettes and cigars, like bubble gum and grape, that public health experts say lure children to use the products, or any move to restrict the marketing of e-cigarettes as is done for traditional cigarettes, which are banned from television, for example.

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Health » Scientific American Volume 310, Issue 5 » The Science of Health



See Inside

Smoke Screen: Are E-Cigarettes Safe?

Even without tobacco, the poorly regulated devices may pose unique dangers

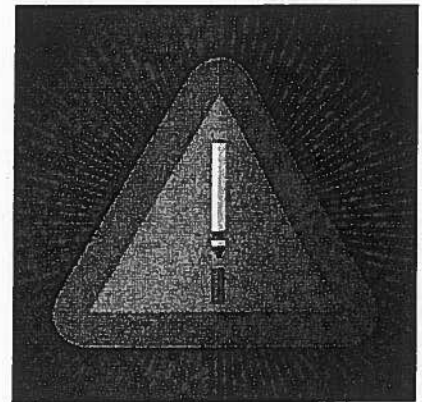
May 1, 2014 | By Dina Fine Maron |

Television advertisements for cigarettes have been banned in the U.S. since 1971, but in the past few years supposedly healthier, battery-powered alternatives have landed numerous prime-time appearances. Electronic cigarettes, or e-cigs, as they are known, soaked up the spotlight in recent Super Bowl commercials, on late-night talk shows and in a comedy sketch during the 2014 Golden Globe Awards. Indeed, a recent survey shows that nearly 60 percent of Americans are now familiar with the sleek, smokeless devices.

The concept behind e-cigs is clever: they allegedly offer all the fun of typical cigarettes without any of the dangers. E-cigs use a small, heated coil to vaporize a nicotine-laced solution into an aerosol mist. By inhaling the mist, users enjoy the same satisfaction they would get from an ordinary cigarette but do not expose themselves to tobacco, which turns into cancer-causing tar when it is burned. Such products free smokers from huddling in the cold or rain and, in many places, from ordinances that forbid smoking in public places.

But are e-cigs truly safe? No one knows for sure. Yet there is no question that the nicotine they contain is addictive—which is one reason many public health experts have grown alarmed by their rapidly increasing popularity. Among their concerns: e-cigs might lure former smokers back to conventional cigarettes, expose users and bystanders alike to unidentified dangers, or become a gateway for teens who might subsequently experiment with tobacco products and other drugs.

The U.S. Food and Drug Administration and the European Union are grappling with these issues as they decide how to regulate the products. Unfortunately, they must act before all the facts are available. Unfettered access could leave people vulnerable to unknown health hazards, but there is also the chance that greater restrictions might hurt folks who are trying to forgo conventional—and more dangerous—tobacco products.



Tom Whalen

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First Puffs

The current iteration of e-cigarettes was invented and popularized by Chinese pharmacist Hon Lik in 2003 and entered the U.S. market some seven years ago. (Earlier attempts at a “smokeless, non-tobacco cigarette,” patented in 1965, never caught on.) Initially the FDA

<http://www.scientificamerican.com/article/smoke-screen-are-e-cigarettes-safe/?print=true>

1/3

tried to regulate them as drug-delivery devices, defined under federal law as items “intended to affect the structure or any function of the body.” E-cigarette company NJOY sued the agency, however, arguing that nicotine-containing devices were similar to tobacco products—which the FDA had also previously tried and failed to have declared drug-delivery systems. A federal appeals court ruled in December 2010 that the agency lacked authority over e-cigs because they offer only the recreational benefits of a regular cigarette. That legal decision allowed sales of e-cigarettes to proceed but left many questions about their safety unaddressed.

In lieu of carcinogenic tobacco, e-cigarettes typically contain three main ingredients: nicotine, a flavoring of some kind and propylene glycol—a syrupy synthetic liquid added to food, cosmetics, and certain medicines to absorb water and help them stay moist. The primary established danger of nicotine is that the stimulant is highly addictive, although emerging science also links it to an impaired immune system. Propylene glycol has been “generally recognized as safe,” or GRAS (an official FDA designation), since 1997. Yet more needs to be understood before e-cigarettes can be given a clean bill of health.

Propylene glycol, for example, is usually eaten (in cupcakes, soft drinks and salad dressings) or slathered onto the body (in soaps, shampoos and antiperspirants)—not breathed into the lungs. Many things that can be safely eaten—such as flour—can damage the lungs when inhaled. No one knows whether propylene glycol falls into that category. “We have little information about what happens to propylene glycol in the air,” the federal Agency for Toxic Substances and Disease Registry says on its Web site. An assessment from the agency, issued in 2008, references only a couple of studies that cover inhalation exposures—all with laboratory animals rather than people.

Beyond the three main ingredients, some researchers worry about by-products from heating electronic cigarettes and the solution inside them. Various studies suggest the vapors from e-cigarettes contain several cancer-causing substances, as well as incredibly tiny particles of tin, chromium, nickel and other heavy metals, which, in large enough concentrations, can damage the lungs. These particles likely fleck off the solder joints or metal coil in the devices when heated. Because they are so small, the tiniest bits of metal, known as nanoparticles, can travel deep into the lungs. There they could exacerbate asthma, bronchitis—an inflammation of the tubes that carry air to and from the lungs—and emphysema—a disease in which the lungs’ many air sacs are destroyed, leaving patients short of breath. So far there are not enough data to say with certainty whether e-cigs worsen these disorders.

Craig Weiss, president and CEO of NJOY, went on NPR during the summer and espoused the safety of e-cigarettes, pointing to “clinical trial” data he said would soon be published in peer-reviewed literature. When Scientific American requested that study, it received a draft of a small study looking at the use of e-cigs for short-term smoking reduction, not the kind of large, long-term, rigorously conducted trial that has become the gold standard in medicine. “It is not a study that would lead to drug approval,” admits Joshua Rabinowitz, NJOY’s chief scientist, but a clinical trial “is defined as a test of biological response in a human in a clinical setting, and that is exactly what was done.”

The few scientists actively trying to fill the gap in the research literature are running into obstacles. When studying tobacco cigarettes, researchers rely on smoking machines that simulate how frequently a typical smoker takes a puff and how much smoke is inhaled with each breath. No one has yet determined how much e-cig vapor the typical user breathes in, so different studies assume different amounts of vapor as their standard, making it difficult to compare their results. Tracing what happens to that vapor once it is inhaled is equally problematic. When the human body breaks down a foreign substance, one can typically find chemical by-products in hair or urine that provide clues about how it has interacted with cells. This is true for nicotine, but in the case of propylene glycol, no one has established what the relevant by-product is or how to best detect it.

Wild West

As scientists struggle to test the safety of e-cigarettes, the devices are becoming more and more popular among teens and preteens. E-cigarette use among U.S. high school students more than doubled from 4.7 percent in 2011 to 10 percent in 2012, according to recent data from the Centers for Disease Control and Prevention’s National Youth Tobacco Survey. At least 160,000 students who had never tried conventional cigarettes puffed on e-cigs. Yet another analysis linked e-cig use with greater odds of trying tobacco. They come in kid-friendly flavors, including chocolate, bubble gum and gummy bear. Sold online and in the mall, e-cigarettes are also easy for minors to acquire.

Federal legislative milestones that protect youngsters from conventional cigarettes—such as blocking sales to minors and preventing commercials targeted at adolescents—do not exist for e-cigarettes. In an attempt to remedy the situation, 40 state attorneys general

signed a letter last September urging the FDA to assume "immediate regulatory oversight of e-cigarettes, an increasingly widespread, addictive product."

Yet there has been hardly any definitive legislation regarding the sale and consumption of e-cigs in the U.S. Meanwhile Canada has made it illegal to sell e-cigarettes preloaded with nicotine in stores, but the regulation is not well enforced, and customers can buy vials of nicotine online. Things are slightly better across the pond. At press time, the European Parliament had approved a ban on e-cigarette advertising starting in mid-2016, and the ban seemed likely to get approval from the E.U.'s member states.

Without regulations, it is the "Wild West" for e-cigarette companies, says Stanton Glantz, director of the Center for Tobacco Control Research and Education at the University of California, San Francisco, and a self-described e-cigarette pessimist. He argues that given the paucity of health data, current indoor smoking bans should apply to e-cigs as well. "One of the real problems [with] these things is that because of the low quality control, you never quite know what you are getting," he says. Those who support minimal regulation contend that limiting the use of e-cigarettes would encourage more people to smoke conventional cigarettes.

As the debate blazes, deep-pocketed big tobacco investors are buying up e-cig companies, injecting millions of dollars into the market and banking on a bright future for the devices. More than 100 e-cigarette companies are now jockeying for the business of smokers and nonsmokers alike. The success of all these enterprises hinges on the claim that e-cigarettes are healthier than traditional cigarettes. Companies like to paint a black-and-white picture of a new era of safe smoking. "Cigarettes, you've met your match," NJOY proudly proclaims. But whether e-cigarettes are genuinely safe is far hazier.

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Dina Fine Maron is an associate editor at Scientific American.

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Boston health chief urges FDA to be tougher on e-cigarettes

By Deborah Kotz | GLOBE STAFF MAY 02, 2014

WASHINGTON — Boston's public health chief joined health officials from 10 other cities in urging the US Food and Drug Administration Thursday to toughen the agency's proposed regulations for electronic cigarettes.

"They don't go far enough," Barbara Ferrer, executive director of the Boston Public Health Commission, said in an interview before an afternoon meeting of policy makers and health advocates on Capitol Hill. "The FDA should aggressively limit access to minors and not allow marketing to them or flavorings like bubble gum."



DAVID L. RYAN/GLOBE STAFF/FILE 2013

Barbara Ferrer, executive director of the Boston Public Health Commission.

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Last week, the agency proposed to regulate e-cigarettes — which contain nicotine in liquid form that is heated and inhaled as vapor — as tobacco products, but stopped short of some of the harsher restrictions that apply to cigarettes.

While the new rule would restrict sales to minors, ban free samples, and place health warning labels on products, it does not limit advertising, ban online sales, or force manufacturers to remove sweet flavorings that appeal to younger people.

“There are gaps in the proposed regulations that must be addressed to protect and promote the public’s health, such as the marketing, flavoring, and manufacturing of e-cigarettes,” the city health officials wrote in a letter sent Thursday to FDA Commissioner Margaret Hamburg.

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FDA outlines plan to regulate e-cigarettes

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No evidence that e-cigarettes help smokers quit

Future cigarette could be non-addictive

A study released Thursday by Legacy, a nonprofit antitobacco organization, found that \$39 million was spent on e-cigarette advertising from June through November 2013, with most of the messages aimed at youth: Eighty-nine percent of teenagers ages 13 to 17 reported that they are aware of e-cigarettes, and 14 percent said they had tried them.

“We don’t want to wait a year or more until there’s implementation of this rule to prohibit young people from purchasing e-cigarettes,” Ferrer said. “We’d like those prohibitions to be effective immediately, once they’re done with the comment period.” The FDA is accepting comments from the public until July 9 and could take months or years to issue a final regulation after reviewing all the comments submitted.

Boston and 51 other municipalities in the state have enacted bans on the use of e-cigarettes in any locations that are smoke-free, including bars, public parks, and workplaces. State legislators are considering whether to pass a statewide law with the same restrictions.

Los Angeles, Chicago, New York City, and Philadelphia all implemented laws in April that forbid e-cigarettes in places where smoking is prohibited. While Boston prohibits the sale of e-cigarettes to anyone under age 18, New York went further, banning the sale of cigarettes and e-cigarettes to anyone under the age of 21.

"We have a big problem on our hands," Dr. Mary Travis Bassett, New York City's health commissioner, said at the meeting. "E-cigarette flavors and marketing are clearly aimed at youth, and it's working."

In Boston, e-cigarette sales are skyrocketing; 310 merchants were granted permits to sell them in all of 2013, compared with 482 who have been granted permits so far this year, according to Ferrer.

She and other city health officials argued that e-cigarettes have not been shown to be safe and contain hazardous chemicals, carcinogens, and varying degrees of nicotine in the liquid cartridges. The FDA proposes to require manufacturers to submit safety studies, list all the ingredients on the label, and stop making unverified health claims such as that the products can help smokers quit.

Dr. Michael Siegel, a tobacco control specialist at the Boston University School of Public Health, said that while he agreed that the FDA should restrict marketing to youth, he thought the agency went too far in not allowing e-cigarette manufacturers to make the claim that their products are safer than cigarettes.

"We can't draw conclusions on the absolute safety of e-cigarettes," Siegel said, "but there's no doubt that they deliver fewer carcinogens and have fewer risks than the real thing." He pointed to recent studies indicating that smokers who switched from tobacco cigarettes to e-cigarettes experienced improvement in their lung function and ability to exercise.

"I also believe there's enough evidence to show that e-cigarettes are effective at helping many smokers quit," Siegel added, "but we don't have a good conception of who these people are and what proportion of the smoking population we're talking about."

The New York Times<http://nyti.ms/1iVJMTo>

BUSINESS DAY | THE NEW SMOKE | NYT NOW

Some E-Cigarettes Deliver a Puff of Carcinogens

By MATT RICHTEL MAY 3, 2014

Electronic cigarettes appear to be safer than ordinary cigarettes for one simple — and simply obvious — reason: people don't light up and smoke them.

With the e-cigarettes, there is no burning tobacco to produce myriad new chemicals, including some 60 carcinogens.

But new research suggests that, even without a match, some popular e-cigarettes get so hot that they, too, can produce a handful of the carcinogens found in cigarettes and at similar levels.

A study to be published this month in the journal *Nicotine and Tobacco Research* found that the high-power e-cigarettes known as tank systems produce formaldehyde, a known carcinogen, along with the nicotine-laced vapor that their users inhale. The toxin is formed when liquid nicotine and other e-cigarette ingredients are subjected to high temperatures, according to the study. A second study that is being prepared for submission to the same journal points to similar findings.

The long-term effects of inhaling nicotine vapor are unclear, but there is no evidence to date that it causes cancer or heart disease as cigarette smoking does. Indeed, many researchers agree that e-cigarettes will turn out to be much safer than conventional cigarettes, an idea that e-cigarette companies have made much of in their advertising.

The website for Janty, a company that manufactures popular tank systems, says the benefits of e-cigarettes include having “no toxins associated with tobacco smoking.”

Nonetheless, the new research suggests how potential health risks are emerging as the multibillion-dollar e-cigarette business rapidly evolves, and how regulators are already struggling to keep pace. While the Food and Drug Administration last month proposed sweeping new rules that for the first time would extend its authority to e-cigarettes, the F.D.A. has focused largely on what goes into these products — currently, an unregulated brew of chemicals and flavorings — rather than on what comes out of them, as wispy plumes of flavored vapor.

The proposed rules give the F.D.A. the power to regulate ingredients, not emissions, although the agency said it could consider such regulations in the future. Even so, some experts contend that the current approach is akin to examining the health risks associated with tobacco leaves rather than with cigarette smoke.

“Looking at ingredients is one thing, and very important,” said Maciej L. Goniewicz, who led the first study, which is scheduled to be published on May 15. “But to have a comprehensive picture, you have to look at the vapor.”

Both studies focused on tank systems, fast-growing members of the e-cigarette family. Unlike disposable e-cigarettes, which tend to mimic the look and feel of conventional smokes, tank systems tend to be larger devices heated with batteries that can vary in voltage, often resembling fountain pens or small flashlights. Users fill them with liquid nicotine, or e-liquid, and the devices are powerful enough to vaporize that fluid quickly, producing thick plumes and a big nicotine kick.

Dr. Goniewicz, an assistant professor of oncology at the Roswell Park Cancer Institute in Buffalo, said people using the systems “want more nicotine, but the problem is they’re also getting more toxicants.”

Complicating the issue is that the tank systems are made by a variety of manufacturers, many overseas, and then sometimes tinkered with and modified by retail shops or users. Still, e-cigarette makers should be measuring emissions, said Josh Rabinowitz, chief scientist at NJoy, a maker of more traditional e-cigarettes, not tank systems.

“We don’t just evaluate the purity of what goes in, but also the purity of the emitted vapor because that’s what the user is exposed to,” said Dr. Rabinowitz. He said NJoy had significantly lower levels of formaldehyde than regular cigarettes.

Like Dr. Goniewicz’s study, which has been subjected to peer review, the second study also centered on the impact of increased heat generated by the systems. In that study, the focus was on how people use the devices to create more — and more potent — vapor. Rather than fill their tank systems with e-liquid, experienced users often trickle drops of the fluid directly onto the device’s heating element, a practice known as “dripping.”

But with dripping, the e-liquid heats with such intensity that formaldehyde and related toxins “approach the concentration in cigarettes,” said Dr. Alan Shihadeh, a project director at the Virginia Commonwealth University’s Center for the Study of Tobacco Products and an associate professor of mechanical engineering at American University in Beirut, who led the research.

Both studies point to the same phenomenon: Intense heat can change the composition of e-liquids, creating new chemicals. Importantly, the researchers said, the chemical reactions apply not only to the liquid nicotine, but also to two other crucial ingredients in most e-liquids: vegetable glycerin and propylene glycol.

Precisely what level of heat causes the reaction is difficult to pinpoint. The Roswell research found, generally, that when battery voltage increased to 4.8 volts from 3.2 volts, toxin levels increased markedly.

“This finding suggests that in certain conditions, E.C.s might expose their users to the same or even higher levels of carcinogenic formaldehyde as tobacco smoke,” the Roswell study says.

Both studies examined only a handful of carcinogens. Traditional cigarettes, by contrast, create thousands of chemicals and dozens of carcinogens, according to Prue Talbot, professor of cell biology at the University of California, Riverside. E-cigarettes do not tend to generate enough heat to create combustion, which is a big reason that many public

health officials and researchers predict they will prove less harmful than cigarettes.

“If I was in a torture chamber and you said I had to puff on something, I’d choose an e-cigarette over a regular cigarette,” Dr. Shihadeh said. “But if you said I could choose an e-cigarette or clean air, I’d definitely choose clean air.”

He added: “And I definitely wouldn’t drip.”

Whatever the health effects of the new systems, they are exploding in popularity and reshaping the market, according to a report issued in March by Bonnie Herzog, a tobacco-industry analyst for Wells Fargo Securities. In 2013, Ms. Herzog projected domestic sales of e-cigarettes at \$1.7 billion a year but, based on surveys with makers and marketers of e-cigarettes, she now expects “in excess of \$2 billion.”

Demand for tank systems, Ms. Herzog wrote, is “accelerating” and “undeniably a key growth driver.” She estimated that the new systems now represent 35 percent of the market, but they are growing twice as fast as the previous models.

Experts say tank systems appeal to young people who like products that can be customized with flavors and power, and are comfortable with fast-changing technology.

At Sky City Vapor in San Diego, the owner, Chris Hayek, said consumers clearly are gravitating toward the more powerful systems and away from the “ciga-likes.”

“The ones shaped like a cigarette, that style doesn’t do it for them,” Mr. Hayek said. “It’s not harsh, it doesn’t produce as much vapor.” He said that only about 5 percent of his customers are regular “drippers” but that the trend in the industry is toward tank systems that produce large amounts of strong vapor.

Some health data seems promising for e-cigarette users, such as a previous study led by the researchers at Roswell Park Cancer Institute. That research, published in 2012 in the journal Tobacco Control, found that the level of some toxic substances in 12 e-cigarette brands was significantly

lower than in cigarette smoke. However, Dr. Goniewicz said that the technology is moving so quickly that many of the products tested are outdated — and some are no longer even on the market.

“Technology is way ahead of the science,” Dr. Shihadeh concurred. “We’re creating this stuff, and we don’t understand the implications.”

A version of this article appears in print on May 4, 2014, on page A1 of the New York edition with the headline: Some E-Cigarettes Deliver a Puff of Carcinogens.

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UCSF e-cigarette study stamps out public health benefits

Victoria Colliver

Updated 7:15 am, Tuesday, May 13, 2014

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If all traditional cigarette smokers switched to electronic cigarettes, lives would be saved and overall public health would improve, scientists and doctors say.

But UCSF researchers, in a paper published Monday, say a growing body of research shows that people who take up e-cigarettes aren't necessarily giving up conventional cigarettes, and on top of that, the devices are being heavily marketed to young people, creating a potential new market for the nicotine and tobacco industry.

"Our bottom line is, at the moment, it doesn't seem like e-cigarettes are having a big impact on the population in terms of quitting," said UCSF's Dr. Neal Benowitz, a leading nicotine researcher and a co-author of the scientific review published in *Circulation*, a journal of the American Heart Association.

E-cigarettes, battery-operated devices that vaporize a nicotine solution, have been sold in the U.S. only since the mid-2000s, but their popularity is exploding, particularly among teenagers.

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The percentage of U.S. middle and high school students who said they've tried e-cigarettes was 3.3 percent in 2011 but rose to 6.8 percent by the following year, according to a survey by the U.S. Centers for Disease Control and Prevention.

Health effects unclear

Some manufacturers claim the devices help people stop smoking and some users agree, but researchers in the study say that's unclear. The paper cites studies that show people tend to use e-cigarettes with combustible cigarettes, rather than as an alternative.

Little is known about the long-term health effects of e-cigarette use because the \$1.5 billion U.S. industry is so young. But the researchers say that while emissions from the devices are less toxic than those from burning cigarettes, they are not "harmless water vapor" as some manufacturers claim.

"As we're getting better and better understanding of the chemistry of these things, they're looking worse and worse," said Stanton Glantz, director of UCSF's Center for Tobacco Control Research and Education and a co-author of the *Circulation* paper.

The researchers described how e-cigarettes deliver nicotine by creating an aerosol of ultra-fine particles. There's not enough evidence to determine the health consequences of those particles, but they noted that previous research has shown frequent low- or short-term exposure to similar fine particles from tobacco or air pollution contribute to systemic inflammatory processes in the body that increase the risk of heart and respiratory disease.

"You can be a lot less bad as a cigarette and still be pretty bad," Glantz said.

Bans enacted

It may take years or even decades for clinical trial data to determine the firsthand and secondhand effects of exposure to the particles, but an increasing number of cities and states aren't waiting to find out.

San Francisco, Chicago, New York and Los Angeles have implemented bans on e-cigarette use in areas where smoking has been banned. New Jersey,

Utah and North Dakota, as well as 172 other municipalities around the country, have enacted similar laws, according to Americans for Nonsmokers' Rights in Berkeley.

Last month, the U.S. Food and Drug Administration announced plans to regulate e-cigarettes for the first time. The agency's action has been both welcomed as a first step and criticized for failing to curb the way the products are marketed to appeal to youths and sold in a variety of e-liquid flavors, ranging from gummy bears to Belgian waffles, something that young people might find attractive.

Oliver Kershaw, who founded the online E-Cigarette Forum in 2007, said he supports the responsible use of e-cigarettes either as a substitute for standard cigarettes or a way to help kick the nicotine habit. Kershaw had not yet seen the UCSF paper.

"It's smoking that is the danger. Everything else pales in comparison," said Kershaw, who traded conventional cigarettes for e-cigarettes five years ago.

But he objects to the wave of anti-e-cigarette legislation that treats the devices like regular cigarettes.

"You're far more likely to be exposed to dangerous compounds from an air freshener than you are from an e-cigarette," Kershaw said. Exposure to diesel fuel fumes and other environmental air pollutants is harmful, he noted.

Safety debated

Dr. Robert Jackler, a professor at the Stanford School of Medicine and researcher on the hazards and marketing of tobacco who was not involved in the study, said he also doesn't want e-cigarettes to go away because the devices could be useful to help people transition from regular cigarettes.

But until the science is better known, he said, e-cigarettes should be treated the same as regular cigarettes when it comes to public use and marketing.

"The burden should be proving it's safe," he said, "not that it's unsafe after hurting hundreds of thousands of people."

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Some Good News for the E-Cig Industry: Vaping Can Help Smokers Quit

By John Tozzi May 21, 2014

The e-cigarette industry got some good news this week: A survey of almost 6,000 smokers in Britain trying to quit found that those who used electronic cigarettes were more likely to stop using smoking tobacco than those who used over-the-counter quitting aids or had no help at all.

The study, accepted by the journal *Addiction* and published online Tuesday, comes as U.S. regulators weigh new rules for nicotine vaporizers. The e-cig industry and public health officials are battling over whether the devices should be treated as less-harmful cigarettes that help smokers give up tobacco or as a gateway that will lead adolescents to a deadly habit. Investigators from a cancer research center at the University College London conducted the study, which was partially funded with government and drug industry grants. None of the authors reported financial ties to e-cigarette companies, which adds to the report's credibility.

The latest analysis drew on surveys of British households from 2009 to 2014 and counted smokers who had tried to quit within the past 12 months. A majority used no help, about one-third tried over-the-counter aids, such as nicotine patches or gums, and 8 percent used e-cigarettes. The study excluded people who used prescription medicines or counseling to quit smoking, as well as those who used both e-cigs and nicotine replacement. E-cig users were more likely to have stopped smoking tobacco by the time of the survey than either of the other groups.

While surely welcome news for fans of vaping, these survey results are not the kind of evidence that proves e-cigarettes are effective quitting aids and would let the industry market them as such. For that, regulators want to see rigorous, randomized control trials that compare e-cigs with placebo treatments. E-cigarettes are also an evolving technology, with varying formulas and designs that may have different effects on users. And the research doesn't address whether smokers relapse more when using e-cigs than other quitting methods.

Scientists also haven't established what risks e-cigarettes might pose to long-term users. It's impossible to know how these products will affect people over decades, because the products are less than 10 years old. Other risks associated with e-cig use: They occasionally explode, and children or pets may accidentally consume the poisonous liquid if it's left unsecured.

While vaping is widely believed to be safer than inhaling tobacco smoke, it's "not safer than just breathing clean air," as Dr. Richard Hurt, former director of the Mayo Clinic's Nicotine Dependence Center, said in a recent interview. Other research in the U.S. suggests that smokers' perception that e-cigarettes are less harmful is declining.

Still, many people report anecdotally that e-cigs help them trade a habit known to be deadly for one

presumed to be less dangerous, even when other approaches failed. To the extent that e-cigs help people quit inhaling tobacco, the study says, "e-cigarettes may substantially improve public health because of their widespread appeal and the huge health gains associated with stopping smoking."



Tozzi is a reporter for *Bloomberg Businessweek* in New York.

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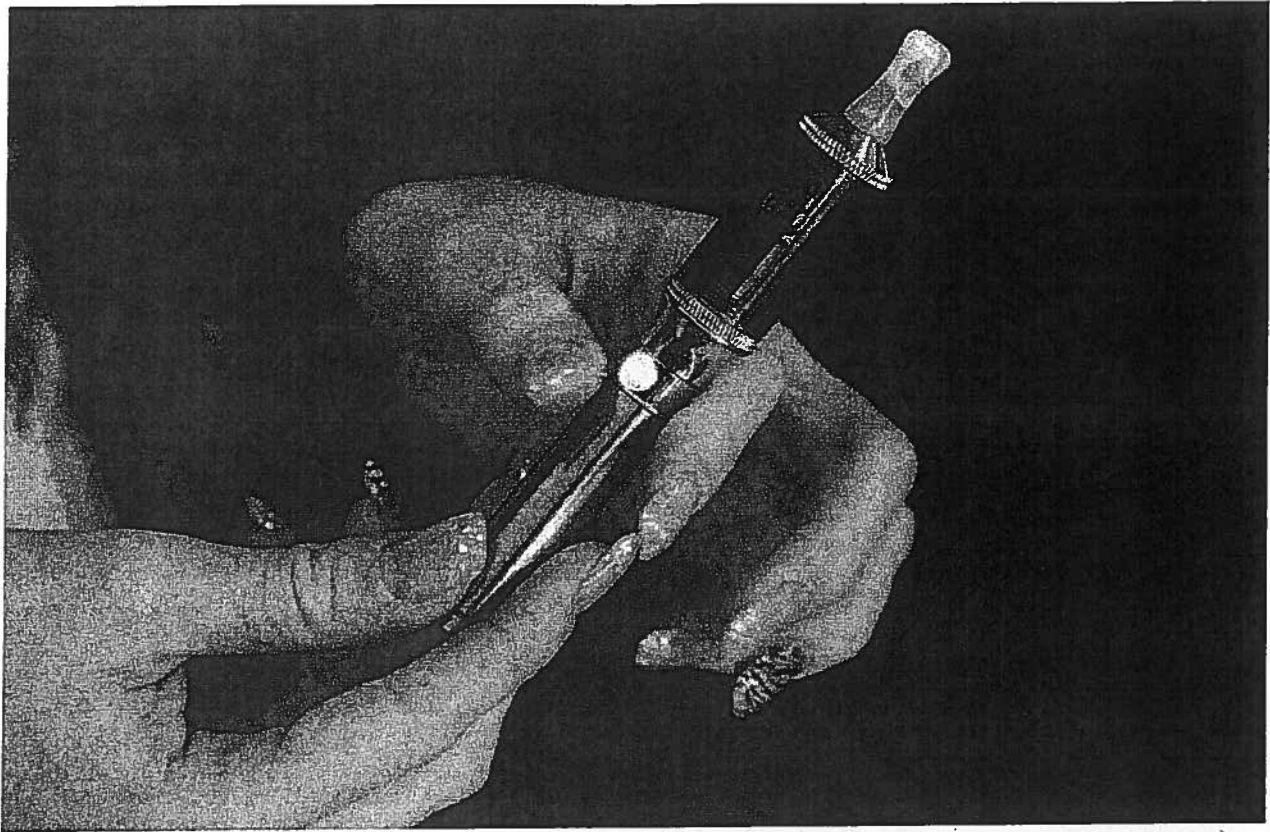
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DAILY DOSE

Evidence builds that e-cigarettes help smokers quit

By Deborah Kotz | GLOBE STAFF MAY 21, 2014



AP / CHATTANOOGA TIMES FREE PRESS, DAN HENRY

Store manager Jessica Tyron held her e-cigarette while waiting for a customer at Sweet Creek Vapors in East Ridge, Tenn.

As a health reporter, I hate covering flip-flopping studies like a March finding that electronic cigarettes don't help smokers quit and a new British study finding that they do. Here's the simple explanation for the conflicting findings: The first study that found e-cigarettes were useless for quitting did not look specifically at those who were actually trying to stop smoking — while the more recent study finding did.

It surveyed 5,863 smokers between 2009 and 2014 who had made a serious attempt to quit over the past year using either e-cigarettes — which have battery-operated cartridges to heat liquid nicotine that's inhaled as a vapor — or over-the-counter cessation aids like nicotine patches, gum or lozenges, or nothing at all to help them quit. The study found that e-cigarette users were 60 percent more likely to have been successful in their quitting efforts compared to those in the other two groups; the researchers took into account income level, nicotine dependence, and other differences between those who used e-cigarettes and those who didn't.

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specifically to help people stop smoking,” said study author Dr Jamie Brown, a senior research associate at University College in London. “The trade-off is we cannot definitively rule out that an unmeasured factor may have influenced the result.”

One clinical trial last year found that e-cigarettes were slightly more effective than nicotine patches for helping smokers quit, while another found that e-cigarettes helped smokers quit regardless of whether they contained nicotine or were placebo devices without any nicotine at all. In both trials, though, fewer than 10 percent of e-cigarette users were able to completely give up smoking tobacco cigarettes by the end of the studies.

In Brown’s population study, nearly 20 percent of the e-cigarette users reported that they were no longer smoking regular cigarettes more than six months after they quit compared to 8 percent of those who used an over-the-counter product and 17 percent who used nothing at all.

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“This finding suggests that there’s a reason to be cautiously optimistic about the effects that e-cigarettes may be having on helping smokers quit,” Brown said. It could be that many find their tobacco cravings are more easily overcome when they mimic the habit of lighting up and puffing.

Still, he added, more studies would help clarify how effective the trendy vapor devices really are for smoking cessation.

There's been a lot more research on the effectiveness of other methods like behavioral counseling with a medical professional or prescription medications approved to help smokers quit like Chantix (varenicline) and Zyban (bupropion). Both of these are more effective than over-the-counter nicotine aids, according to Brown, but whether these are better than e-cigarettes aren't known. His study excluded those who tried to quit using either professional help or prescription medications.

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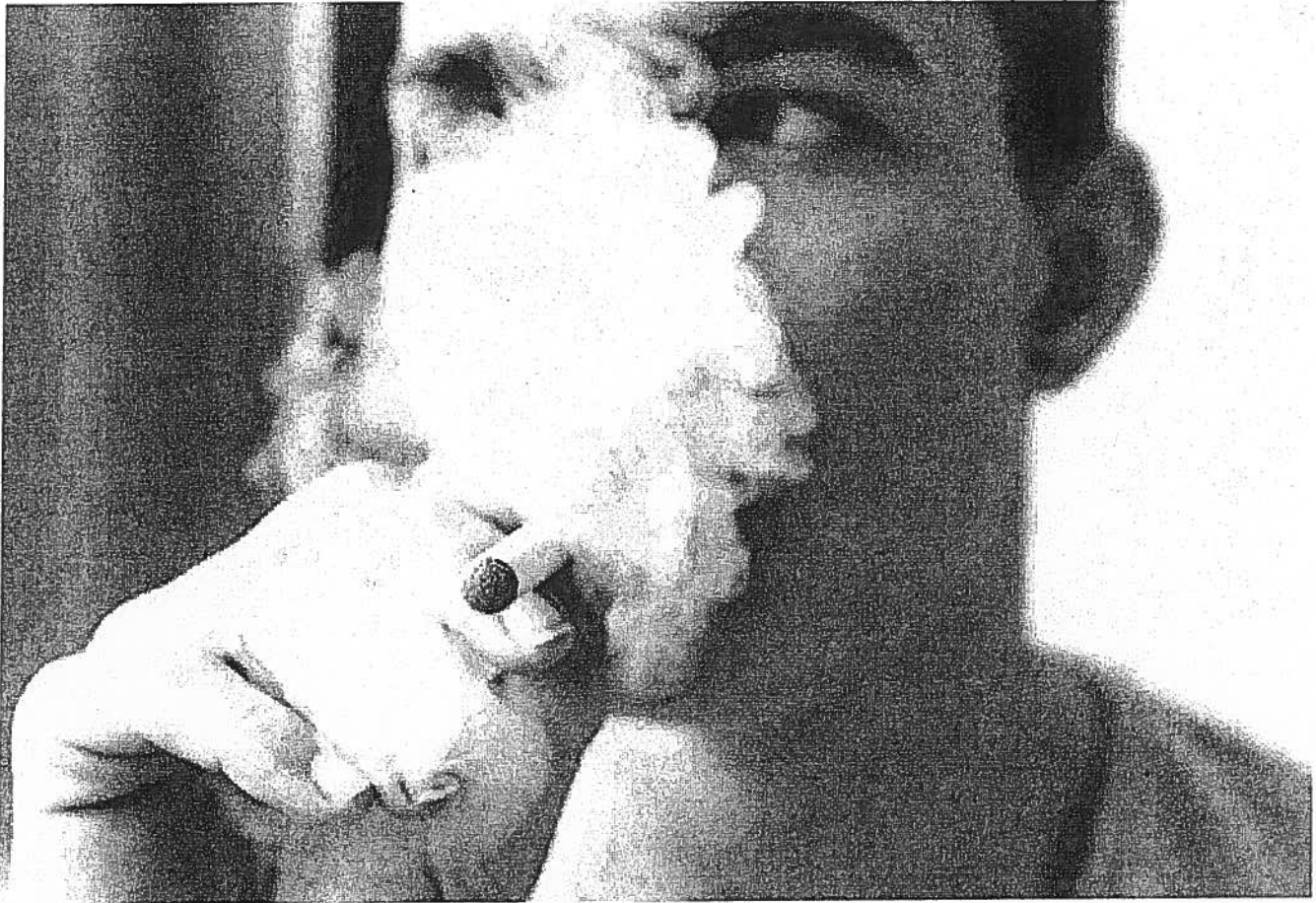
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Use Common Sense on E-Cigarettes

Why the FDA should not regulate e-cigarettes as tobacco products.



Research shows these might help you quit smoking.

By Gregory Conley

July 30, 2014 | 8:00 a.m. EDT

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The Food and Drug Administration's Center for Tobacco Products has two goals that seem to go hand-in-hand: Reduce tobacco use, and reduce the number of smoking-related diseases and deaths. If there was a product that was achieving both goals, why would the FDA take the nonsensical step of classifying it as a tobacco product?

It shouldn't. Yet, that is exactly what the FDA is proposing to do.

The FDA is pushing a new set of rules that would classify e-cigarettes, which are non-combustible products that use no tobacco, as tobacco products. If approved, the rules would stifle a fast-growing, U.S.-based industry that makes one of the most effective methods of helping people to stop smoking. The rules would also snuff out thousands of independent,

family-owned businesses and, in effect, turn over the e-cigarette business to big tobacco companies.

Recent research shows that e-cigarettes – battery-powered devices that heat a liquid nicotine solution and create an inhalable vapor – work exceptionally well to help people kick the smoking habit, better than patches, gum or any other smoking-cessation methods.

[SEE: Political Cartoons]

A 2014 study in England published in the medical journal *Addiction* surveyed 6,000 smokers who tried to quit. Among the respondents that had used e-cigarettes in their most recent quit attempt, 20 percent had successfully broken their tobacco habit. In contrast, less success was had by those who quit without help (15 percent) and those who used nicotine-replacement therapy such as gum or a patch (10 percent).

Similar reports are beginning to emerge from U.S. research institutions. Just last month, the *American Journal of Preventive Medicine* released a study of 2,136 current and former smokers. The study found that former smokers were nearly three times as likely to be regular users of e-cigarettes than current every day smokers, a finding that suggests that smokers often use e-cigarettes to stop smoking. Moreover, these results rebut the oft-used argument of e-cigarette critics that the devices, rather than helping smokers quit, simply lead smokers to use both cigarettes and e-cigarettes.

E-cigarettes are a disruptive technology that have enjoyed incredibly fast consumer uptake, much like Uber and Lyft in the transportation realm. As with other such technologies, e-cigarettes don't neatly fit into regulatory niches. The federal government is struggling to understand how to regulate e-cigarettes and, sadly, is on the verge of making a harmful first step with the FDA's proposed rules.

If FDA's rules are approved, e-cigarettes would face the same regulations as cigarettes, which are the leading cause of preventable death in the U.S., according to the Centers for Disease Control and Prevention. By dramatically reducing the number of e-cigarette products on the market and stifling innovation, the FDA's proposals would serve as a barrier to keep adult smokers from using e-cigarettes, taking away one of the best tools they have for quitting smoking.

[SEE: Cartoons about the Republican Party]

Big Tobacco can afford to comply with the regulations FDA is considering, but not the many smaller e-cigarette companies that have emerged and grown over the past five years. The members of the American Vaping Association, which represents U.S.-based, family-owned-and-operated e-cigarette manufacturers, would be hard pressed to meet FDA's requirements. The rules, in short, would needlessly drive these companies out of business and reduce the e-cigarette options for smokers who want to quit.

The e-cigarette industry supports smart, reasonable regulation, such as a ban on sales to minors. We also back legislation by Sen. Tom Harkin, D-Iowa, that would require childproof packaging for liquids used in e-cigarettes. And surely e-cigarettes must pass regulatory scrutiny of some kind, but not the extra-rigorous demands imposed on products like cigarettes that actually kill people.

We understand that the rapid acceptance of e-cigarettes by the public has outpaced federal and state regulations and the industry looks forward to working with lawmakers and regulators to create common-sense rules. But e-cigarettes are not tobacco products and should not be regulated as such. E-cigarettes are a boon for public health because they help smokers quit using cigarettes, thereby reducing tobacco-related diseases and deaths. The FDA and Congress should recognize this and propose an alternate regulatory pathway.

The E-Cigarette Gateway Myth

The evidence is lacking that people who use them go on to become addicted to cigarette smoking.

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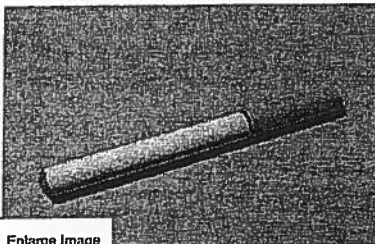
By MICHAEL B. SIEGEL

Aug. 5, 2014 8:05 p.m. ET

Fifty years after the Surgeon General's landmark report on smoking and health, cigarettes remain the leading preventable cause of death in the U.S., and some 40 million Americans still smoke.

Enter the electronic cigarette, which has enormous potential to improve public health because many smokers can replace the deadly cigarettes that burn tobacco, producing tens of thousands of toxins, including more than 60 known human carcinogens. The e-cigarette is a battery-powered, smoke-free device that delivers nicotine vapor without most of the carcinogens produced by tobacco combustion. Yet it is feared and stigmatized by legislators and health officials, and may even be regulated out of existence.

One reason is the so-called gateway theory, which has been the subject of newspaper headlines and city council meetings, and even prompted a Senate investigation. Last September, in an [interview](#) with Medscape (a website for medical professionals) [Thomas Frieden](#), director of the Centers for Disease Control and Prevention said that "many kids are starting out with e-cigarettes and then going on to smoke conventional cigarettes." The same month he was [quoted](#) by the Associated Press as warning that e-cigarettes are "condemning many kids to struggling with a lifelong addiction to nicotine."



Enlarge Image

E-cigarette *Getty Images*

The gateway hypothesis is a myth. The evidence shows that very few nonsmokers "vape." The primary reason people use e-cigarettes is to quit or cut back on smoking conventional cigarettes. Moreover, of the few nonsmoking youths who do experiment with e-cigarettes, there is currently no evidence that they subsequently progress to cigarette smoking.

The first study to examine the gateway hypothesis was by Dr. Ted Wagener from the University of Oklahoma Health Sciences Center. His [research](#), presented at the annual meeting of the American Association for Cancer Research last October, found only one young person out of a sample of 1,300 college students who initiated nicotine use with vapor products and then went on to smoke cigarettes.

In June, Dr. Constantine Vardavas of the Harvard School of Public Health published a broader [analysis](#) of 26,566 European smokers in the journal *Tobacco Control*. It showed that e-cigarette users are likely to be heavy smokers who have tried to kick the cigarette habit over the prior year. Dr. Vardavas and his two colleagues found that just 1% of nonsmokers tried vaporizing products like e-cigarettes.

Cigarette smoking among young people, whom public-health experts are rightfully focused on protecting from use of either type of product, continues to decline. The CDC's National Youth Risk Behavior Survey shows that teenage smoking has

dropped over the last several years, falling to 15.7% in 2013 from 18.1% in 2011. The smoking rate among U.S. high-school students in 2013 was the lowest level since the survey began in 1991. Meanwhile, experimentation with e-cigarettes among high-school students doubled from 2011 to 2012.

Recent data from the U.K. confirm the same phenomenon. Despite a dramatic increase in e-cigarette experimentation among young people, smoking rates in England in 2013 reached a historic low, according to a report from the U.K.'s Health and Social Care Information Centre.

By promoting a message that flies in the face of the government's own statistics—which show a sharp decline in youth smoking concurrent with a dramatic increase in e-cigarette experimentation—some federal public-health officials appear to be trying to create a "gateway" narrative where none exists.

The government has an obligation to carefully scrutinize any new consumer product that is presented as an alternative to smoking. But government agencies and public-health officials have no business discouraging or disparaging e-cigarettes in the absence of any data that they are causing harm. This is especially the case when these products have so much potential to curb cigarette smoking, the public health scourge that still claims half a million lives a year.

Dr. Siegel is a professor at Boston University's School of Public Health. He has 25 years of experience in tobacco control, including two years at the Centers for Disease Control and Prevention.

American Heart Association supports e-cigarettes for quitting tobacco

AHA says e-cigarettes a 'reasonable' way to quit smoking, but only as a last resort; calls for ban on sales to minors

August 25, 2014 3:15PM ET

by **Marisa Taylor** @marisahtaylor

The American Heart Association circulated its official policy recommendation on electronic cigarettes Monday, saying that e-cigarettes can be used to quit smoking tobacco, but only as a last resort.

The association added that electronic cigarettes should be regulated in the same way as tobacco products, meaning stricter advertising restrictions and a ban on selling to minors. "We also support the inclusion of e-cigarettes in smoke-free air laws," it said in its position paper, published in the journal *Circulation*.

"Recent studies raise concerns that e-cigarettes may be a gateway to traditional tobacco products for the nation's youth and could renormalize smoking in our society," Nancy Brown, chief executive officer of the American Heart Association, said in a news release. "These disturbing developments have helped convince the association that e-cigarettes need to be strongly regulated, thoroughly researched and closely monitored."

The heart association said evidence that e-cigarettes help smokers quit is "sparse." They cited the few controlled studies and said they showed a "modest effect" on quitting, about equal to or slightly better than nicotine patches.

If a patient has "failed initial treatment" or does not want to use other means such as nicotine patches, "it is reasonable to support the attempt" of using e-cigarettes, the association said. It added that patients should be told that e-cigarettes, while far less toxic than tobacco cigarettes, are unregulated and "have not been proven as cessation devices."

Electronic cigarettes are battery-powered devices that use an atomizer to heat a nicotine-laced solution into a vapor for the smoker to inhale, or "vape," as users have dubbed it.

After first entering the United States in 2007 from Asia, their popularity has exploded into an estimated \$2 billion in global e-cigarette sales, according to consumer analysis firm Euromonitor International.

As a relatively new product, e-cigarettes do not face the same stringent regulations that were eventually placed on tobacco products after scientists linked them to cancer and heart disease. While traditional cigarettes are banned from TV ads, cannot be sold to minors and come with warning labels, e-cigarettes are hawked on television by celebrities as alternatives to regular cigarettes.

The World Health Organization warned last year that the safety of e-cigarettes has not been scientifically demonstrated. It said it is reviewing the existing research and will come up with an updated conclusion later this year.

The U.S. Food and Drug Administration in 2011 announced its intent to regulate e-cigarettes the same way it does tobacco products, and in April proposed a rule that makers of new e-cigarette brands would be subject to tobacco regulation. Some U.S. cities including New York have banned e-cigarettes indoors and in parks, and the Department of Transportation has banned them on planes.

Most experts agree that e-cigarettes should be more heavily regulated, but they are divided as to the devices' potential effectiveness in helping people quit. While some experts cite the many fans of e-cigarettes who have reported quitting tobacco, others fear it could help normalize smoking again.

"We have to look at the science, and what the science tells us is that there are many, many smokers who say they are a very effective method for actually getting them to quit smoking," said Dr. Michael Siegel, a professor of community health sciences at Boston University's School of Public Health. "There are literally thousands of ex-smokers out there who have quit using electronic cigarettes, many of them who did not think they would be successful."

The major benefit, Siegel said, is that unlike nicotine patches, e-cigarettes actually simulate the smoking of a cigarette — but he thinks that aspect is what fuels their detractors. "There's no reason we should exclude them or not recommend them simply because we're fearful of them because they look like cigarettes," he said. "The fact is, that's what makes them so effective."

But the Centers for Disease Control has cautioned that electronic cigarettes could function as a "gateway" to smoking. On Monday, it released new data showing that a quarter-million U.S. middle and high school kids who had never smoked a cigarette had smoked e-cigarettes in 2013, triple the number who said the same in 2011, according to its annual National Youth Tobacco Surveys.

But according to Maciej Goniewicz, an oncology professor at the Roswell Park Cancer Institute in Buffalo, N.Y. who has studied the ingredients and teenage use patterns of e-cigarettes, the gateway theory has not been clearly established.

While he admits that electronic cigarettes are becoming more and more popular, and are certainly very visible to kids and teens, "I'm not sure if we can clearly say this is a gateway" to regular tobacco smoking, he said. "Right now, I'd say there is a danger, or some evidence, and I think we have to be very careful."

"Right now we are gaining more and more evidence that [e-cigarettes] might be a problem," he added. "But we still don't have a clear link between the electronic cigarettes and the initiation of smoking."

BUSINESS

World Health Organization Calls for Tougher Rules on E-Cigarettes

UN Agency Also Concerned by Expanding Role of Major Tobacco Companies in the Fast-Growing Market

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By MIKE ESTERL in Atlanta And PETER EVANS in London **CONNECT**

Updated Aug. 26, 2014 2:14 p.m. ET



Armando Peruga, left, and Douglas Bettcher of the World Health Organization speak about the UN agency's recommended limits on electronic cigarettes in Geneva on Tuesday. *Pierre Albouy/REUTERS*

The World Health Organization on Tuesday called for tougher restrictions on electronic cigarettes, including curbs on advertising, indoor use and such flavors as fruit and candy.

The United Nations agency also voiced "grave concern" at the expanding role of major tobacco companies in the small but fast-growing market for the battery-powered devices that heat nicotine-laced liquid into vapor, warning they could increase tobacco use.

The WHO's critical report, its most detailed assessment yet of e-cigarettes, could heighten pressure in several countries to regulate the gadgets more like regular cigarettes. E-cigarettes are believed to be less harmful than regular cigarettes, which release toxins through combustion, but critics warn enough isn't known yet about their health impact and that they could addict a new generation to nicotine.

The report will be discussed at an October meeting of the WHO Framework Convention on Tobacco Control. The treaty, which aims to clamp down on cigarettes and tobacco use, has been signed by nearly 180 countries since entering force in 2005.

Countries that have ratified the treaty are expected to implement its measures, which

are reached through consensus at WHO conferences held every two years. But its recommendations aren't legally binding and a handful of countries, most notably the U.S., haven't ratified the treaty.

The U.S. Food and Drug Administration proposed in April that e-cigarettes be banned to those under 18 years of age and include health warning labels, but final rules are still months or even years away. The European Union has proposed curbs, including some on advertising, slated to go into effect in 2016.

Geneva-based WHO said at least 59 countries already regulate e-cigarettes, which it estimated represents a \$3 billion industry globally. Current restrictions include advertising and sponsorship bans in 39 countries and prohibiting their use in enclosed public spaces in 30 countries.

The global health agency said in its report that e-cigarettes are "likely to be less toxic" than combustible cigarettes but that the amount of risk reduction remains unknown. It added that nicotine vapor products still pose serious health threats to adolescents and fetuses, in addition to exposing bystanders to nicotine and toxicants.

It recommended governments should prohibit e-cigarette manufacturers from making health claims, including marketing the devices as smoking-cessation aids, until they produce scientific evidence. It also recommended banning e-cigarettes in public indoor areas and restricting advertising, promotion and sponsorships.

Governments should also require health warnings on e-cigarettes, including the potential for nicotine addiction and respiratory irritation, and prohibit their sale to minors, according to the WHO. It recommended a ban on e-cigarettes with fruit, candy and alcohol flavors until they're proven to not attract youth.

"E-cigarettes have been marketed in almost 8,000 flavors, and there is concern they will serve as a gateway to nicotine addiction and, ultimately, smoking, particularly for young people," the agency warned.

WHO said it is also worried about the growing clout of transnational tobacco companies after the e-cigarette industry was initially dominated by companies that didn't sell regular cigarettes or other tobacco products.

"The tobacco industry has a history of deception when using harm-reduction marketing ploys to promote tobacco products with the pretense of being less harmful," Douglas Bettcher, director of the WHO's Department for the Prevention of Noncommunicable Diseases, said Tuesday at a news conference in Geneva.

Philip Morris International Inc., **PM +0.90%** the largest cigarette company by volume after China's state-owned China National Tobacco Corp., said in a statement Tuesday that "the WHO has once again called for de facto exclusion of tobacco companies in the democratic process."

"This view ignores the fact that product innovation to develop and assess truly reduced risk alternatives to combustible cigarettes can play an important role for public health, and companies like ours are not only driving this innovation, but have the necessary knowledge and resources to contribute to achieving that goal," it said.

Philip Morris and Altria Group Inc., **MO -0.22%** the largest cigarette seller in the U.S., announced a partnership in December giving Philip Morris exclusive rights to sell Altria's e-cigarettes outside the U.S.

U.K.-listed British American Tobacco **BATS.LN -0.57%** PLC and Imperial Tobacco Group **IMT.LN +0.91%** PLC, two of the world's biggest cigarette makers, are also among the companies that have made big plays in e-cigarettes in recent months.

Imperial is planning an international push for Lorillard Inc. **LO -0.71%**'s Blu, America's top-selling e-cigarette brand, which it last month agreed to buy from Reynolds American Inc. **RAI +0.60%** after Reynolds buys Lorillard. Imperial

said last week it expects that deal to complete in 2015.

Imperial launched Puritane, its first e-cigarette, in Britain earlier this year through a subsidiary it calls Fontem Ventures. "We welcome the push for higher standards in the industry. But it is illogical to recommend a premature ban on smoking e-cigarettes indoors," said a Fontem spokesman.

British American Tobacco plans to launch a new version of Vype, its e-cigarette brand, later this month. The company said "overly restrictive regulations" would hamper the growth of e-cigarettes and have a negative effect on public health. "Allowing the products to be used by adult smokers looking for a choice will be crucial to the category's future success," said a British American spokesman.

Altria and Reynolds American, which together sell about three in four cigarettes in the U.S., began national launches of e-cigarettes earlier this summer. Altria, maker of Marlboro cigarettes, is rolling out MarkTen e-cigarettes. Reynolds, which sells Camel and Pall Mall cigarettes, is marketing Vuse e-cigarettes.

Write to Mike Esterl at mike.esterl@wsj.com and Peter Evans at peter.evans@wsj.com



USC News

Health Science/Technology

E-cigarette smoke found to contain toxic metals

USC researchers and colleagues discover chromium and nickel at levels unseen in traditional cigarettes



by Robert Perkins

August 28, 2014

E-cigarettes are healthier for your neighbors than traditional cigarettes, but still release toxins into the air, according to a new study from USC.

Scientists studying secondhand smoke from e-cigarettes discovered an overall 10-fold decrease in exposure to harmful particles, with close-to-zero exposure to organic carcinogens. However, levels of exposure to some harmful metals in secondhand e-cigarette smoke were found to be significantly higher.

Constantinos Sioutas

While tobacco smoke contains high levels of polycyclic aromatic hydrocarbons — cancer-causing organic compounds — the level of exposure to these substances was reduced to almost zero in secondhand e-cigarette smoke, due to the fact that they do not burn organic material the way old-fashioned cigarettes do.

However, despite the lack of harmful organic material and a decrease in the majority of toxic metals emissions, e-cigarette smoke contains the toxic element chromium, absent from traditional cigarettes, as well as nickel at levels four times higher than normal cigarettes. In addition, several other toxic metals such as lead and zinc were also found in secondhand e-cigarette smoke, though in concentrations lower than for normal cigarettes.

“Our results demonstrate that overall electronic cigarettes seem to be less harmful than regular cigarettes, but their elevated content of toxic metals such as nickel and chromium do raise concerns,” said Constantinos Sioutas, professor at the USC Viterbi School of Engineering and corresponding author of the study, which was published online on Aug. 22 by the Journal of Environmental Science, Processes and Impacts

<http://pubs.rsc.org/en/content/articlehtml/2014/em/c4em00415a>].

Harmful organics and metals

Sioutas and his colleagues at Fondazione IRCCS Istituto Nazionale dei Tumori (National Institute of Cancer Research) in Milan, Italy, began this study with the goal of quantifying the level of exposure to harmful organics and metals in secondhand e-cigarette smoke, in hopes of providing insight for the regulatory authorities.

“The metal particles likely come from the cartridge of the e-cigarette devices themselves, which opens up the possibility that better manufacturing standards for the devices could reduce the quantity of metals in the smoke,” said Arian Saffari, a Ph.D. student at USC Viterbi and lead author of the paper. “Studies of this kind are necessary for implementing effective regulatory measures. E-cigarettes are so new, there just isn’t much research available on them yet.”

For this study, the researchers conducted all of the experiments in offices and rooms. While volunteer subjects were smoking regular cigarettes and e-cigarettes, the researchers collected particles in the indoor air and studied the chemical content and sources of the samples.

“Offices and rooms — not laboratories — are the environments where you’re likely to be exposed to secondhand e-cigarette smoke, so we did our testing there to better simulate real-life exposure conditions,” Saffari said.

Sioutas and Saffari compared the smoke from a common traditional cigarette brand with smoke from an Elips Serie C e-cigarette, one of the most popular European brands. The results could vary based on which type of cigarettes and e-cigarettes are tested, the researchers noted.

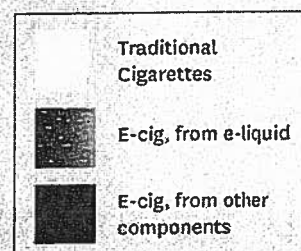
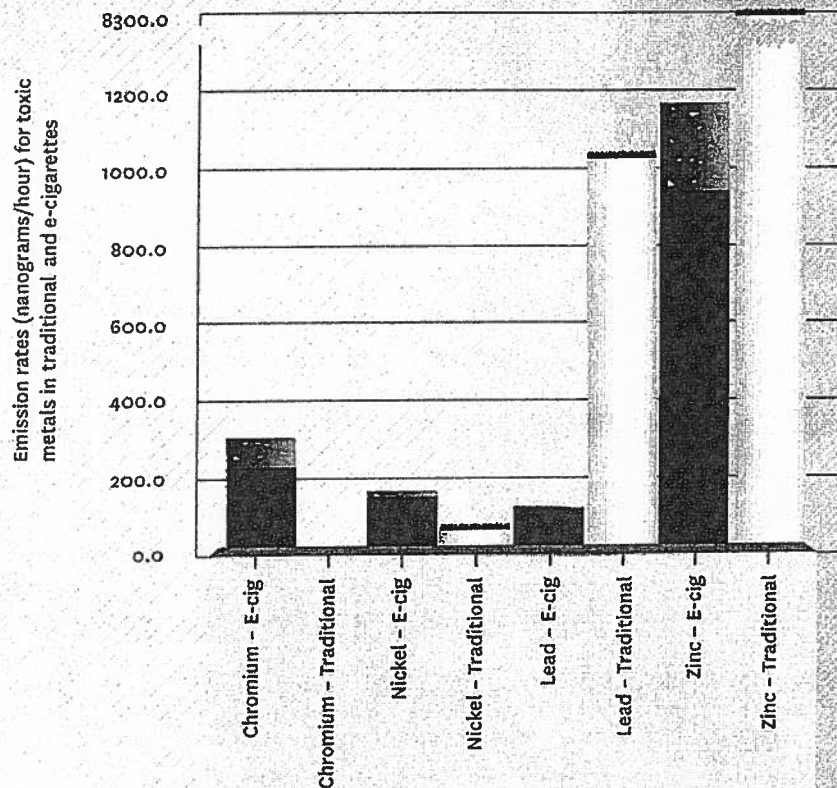
Sioutas and Saffari collaborated with researchers from LARS Laboratorio and the Fondazione IRCCS Istituto, as well as the University of Wisconsin-Madison and Cornell University.

Financial support for the study was provided by the Fondazione IRCCS Istituto.

Second-Hand Smoke: Toxic Heavy Metals in E-Cigarettes and Traditional Cigarettes

Despite a 10-fold decrease in overall exposure to carcinogenic particulate matter, researchers have found increased levels of certain toxic metals in e-cigarette second-hand smoke. **E-cigarette smoke contains the toxic element chromium, absent from traditional cigarettes, as well as nickel at levels four times higher than traditional cigarettes.** Several other toxic metals such as lead and zinc were also found in second-hand e-cigarette smoke – though in concentrations lower than traditional cigarettes.

Furthermore, researchers found that **much of the toxic metals did not come from the e-cigarette liquid, but most likely from the cartridge.** Therefore, better manufacturing standards for the devices could reduce the quantity of metals in e-cigarette smoke.



This data is from a study published in *Environmental Science, Processes and Impacts* (August 22, 2014) by the USC Viterbi School of Engineering, University of Wisconsin-Madison's Environmental Chemistry and Technology Program, and Cornell University's School of Mechanical and Aerospace Engineering in the United States, as well as the LARS Laboratorio di Ricerca Ambientale SIMG/ISDE and the Fondazione IRCCS Istituto Nazionale dei Tumori (National Institute of Cancer Research) Tobacco Control Unit in Milan, Italy.



Allow use of electronic cigarettes to assess risk

Monitoring the outcomes of incentivized e-cigarette use, not endless research, will be the key to sensible regulation, says Daniel Sarewitz.

Electronic cigarettes are growing rapidly in popularity. In the United States they remain unregulated, but 8 August marked the end of the public comment period on a proposal by the US Food and Drug Administration (FDA) that would bring e-cigarettes under its authority. Now the FDA must act.

That action must be based on science. The FDA's background document explains: "We do not currently have sufficient data about these products to determine what effects e-cigarettes have on the public health." Only if e-cigarettes are deemed a tobacco product, as under the proposal, can the agency begin to collect the data that can permit it to "account for the net public health impacts". On the basis of this assessment, the FDA can decide how to craft regulations to protect and improve public health.

When it comes to the direct impact of these devices on public health, the tenor of the FDA's language, and of comments from many relevant organizations, is precautionary. The American Cancer Society (ACS) says: "Until electronic cigarettes are scientifically proven to be safe and effective, ACS will support the regulation of e-cigarettes and laws that treat them like all other tobacco products." The Forum of International Respiratory Societies goes further, saying that the risks of e-cigarettes have not been adequately studied and as a precaution, such devices "should be restricted or banned until more information about their safety is available". A group of 29 state attorneys general sent a 33-page letter to the FDA arguing that "e-cigarettes contain and deliver nicotine — a well-recognized addictive chemical — in amounts comparable to traditional cigarettes. Accordingly, e-cigarettes should be assumed to be both harmful and addictive."

Bollocks. Let's do a thought experiment. Imagine that every smoker in the United States changed to e-cigarettes. What would be the consequences? An e-cigarette, in essence, allows you to be addicted to nicotine (which is not carcinogenic), and to enjoy the tactile pleasures of smoking without exposing yourself to the 60 or more cancer-causing agents, or to most of the hundreds of other toxic chemicals, that are released from burning tobacco. If all US smokers 'vaped' (the verb coined to distinguish inhaling e-cigarette vapours from inhaling tobacco smoke) instead of smoked, about 480,000 deaths might eventually be avoided per year. We may never approach such a full transition, but the point is that the causal relationship between inhaling tobacco smoke and dying from cancer and other diseases is very robust.

How many people would e-cigarettes kill instead? Evidence of the effects of widespread vaping is limited and contradictory. Some studies show that e-cigarettes can wean people from smoking, others suggest that the effect is, at best,

modest and short-lived. Still others suggest that anything that makes vaping seem desirable might coax non-smokers to smoke.

Unanticipated potential risks are being discovered and debated. Studies have shown that e-cigarette vapour includes various fine particulates, some of which are toxic; other research indicates that exposure levels are too low to be dangerous. More science will expand the evidence and the potential risks, but as complexities and questions emerge it will also increase, rather than reduce, the contradictions and uncertainties. The extraordinary difficulty of demonstrating the benefits of salt reduction, mammography, or various diets, for example, ought to serve as cautionary lessons. Given the millions who will die from smoking in the near future, does it make sense to spend years discovering, characterizing and debating ancillary risks of vaping that are almost certainly less serious than the known risks of smoking as a precondition for responsible policy-making? This is precaution?

E-cigarettes must be regulated. Ingredients should be labelled. No responsible voices would allow them to be sold to children. Such requirements are already in force in the European Union. The more important question is whether regulation should be driven by the risks of e-cigarette use, or by the risks of not using them. The former promises endless research, uncertainty, and debate; the latter may offer a technological short-cut to solving one of the world's most serious public-health problems.

No one knows to what extent vaping will displace smoking, but the sure way never to find out is to make policies hostage to endless studies on population-wide risks. Instead we should

test the effectiveness of policies, perhaps in limited jurisdictions, that encourage vaping among smokers and potential smokers. Keep the tax burden, and thus cost, low relative to cigarettes. Allow advertisements. With George Clooney. Continue to allow vaping in bars, restaurants and workplaces. Make smoking uncool, expensive and stupid, and vaping cool and smart. If people must get addicted to something, let them get addicted to a thing that does not give them or their families cancer. And carefully monitor the outcomes.

As research for this column, I tried vaping. The taste was perfectly pleasant, and my office colleagues said that the white-ish clouds I exhaled had no smell. I am not a smoker, so I cannot rate how the overall experience compares to cigarettes, and I have not vaped enough to recognize any physiological response. But then again, I am already addicted to the pleasures of caffeine, and one costly addiction is enough. ■

Daniel Sarewitz is co-director of the Consortium for Science, Policy and Outcomes at Arizona State University, and is based in Washington DC. e-mail: daniel.sarewitz@asu.edu

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Study: Second-hand smoke from e-cigarettes contains toxic metals

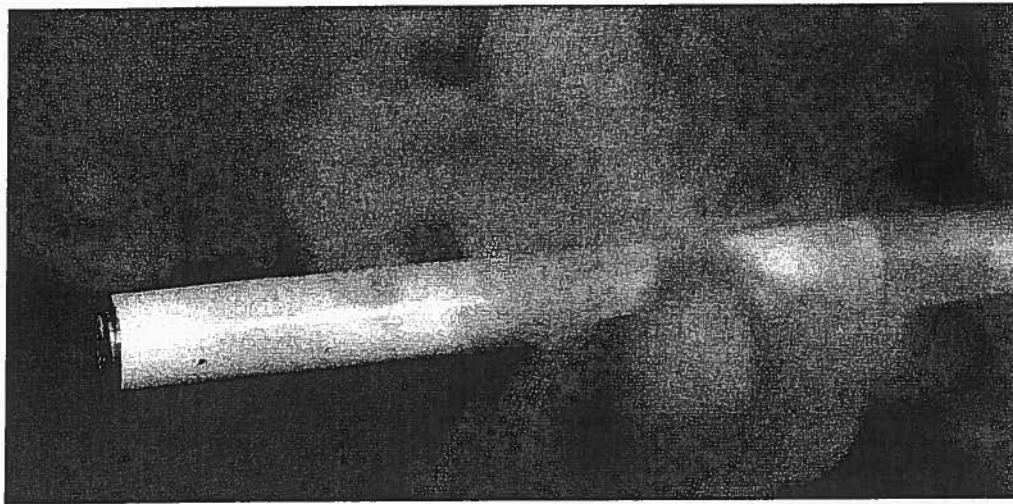
Published August 29, 2014

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REUTERS/Christian Hartmann

Second-hand smoke from electronic cigarettes may be less harmful than their tobacco-laden cousins, but they still release toxins into the air, according to a new study.

For the study, published in the *Journal of Environmental Science, Processes and Impacts*, researchers at the University of Southern California analyzed second-hand smoke from e-cigarettes and found an overall 10-fold decrease in exposure to harmful particles compared to traditional cigarette smoke. However, they did find a significant increase in exposure to some harmful metals coming from e-cigarette smoke.

Second-hand smoke from e-cigarettes also yielded exposure to almost no polycyclic aromatic hydrocarbons — cancer-causing compounds known as organic carcinogens — that are released into the air as tobacco cigarettes burn. But despite having less harmful organic compounds and an overall decrease in toxic metal emissions, e-cigarette smoke did contain chromium and nickel at levels four times higher than tobacco cigarettes. Lead and zinc were also found in the smoke, but they occurred at levels lower than regular cigarettes.

"Our results demonstrate that overall electronic cigarettes seem to be less harmful than regular cigarettes, but their elevated content of toxic metals such as nickel and chromium do raise concerns," said study author Constantinos Sioutas, a professor at the USC Viterbi School of Engineering.

E-cigarettes have come under intense scrutiny recently with the World Health Organization calling for stiff regulations and bans on using the devices indoors. The Centers for Disease Control and Prevention released a report Monday stating that e-cigarettes may be more tempting to non-smoking youths than conventional cigarettes, and once young people have tried e-cigarettes they are more inclined to give regular cigarettes a try.

"The metal particles likely come from the cartridge of the e-cigarette devices themselves — which opens up the possibility that better manufacturing standards for the devices could reduce the quantity of metals in the smoke," said Arian Saffari, a PhD student at USC Viterbi and lead author of the paper. "Studies of this kind are necessary for implementing effective regulatory measures. E-cigarettes are so new, there just isn't much research available on them yet."

The study authors compared the smoke from a common traditional cigarette brand with smoke from an Elips Serie C e-cigarette, one of the most popular European brands. They noted that the results could vary based on which type of cigarettes and e-cigarettes are tested.

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E-cigarettes could be gateway to hard drugs, study finds

A research team went over data stretching back to the mid-1970s in the wake of electronic cigarettes' popularity. Health organizations have recently spoken out about the dangers of e-cigarettes, too.

BY MEREDITH ENGEL [Follow](#) / NEW YORK DAILY NEWS / Wednesday, September 3, 2014, 5:56 PM A A A

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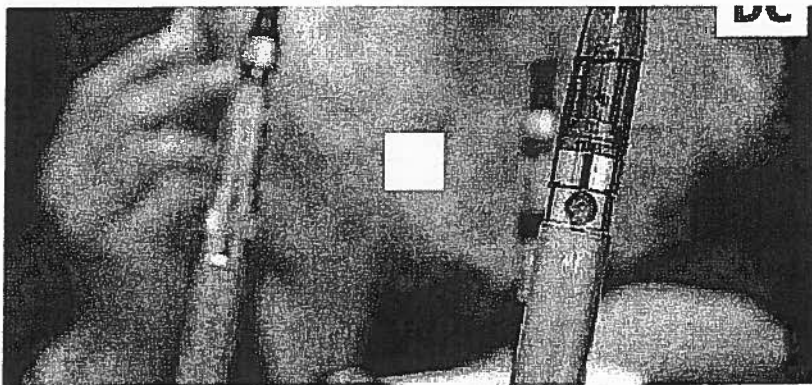
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Nicotine — whether it comes from a traditional or electronic cigarette — could be a gateway drug to marijuana and cocaine, according to a study in the New England Journal of Medicine.

"While e-cigarettes do eliminate some of the health effects associated with combustible tobacco, they are pure nicotine-delivery devices," said co-author Dr. Denise B. Kandel, a professor of sociomedical sciences at Columbia University Medical Center and a research scientist at the New York State Psychiatric Institute.

Kandel and her husband, Eric, also of CUMC, reviewed her research dating back to 1975 that purported nicotine to be a gateway drug. But they weren't sure if that was because nicotine was a readily available drug or because there was something in it that altered other drugs' effects.

To investigate that, they also went over previous studies they did on mice that found that rodents exposed to nicotine had altered brain chemistry and activated genes that deal with rewards. They had given those mice nicotine and found that the cocaine worked at an amplified effect. And it only worked if mice were given nicotine first and cocaine second, not the other way around.

"One drug alters the brain's circuitry in a way that enhances the effects of a subsequent drug," Dr. Eric Kandel said.

Then, Dr. Denise Kandel looked at 2004 data and found that cocaine dependence was highest in users who started the drug while smoking cigarettes. This meshed with her findings that mice exposed to cocaine days after exposure to nicotine didn't show the amped effects of the drug — the nicotine and cocaine use had to be taken within a small window.

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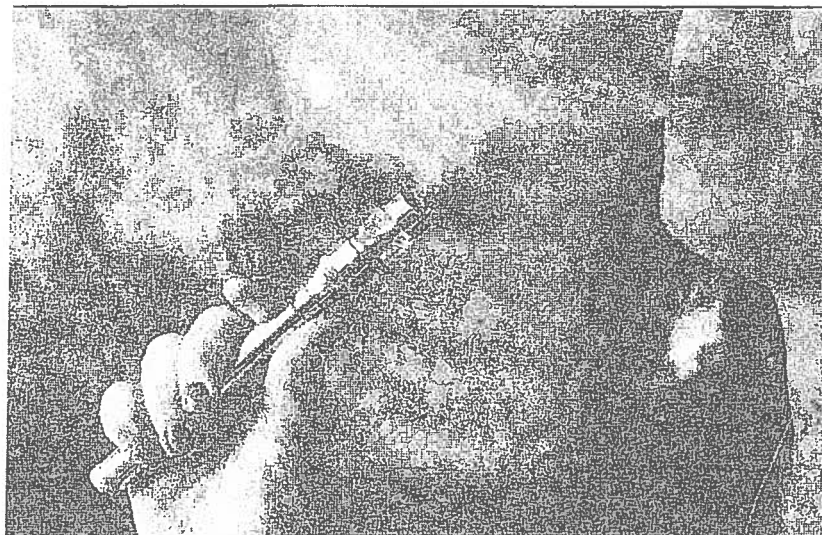


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Columbia University researchers said that the nicotine in e-cigarettes is just as dangerous as that in traditional cigarettes.

The scientists say that e-cigarettes pose the same risks for addiction to nicotine and, as a result, cocaine, as traditional cigarettes, especially during adolescence when the brain is developing.

"Nicotine clearly acts as a gateway drug on the brain, and this effect is likely to occur whether the exposure comes from smoking cigarettes, passive tobacco smoke or e-cigarettes," they said.

This is the latest study to call into question the safety of electronic cigarettes. Recent research showed that they emit toxic metals in the air, and the World Health Organization made recommendations last week calling for the prohibition of indoor smoking and sales and advertising to minors. The American Heart Association, too, issued a statement in August calling for regulations on e-cigarettes.



FREDERIC J. BROWN/AFP/GETTY IMAGES

The creator of the electronic cigarette, Hon Lik, smokes his invention in Beijing in May 2009.

But not everyone agrees with the Kandels' conclusions.

"If their theory was correct, we should have expected a surge in cocaine use associated first with tobacco use and later with nicotine replacement products. In fact, we observe the opposite," Derek Yach, executive director of the Vitality Institute in New York City, which advocates for preventive health, told the Daily News. "Their message might apply to lab rats, but smokers trying to quit should



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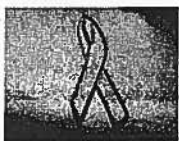
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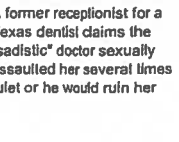
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follow the advice of the Royal College of Physicians and try e-cigs. Their risks of death and disease will decline as they succeed."

David Nutt, professor of neuropsychopharmacology at Imperial College in London, told an online discussion of tobacco scientists, "This is another example of journal press offices making routine studies 'news' by distorting the data interpretation."

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E-cigarette refills pose danger to kids

Updated: Sep 09, 2014 09:25 AM

TUESDAY, Sept. 9, 2014 (HealthDay News) — Nicotine refill cartridges used in e-cigarettes can be opened by young children, putting them at risk for nicotine poisoning, doctors warn.

The safety of the electronic cigarette cartridges must be improved in order to reduce this threat, said the authors of an article published Sept. 9 in the journal *Archives of Disease in Childhood*.

Figures released earlier this year by the U.S. Centers for Disease Control and Prevention show a "massive rise" in calls to poison centers about accidental swallowing of liquid nicotine from e-cigarette refill cartridges, the British researchers noted.

The calls increased from just one in September 2010 to 215 a month by February 2014, and more than half of the calls involved children younger than 5.

In children that young, just a few drops of liquid nicotine can have serious effects, including irregular heartbeat, coma, convulsions and cardiac arrest, the researchers said.

"The exploratory nature of young children and the attractive packaging of refills is a dangerous combination likely to lead to a growing incidence of accidental exposure to concentrated nicotine solution," wrote Dr. Sanjay Gupta, of Good Hope Hospital in Birmingham, and colleagues.

"The risk posed by nicotine liquid to children needs to be recognized, acknowledged and acted upon by all. This includes public education and legislation to improve the safety profile of e-liquid containers," they concluded.

Early signs of accidental nicotine poisoning include: burning in the mouth and throat; nausea and/or vomiting; confusion and dizziness; weakness and excess saliva.

More information

The U.S. National Library of Medicine has more about [nicotine poisoning](#).

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Study of smoking cancer patients fuels e-cigarette debate

Mon, Sep 22 2014

By Kate Kelland

LONDON (Reuters) - The fierce debate over whether e-cigarettes can help people quit smoking took another twist on Monday as a research paper on their use by cancer patients was criticized as flawed.

The study of cancer patients who smoke found that those using e-cigarettes as well as tobacco cigarettes were more nicotine dependent and equally or less likely to have quit than those who didn't use e-cigarettes.

The scientists behind the research, which was published online in *Cancer*, the journal of the American Cancer Society, said their results raised doubts about whether e-cigarettes had any benefit in helping cancer patients to give up smoking.

But that conclusion was questioned by other tobacco and addiction researchers, who said the selection of patients for the study had given it an inherent bias.

The uptake of e-cigarettes, which use battery-powered cartridges to produce a nicotine-laced vapor for the "smoker" to inhale, has rocketed in the past two years, but there is fierce debate about their potential risks and benefits.

Because they are new, there is a lack of long-term scientific evidence on their safety. Some experts fear they could lead to nicotine addiction and be a gateway to tobacco smoking, while others say they have enormous potential to help millions of smokers around the world to quit.

What few studies there are give a mixed picture, with some concluding that e-cigarettes can help people give up a deadly tobacco habit, while others suggest they may carry health risks of their own.

A World Health Organization (WHO) report last month called for stiff regulation of e-cigarettes as well as bans on indoor use, advertising and sales to minors.

But that report itself was also criticized by experts who said it contained errors, misinterpretations and misrepresentations.

For the *Cancer* journal study, researchers led by Jamie Ostroff of the Memorial Sloan Kettering Cancer Center in New York City studied 1,074 cancer patients who smoked and who were enrolled between 2012 and 2013 in a tobacco treatment program at a cancer center.

They found a three-fold increase in e-cigarette use from 2012 to 2013 - rising from 10.6 percent to 38.5 percent.

At enrolment onto the program, the researchers' analysis found, the e-cigarette users were more nicotine dependent than non-users, had more prior quit attempts, and were more likely to be diagnosed with lung or head and neck cancers.

By the end of the study period, the researchers said, e-cigarette users were just as likely as non-users of e-cigarettes to be smoking.

But Robert West, director of tobacco research at University College London, said the study was not able to assess whether or not for cancer patients who smoke using an e-cigarette to try and quit is beneficial "because the sample could consist of e-cigarette users who had already failed in a quit attempt, so all those who would have succeeded already would be ruled out".

Peter Hajek, director of the Tobacco Dependence Research Unit at Queen Mary, University of London, agreed that the study's data did not justify the conclusions.

"The authors followed up smokers who tried e-cigarettes but did not stop smoking, and excluded smokers who tried e-cigarettes and stopped smoking," he said.

"Like smokers who fail with any method, these were highly dependent smokers who found quitting difficult. The authors concluded that e-cigarette (use) was not helpful, but that would be true for any treatment however effective if only treatment failures were evaluated."

(Editing by Mark Potter)



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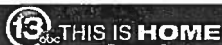


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E-cigarettes don't help cancer patients quit smoking

Updated: Sep 22, 2014 12:30 PM PDT

(HealthDay News) — New research raises doubts about the possible benefits of e-cigarettes for people with cancer.

Smokers with cancer who used e-cigarettes along with traditional cigarettes were more dependent on nicotine than those who didn't use the devices, a Memorial Sloan Kettering study found. These patients were also just as likely — or less likely — to have quit smoking than patients who didn't use e-cigarettes.

The study, published online Sept. 22 in *Cancer*, involved almost 1,100 cancer patients who smoked. Between 2012 and 2013, the patients were enrolled in a tobacco treatment program at a comprehensive cancer center.

During that time, e-cigarette use jumped from nearly 11 percent to 38.5 percent — more than a threefold increase. When the study began, the patients who used e-cigarettes were more dependent on nicotine than those who didn't use them. They also had tried to quit more times in the past and were more likely to be diagnosed with cancers of the lung, head and neck, the study authors found.

During a follow-up, the researchers also found the patients who used e-cigarettes were no less likely than those who didn't to still be smoking.

Although all smokers with cancer should quit, the researchers concluded that questions remain about the long-term safety and effectiveness of e-cigarettes.

"Controlled research is needed to evaluate the potential harms and benefits of e-cigarettes as a potential cessation approach for cancer patients," explained Jamie Ostroff, from the Memorial Sloan Kettering Cancer Center in New York City, in *Journal* news release.

"In the meantime, oncologists should advise all smokers to quit smoking traditional combustible cigarettes, encourage use of FDA-approved cessation medications, refer patients for smoking cessation counseling, and provide education about the potential risks and lack of known benefits of long-term e-cigarette use," Ostroff said.

More information

The U.S. Food and Drug Administration has more about [e-cigarettes](#).

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TECH + HEALTH 09.25.14

DailyBurn

E-Cigarettes: The Side Effects Nobody Talks About

By Amanda Woerner for Life by DailyBurn

These days it's nearly unfathomable to imagine a marathoner crossing the finish line, only to light up cigarette. And even ordinary exercisers may subject themselves to dirty looks if they puff near their gym. But what if they're smoking an e-cigarette?

Introduced to the public as a product with the potential to shield smokers from the dangerous effects of Marlboros, e-cigarettes are marketed as a way to get your nicotine fix without inhaling all that lung-blackening smoke that's been directly linked to cancer and heart disease.

But it turns out e-cigarette vapors may be full of suspected lung irritants, chemicals with addictive properties that could contribute to heart troubles down the road, says Dr. Norman Edelman, senior consultant for scientific affairs at the American Lung Association and a professor of preventive medicine and internal medicine at Stony Brook University on Long Island.

Here's the scoop on how this controversial device could impact your health—and your workouts.

The “Health Halo” Surrounding E-Cigarettes

According to the U.S. Centers for Disease Control and Prevention (CDC), nearly 250,000 youths who had never before smoked tried e-

cigs in 2013 — a threefold increase since 2011. What's more, about three out of every four teen smokers goes on to smoke as an adult, due to their addiction to nicotine (the primary ingredient in e-cigs), according to the CDC.

Young and otherwise healthy people might be reaching for an electronic fix for numerous reasons, including the potential for nicotine to reduce appetite, boost mood or increase their heart rate and alertness.

Nicotine is also a known stimulant, and has been shown in studies to have a positive effect on endurance, according to Dr. Robert E. Sallis, co-director of the Sports Medicine Fellowship at Kaiser Permanente.

"At best it might be described as weakly ergogenic, or performance enhancing," Sallis says. "There are some pretty good studies that show modest improvements in things like time-to-exhaustion, that people perceive that exercise is not as difficult and that it's a little bit of a stimulating effect that wakes you up and prepares you for a competition."

Yet, evidence is emerging indicating that e-cigarette vapors might not be all that innocent.

"We don't know what's in [the e-cigarette vapors], because they are not regulated and the manufacturers are not yet required to tell what's in the solution," Edelman says.

Bad News for Your Lungs

E-cigs may not contain real smoke, but they can still do a number on your lungs. "They do cause an inflammation," Edelman says. "It would be similar to smoking, only less...and you might get a chronic cough, or raise a little [mucus]."

While casual exercisers might not notice any difference in lung capacity,

intense gym-goers might feel the effects of an e-cig. "For people who exercise to the [full] capacity of their lungs, then of course any decrease in lung function will impair your ability to exercise," Edelman says.

Digital smokes have also been called out by the American College of Allergy, Asthma and Immunology (ACAAI) as a potential cause of asthma attacks and allergies.

"Lack of production oversight for any inhaled product raises a concern for impurities or contaminants," says Dr. Andrew Nickels, Allergy and Immunology Fellow at the Mayo Clinic in Rochester, Minnesota. Though he has not yet had a patient complain of e-cig allergies, "From an allergy standpoint, additives such as flavors, could be a source of allergic reactions."

Allergies release inflammatory chemicals called histamines, which can make it difficult to breathe during a tough workout, and could even induce the onset of asthma symptoms.

In or out of the gym, there's more cause for concern: Early research on human cells has indicated that e-cigarette vapor may act on lung cells in a way similar to cigarette smoke, pointing to a potential link between vaping and an increased risk for lung cancer.

Harmful to Your Heart

Unsurprisingly, quitting smoking has been proven to improve health and, more specifically, increase an individual's overall level of fitness, according to Edelman. "It's not clear if it's because the lungs are better [after quitting] or [blood] circulation is better, but the bottom line is: Smoking impairs fitness and we know because people stop smoking and fitness improves," Edelman says. But whether this is true of e-cigs remains to be seen.

If smoking's impact on blood flow to the body's muscles and heart is to blame for impeding fitness, nicotine may be at fault—and that's an indicator that e-cigarettes could carry a similar physical burden. "E-cigarettes irritate the lungs less than regular cigarettes, but they deliver as much or more nicotine, and nicotine constricts blood vessels," Edelman says.

Because the U.S. Food and Drug Administration does not yet regulate e-

cigarettes, some brands are suspected to contain levels of nicotine significantly higher than what is found in an old-school pack of smokes.

“Nicotine is a poison and you don’t have to smoke or inhale that much to get nicotine poisoning,” Edelman says. “The fact that people may be using very high doses is a concern. It’s likely to have an effect on the circulatory system.”

On top of that, a study from Brown University recently discovered that prolonged exposure to nicotine may be linked to an increased risk for atherosclerosis, or a hardening of the arteries that can cause heart attacks.

In other words, perhaps we should think of smoking e-cigarettes the same way we think about eating cheeseburgers. Yes, they can be enjoyable. And sure, they aren’t linked as strongly to an increased risk of death as other tobacco products. But they’re linked to some potentially dangerous health problems that could affect you down the road.

A Call for More Research and Regulation

A recent study published in the journal *Nicotine and Tobacco Research* revealed that while secondhand exposure to e-cigarettes is likely less harmful than tobacco smoke, it still exposes bystanders to some levels of nicotine. Until more research can be done, organizations like the ALA are strongly urging the FDA to “move and move quickly” to regulate e-cigarettes the same way they do tobacco products, according to Edelman. In the meantime, he says he’ll continue to advise patients to steer clear of the e-cig.

“If they want to use it for smoking cessation I will say there are tested, FDA-approved products that are useful and why use something that hasn’t been tested?” Edelman says. And as for how e-cigs could impact fitness, “There are theoretical reasons to believe that e-cigarettes will impair performance in a manner similar to tobacco cigarettes, but that’s as far as we know at the moment.”

EXHIBIT 5

E-Cigarettes: A Scientific Review
Rachel Grana, Neal Benowitz and Stanton A. Glantz

Circulation. 2014;129:1972-1986

doi: 10.1161/CIRCULATIONAHA.114.007667

Circulation is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231

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Print ISSN: 0009-7322. Online ISSN: 1524-4539

The online version of this article, along with updated information and services, is located on the
World Wide Web at:

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E-Cigarettes A Scientific Review

Rachel Grana, PhD, MPH; Neal Benowitz, MD; Stanton A. Glantz, PhD

Electronic cigarettes (e-cigarettes) are products that deliver a nicotine-containing aerosol (commonly called vapor) to users by heating a solution typically made up of propylene glycol or glycerol (glycerin), nicotine, and flavoring agents (Figure 1) invented in their current form by Chinese pharmacist Hon Lik in the early 2000s.¹ The US patent application describes the e-cigarette device as “an electronic atomization cigarette that functions as substitutes [sic] for quitting smoking and cigarette substitutes” (patent No. 8,490,628 B2). By 2013, the major multinational tobacco companies had entered the e-cigarette market. E-cigarettes are marketed via television, the Internet, and print advertisements (that often feature celebrities)² as healthier alternatives to tobacco smoking, as useful for quitting smoking and reducing cigarette consumption, and as a way to circumvent smoke-free laws by enabling users to “smoke anywhere.”³

There has been rapid market penetration of e-cigarettes despite many unanswered questions about their safety, efficacy for harm reduction and cessation, and total impact on public health. E-cigarette products are changing quickly, and many of the findings from studies of older products may not be relevant to the assessment of newer products that could be safer and more effective as nicotine delivery devices. In addition, marketing and other environmental influences may vary from country to country, so patterns of use and the ultimate impact on public health may differ. The individual risks and benefits and the total impact of these products occur in the context of the widespread and continuing availability of conventional cigarettes and other tobacco products, with high levels of dual use of e-cigarettes and conventional cigarettes at the same time among adults⁴⁻⁸ and youth.⁹⁻¹¹ It is important to assess e-cigarette toxicant exposure and individual risk, as well as the health effects, of e-cigarettes as they are actually used to ensure safety and to develop an evidence-based regulatory scheme that protects the entire population—children and adults, smokers and nonsmokers—in the context of how the tobacco industry is marketing and promoting these products. Health claims and claims of efficacy for quitting smoking are unsupported by the scientific evidence to date. To minimize the potential negative

impacts on prevention and cessation and the undermining of existing tobacco control measures, e-cigarette use should be prohibited where tobacco cigarette use is prohibited, and the products should be subject to the same marketing restrictions as tobacco cigarettes.

Methods

Initial searches conducted via PubMed using the key words electronic cigarette, e-cigarette, and electronic nicotine delivery systems yielded 151 studies (Figure 2). Seventy-one articles presented original data and were included. Eighty articles were excluded because they were not relevant, were not in English, or were reviews or commentaries that did not provide original data, although some are cited for background and context. Searches using the same search terms were conducted using World Health Organization regional databases; only BIBLIOTECA Virtual em Saude Latin America and Caribbean included relevant papers, all of which had already been located with PubMed. Working with the World Health Organization, we also contacted investigators to locate other studies, some of which had not yet been published (submitted or in press). We also reviewed technical reports prepared by health organizations,¹²⁻¹⁵ news articles, and relevant Web sites. The results of these searches were used to prepare a report commissioned by the World Health Organization Tobacco Free Initiative, which provides details of individual studies, including some studies that are not discussed in this article because of length constraints.¹ After the manuscript was submitted for peer review, 5 more articles became available, resulting in a total of 82 articles forming the basis for this review.

The Product

E-cigarette devices are manufactured mainly in China. As of late 2013, there was wide variability in e-cigarette product engineering, including varying nicotine concentrations in the solution used to generate the nicotine aerosol (also called e-liquid), varying volumes of solution in the product, different carrier compounds (most commonly propylene glycol with or without glycerol [glycerin]), a wide range of additives and flavors, and battery voltage. Quality control is variable,¹⁶ and users can modify many of the products, including using them to deliver other drugs such as marijuana.^{17,18} These engineering differences result in variability in how e-cigarettes heat and convert the nicotine solution to an aerosol and consequently the levels of nicotine and other

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DOI: 10.1161/CIRCULATIONAHA.114.007667

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Product	Description	Some Brands
Disposable e-cigarette 	Cigarette-shaped device consisting of a battery and a cartridge containing an atomizer to heat a solution (with or without nicotine). Not rechargeable or refillable and is intended to be discarded after product stops producing aerosol. Sometimes called an e-hookah.	NJOY OneJoy, Aer Disposable, Flavorvapes
Rechargeable e-cigarette 	Cigarette-shaped device consisting of a battery that connects to an atomizer used to heat a solution typically containing nicotine. Often contains an element that regulates puff duration and /or how many puffs may be taken consecutively.	Blu, GreenSmoke, EonSmoke
Pen-style, medium-sized rechargeable e-cigarette 	Larger than a cigarette, often with a higher capacity battery, may contain a prefilled cartridge or a refillable cartridge (often called a clearomizer). These devices often come with a manual switch allowing to regulate length and frequency of puffs.	Vapor King Storm, Totally Wicked Tornado
Tank-style, large-sized rechargeable e-cigarette 	Much larger than a cigarette with a higher capacity battery and typically contains a large, refillable cartridge. Often contains manual switches and a battery casing for customizing battery capacity. Can be easily modified.	Volcano Lavatube

Figure 1. Examples of different electronic cigarette (e-cigarette) products. Reproduced from Grana et al.¹

chemicals delivered to users and the air pollution generated by the exhaled aerosol.¹⁹

E-liquids are flavored, including tobacco, menthol, coffee, fruit, candy, and alcohol flavors, as well as unusual flavors such as cola and Belgian waffle.³ Flavored (conventional) tobacco products are used disproportionately by youth and initiators,²⁰ and cigarettes with characterizing flavors (except menthol) have been banned in the United States.

Marketing and Media Research

Consumer perceptions of the risks and benefits and decisions to use e-cigarettes are heavily influenced by how they are marketed. Celebrities have been used to market e-cigarettes since at least 2009.²¹ Grana and Ling³ reviewed 59 single-brand e-cigarette retail Web sites in 2012 and found that the most popular claims were that the products are healthier (95%), cheaper (93%), and cleaner (95%) than cigarettes; can be smoked anywhere (88%); can be used to circumvent smoke-free policies (71%); do not produce secondhand smoke (76%); and are modern (73%). Health claims made through text and pictorial and video representations of doctors were present on 22% of sites. Cessation-related claims (direct and indirect statements) were found on 64% of sites. Marketing on the sites commonly stated that e-cigarettes produce only "harmless

water vapor." Similar messaging strategies were being used in the United Kingdom.²²

These marketing messages have been repeated in the media. A thematic analysis of newspaper and online media coverage about e-cigarettes in the United Kingdom and Scotland from July 2007 to June 2012 found 5 themes: healthier choice, circumventing smoke-free restrictions, celebrity use, price, and risk and uncertainty.²³ Coverage often included anecdotes about having tried nicotine replacement therapies (NRTs), failing to quit, and then trying the e-cigarette (such as the celebrity endorsement by actress Katherine Heigl on the US David Letterman television program²¹), implying that e-cigarettes are a more effective form of NRT.

E-cigarette companies also have a strong presence in social media, which reinforces their marketing messages, including repeating the use of celebrity endorsements (eg, Heigl) and spreading images of the UK musical group Girls Aloud "puffing on e-cigarettes to cope with the stress of their 10th anniversary tour."²²

Cigarette and other tobacco companies have been unable to market their products on television and radio since the 1970s. E-cigarette advertising on television and radio is mass marketing of an addictive nicotine product for use in a recreational manner to new generations who have never experienced such marketing. In an online convenience sample of 519 adult

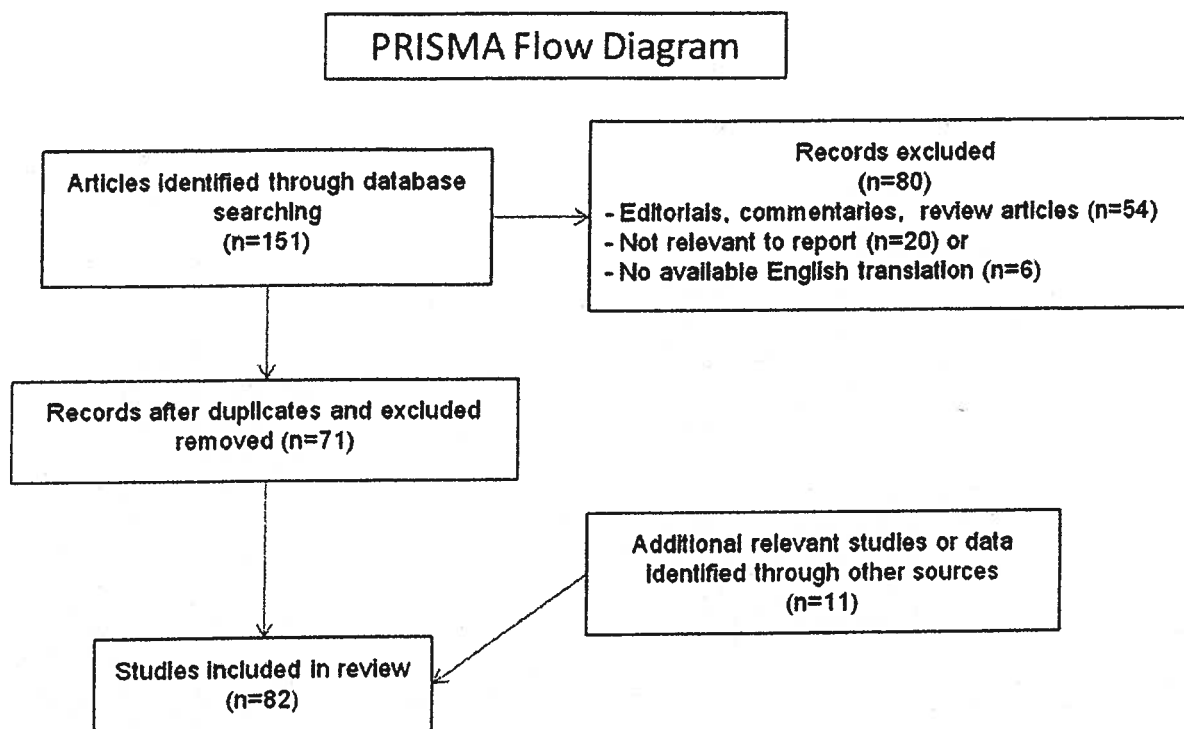


Figure 2. Studies screened and selected for inclusion. PRISMA Indicates Preferred Reporting Items for Systematic Reviews and Meta-Analyses.

smokers and recent quitters who viewed a television commercial for Blu e-cigarettes, 76% of current smokers reported that the ad made them think about smoking cigarettes, 74% reported it made them think about quitting, and 66% said it made them likely to try an e-cigarette in the future.²⁴ The 34% of participants who had used e-cigarettes were significantly more likely to think about smoking cigarettes after viewing the ad than nonusers (83% and 72%, respectively), suggesting that viewing an e-cigarette commercial may induce thoughts about smoking and cue the urge to smoke.²⁴

Prevalence

Awareness of e-cigarettes and e-cigarette trial have at least doubled among both adults and adolescents in several countries from 2008 to 2012. In the United States, awareness is more prevalent among men, but trying e-cigarettes is more prevalent among women. Almost the same percent of European Union and US adult respondents to national surveys reported having tried e-cigarettes (7% in 2012 versus 6.2% in 2011, respectively).^{5,25} All population-based studies of adult use show the highest rate of e-cigarette use among current smokers, followed by former smokers, with little use among nonsmokers, although e-cigarette trial and use rose in all of these categories.⁴⁻⁶ Etter and Bullen²⁶ followed up a sample of e-cigarette users recruited from Web sites dedicated to e-cigarettes and smoking cessation, most (72%) of whom were former smokers at baseline. At the 1-year follow up, 6% of former smokers who were daily e-cigarette users at baseline relapsed to smoking cigarettes, and almost all (92%) of

the former smokers using e-cigarettes daily at baseline were still using e-cigarettes daily at follow-up. Among 36 dual users at baseline, 16 (44%) had stopped smoking after 1 year. The epidemiological, population-based studies indicate that, across countries, e-cigarettes are most commonly being used concurrently with conventional tobacco cigarettes (dual use). Consistent with marketing messages, the most common reasons given for trying e-cigarettes are for use in places where smoking is restricted, to cut down on smoking, and for help with quitting smoking.^{6,27-30}

Choi and Forster³¹ followed up a cohort of Midwestern young adults (mean age, 24.1 years) who had never used e-cigarettes from 2010 to 2011 and found that 21.6% of baseline current smokers, 11.9% of baseline former smokers, and 2.9% of baseline nonsmokers reported having ever used e-cigarettes at follow-up. Those who believed at baseline that e-cigarettes could help with quitting smoking and perceived e-cigarettes to be less harmful than cigarettes were more likely to report experimenting with e-cigarettes at follow-up (adjusted odds ratio [OR], 1.98; 95% confidence interval [CI], 1.29–3.04; and adjusted OR, 2.34; 95% CI, 1.49–3.69, respectively).

Data on e-cigarette use among adolescents are more limited but, like for adults, show rapid increases in awareness and use in 5 countries (United States, Poland, Latvia, Finland, and Korea), with higher rates of trial and current use in European countries than the United States or Korea.^{9,10,32,33} In Korea, youth ever use of e-cigarettes rose from 0.5% in 2008 to 9.4% in 2011,¹⁰ and in the United States, it rose from 3.3% in 2011 to 6.8% in 2012.⁹ As with adult population-based studies, data

suggest that e-cigarette use is most appealing and prevalent among youth who are also experimenting with or are current users of tobacco cigarettes. Dual use with conventional cigarettes is the predominant pattern of e-cigarette use: 61% in US middle school students and 80% among US high school students in 2011.⁹ These results indicate rapid market penetration of e-cigarettes among youth, with trial among US high school students (10.0%) in 2012 even higher than the 2011 rate for adults (6.2%).⁵ Despite a law prohibiting e-cigarette sales to minors, e-cigarette use among Utah youth (grades 8, 10, and 12) tripled between 2011 and 2013, with youth 3 times more likely to report current e-cigarette use than adults.³⁴

Although dual use with cigarettes is high, some youth experimenting with e-cigarettes have never tried a tobacco cigarette, which indicates that some youth are initiating use of nicotine, an addictive drug, with e-cigarettes. In 2012, 20.3% of middle school and 7.2% of high school ever e-cigarette users reported never smoking conventional cigarettes.⁹ Similarly, in 2011 in Korea, 15% of students in grades 7 through 12 who had ever used e-cigarettes had never smoked a cigarette.¹⁰ The Utah Department of Health found that 32% of ever e-cigarette users reported that they had never smoked conventional cigarettes.³⁴

E-Cigarette E-Fluid and Vapor

Chemical Constituents

The nicotine content of the cartridge e-liquid from some brands revealed poor concordance of labeled and actual nicotine content.^{35–39} Simulated e-cigarette use revealed that individual puffs contained from 0 to 35 µg nicotine per puff.³⁷ Assuming a high nicotine delivery of 30 µg per puff, it would take ≈30 puffs to deliver the 1 mg nicotine typically delivered by smoking a conventional cigarette. A puff of the e-cigarette with the highest nicotine content contained 20% of the nicotine contained in a puff of a conventional cigarette.³⁷ Actual nicotine delivery from an e-cigarette would likely be affected by users' smoking behavior. An analysis of UK brand e-cigarettes and the resulting aerosol demonstrated that, across brands, nicotine content of the e-liquid in the cartridges was not significantly correlated with the amount found in the

resulting aerosol, indicating differences in the engineering characteristics of the device that strongly influence nicotine delivery even with a consistent puffing protocol.⁴⁰

Goniewicz et al⁴¹ analyzed the aerosol from 12 brands of e-cigarettes, a conventional cigarette, and a nicotine inhaler for toxic and carcinogenic compounds. The levels of toxicants in the aerosol were 1 to 2 orders of magnitude lower than in cigarette smoke but higher than with a nicotine inhaler (Table 1).

Kim and Shin⁴² analyzed the tobacco-specific nitrosamines NNN, NNK, and NAT and total tobacco-specific nitrosamines in 105 refill fluids from 11 companies in the Korean market and found nearly a 3-order-of-magnitude variation in tobacco-specific nitrosamine concentrations, with total tobacco-specific nitrosamine concentration ranging from 330 to 8600 µg/mL.

Cytotoxicity

Bahl et al⁴³ screened 41 e-cigarette refill fluids from 4 companies for cytotoxicity using 3 cell types: human pulmonary fibroblasts, human embryonic stem cells, and mouse neural stem cells. Cytotoxicity varied among products from highly toxic to low or no cytotoxicity. The authors determined that nicotine did not cause cytotoxicity, that some products were noncytotoxic to pulmonary fibroblasts but cytotoxic to both types of stem cells, and that cytotoxicity was related to the concentration and number of flavorings used. The finding that the stem cells are more sensitive than the differentiated adult pulmonary fibroblasts cells suggests that adult lungs are probably not the most sensitive system to assess the effects of exposure to e-cigarette aerosol. These findings also raise concerns about pregnant women who use e-cigarettes or are exposed to secondhand e-cigarette aerosol.

In a study funded by the FlavorArt e-cigarette liquid manufacturers, Romagna et al⁴⁴ compared the cytotoxicity of aerosol produced from 21 nicotine-containing, flavored (12 tobacco flavored and 9 fruit or candied flavored) brands of e-cigarette liquid with smoke from a conventional cigarette using embryonic mouse fibroblast cells. Only aerosol from coffee-flavored e-liquid produced a cytotoxic effect (average, 51% viability at 100% concentration of solution).

Table 1. Levels of Toxicants in E-Cigarette Aerosol Compared With Nicotine Inhaler and Cigarette Smoke

Toxicant	Range in Content in Aerosol From 12 E-Cigarette Samples per 15 Puffs*	Range in Content in Conventional Cigarette Micrograms in Mainstream Smoke From 1 Cigarette	Content in Nicotine Inhaler Mist per 15 Puffs*
Formaldehyde, µg	0.2–5.61	1.6–52	0.2
Acetaldehyde, µg	0.11–1.36	52–140	0.11
Acrolein, µg	0.07–4.19	2.4–62	ND
o-Methylbenzaldehyde, µg	0.13–0.71	...	0.07
Toluene, µg	ND–0.83	8.3–70	ND
p,m-xylene, µg	ND–0.2	...	ND
NNN, ng	ND–0.00043	0.0005–0.19	ND
NNK, ng	ND–0.00283	0.012–0.11	ND
Cadmium, ng	ND–0.022	...	0.003
Nickel, ng	0.011–0.029	...	0.019
Lead, ng	0.003–0.057	...	0.004

Prepared using data from Goniewicz et al.⁴¹ E-cigarette indicates electronic cigarette; and ND, not determined.

Farsalinos et al⁴⁵ tested cytotoxicity in cultured rat cardiac myoblasts of exposure to aerosol generated from 20 refill solutions from 5 manufacturers containing 6 to 24 mg/mL nicotine in various flavors, a "base"-only solution (50% propylene glycol and 50% glycerol), and conventional cigarette smoke. The aerosol from 3 fluids was cytotoxic at 100% and 50% dilution; 2 were tobacco flavored and 1 was cinnamon cookie flavored. Cigarette smoke was cytotoxic at 100% and all dilutions except 6.25%.

Secondhand Exposure

E-cigarettes do not burn or smolder the way conventional cigarettes do, so they do not emit side-stream smoke; however, bystanders are exposed to aerosol exhaled by the user. Schripp et al⁴⁶ conducted chamber studies in which subjects used 3 e-liquids (0 mg nicotine, apple flavor; 18 mg nicotine, apple flavor; 18 mg nicotine, tobacco flavor) and 1 tobacco cigarette and measured levels of several toxins and nicotine in the resulting aerosol. Three e-cigarette devices were used for these experiments: 2 that used a tank system that is directly filled with e-liquid and one that used a cartridge with a cotton fiber on which to drip the liquid. They found low levels of formaldehyde, acetaldehyde, isoprene, acetic acid, 2-butanodione, acetone, propanol, propylene glycol, and diacetyl (from flavoring), traces of apple oil (3-methylbutyl-3-methylbutanoate), and nicotine (with differing levels depending on the specific protocols) emitted into the air. Toxins in the e-cigarette aerosol were at much lower levels compared with the conventional cigarette emissions.⁴⁶

In another chamber study, Flouris et al⁴⁷ compared emissions of conventional cigarettes and e-cigarettes in conditions designed to approximate a smoky bar (target air CO of 23 ppm) using machine-smoked e-cigarettes and cigarettes. E-cigarette aerosol (using a single brand of e-cigarette made in Greece and a single e-liquid with at least 60% propylene glycol, 11 mg/mL nicotine) was generated with a pump that operated for the same duration as the cigarette smoking, and aerosol was released into the room. (A person inhaling a nicotine aerosol usually absorbs 80% of the nicotine,⁴⁸ whereas the pump discharges all nicotine into the environment, so the nicotine exposure may be higher in this study than would be the case with actual secondhand aerosol exposure.) Serum cotinine in nonsmokers sitting in the chamber was similar for cigarette smoke and e-cigarette aerosol exposure (average, 0.8 ng/mL for tobacco cigarette and 0.5 ng/mL for e-cigarette).

Schober et al³⁹ measured indoor pollution from 3 people using e-cigarettes over a 2-hour period in a realistic environment modeled on a café. They found elevated nicotine, 1,2-propanediol, glycerin, aluminum, and 7 polycyclic aromatic hydrocarbons classified as probable carcinogens by the International Agency for Research on Cancer in the room air.

Czogala et al⁴⁹ conducted a chamber study of secondhand exposure to e-cigarette aerosol compared with cigarette smoke, finding that, on average, bystanders would be exposed to nicotine but at levels 1/10th that of cigarette smoke (e-cigarette aerosol, $3.32 \pm 2.49 \mu\text{g}/\text{m}^3$; cigarette smoke, $31.60 \pm 6.91 \mu\text{g}/\text{m}^3$; $P=0.008$). Both e-cigarette aerosol and cigarette smoke contained fine particles ($\text{PM}_{2.5}$), with e-cigarette aerosol particle concentrations ranging from 6.6 to 85.0 $\mu\text{g}/\text{m}^3$. E-cigarette

aerosol was not a source of exposure to carbon monoxide, a key combustion element of conventional cigarette smoke.

Particulate Matter

E-cigarettes deliver nicotine by creating an aerosol of ultrafine particles. Fine particles can be variable and chemically complex, and the specific components responsible for toxicity and the relative importance of particle size and particle composition are generally not known.⁵⁰ Given these uncertainties, it is not clear whether the ultrafine particles delivered by e-cigarettes have health effects and toxicity similar to the ambient fine particles generated by conventional cigarette smoke or secondhand smoke. There is strong evidence, however, that frequent low or short-term levels of exposure to fine and ultrafine particles from tobacco smoke or air pollution can contribute to pulmonary and systemic inflammatory processes and increase the risk of cardiovascular and respiratory disease and death.^{51–54}

Fuoco et al⁵⁵ examined particle number concentration and distribution and performed a volatility analysis of the e-cigarette aerosol generated from 3 devices (2 rechargeable and 1 disposable) using 4 refill e-liquids with varying levels of nicotine and flavorants. They found that higher e-liquid nicotine content was associated with higher particle numbers in the resulting aerosol, with little effect on the particle size distribution. Longer puffing time resulted in more particles. Flavor was not associated with differences in particle number or size distribution. Consistent with other studies,^{46,56–58} the particle size distribution (range of modes, ≈ 120 – 165 nm) was similar to that of conventional cigarettes, with some e-cigarettes delivering more particles than conventional cigarettes (Figure 3).

Zhang et al⁵⁷ examined the size of e-cigarette aerosol particles and likely deposition in the human body (using a single brand, BloogMaxXFusion) with both propylene glycol and vegetable glycerin-based liquids. Using particle size and lung ventilation rates (1 for a "reference worker" and 1 for a "heavy worker": 1.2 and 1.688 m^3/h , respectively), their human deposition model estimated that 73% to 80% of particles would be distributed into the exhaled aerosol, whereas 9% to 18% of particles would be deposited in alveoli resulting in arterial delivery, and 9% to 17% would be deposited in the head and airways, resulting in venous delivery. As expected, the heavy worker model showed more alveolar delivery across puffs compared with the reference worker, who would have more head and airway delivery. In total, $\approx 20\%$ to 27% of particles are estimated to be deposited in the circulatory system and into organs from e-cigarette aerosol, which is comparable to the 25% to 35% for conventional cigarette smoke.

In their study of passive exposure to exhaled e-cigarette aerosol in a simulated café, Schober et al³⁹ found that concentrations of fine particles in the air increased from a median of 400 particles per 1 cm^3 with people simply sitting in the room for 2 hours to medians of 49 000 to 88 000 particles per 1 cm^3 (depending on the e-cigarette fluid used) after 2 hours of e-cigarette use in the same room.

Both the e-liquid and the Poly-fil fibers that are used to absorb the e-liquid for heating and conversion to an aerosol come into contact with heating elements that contain heavy

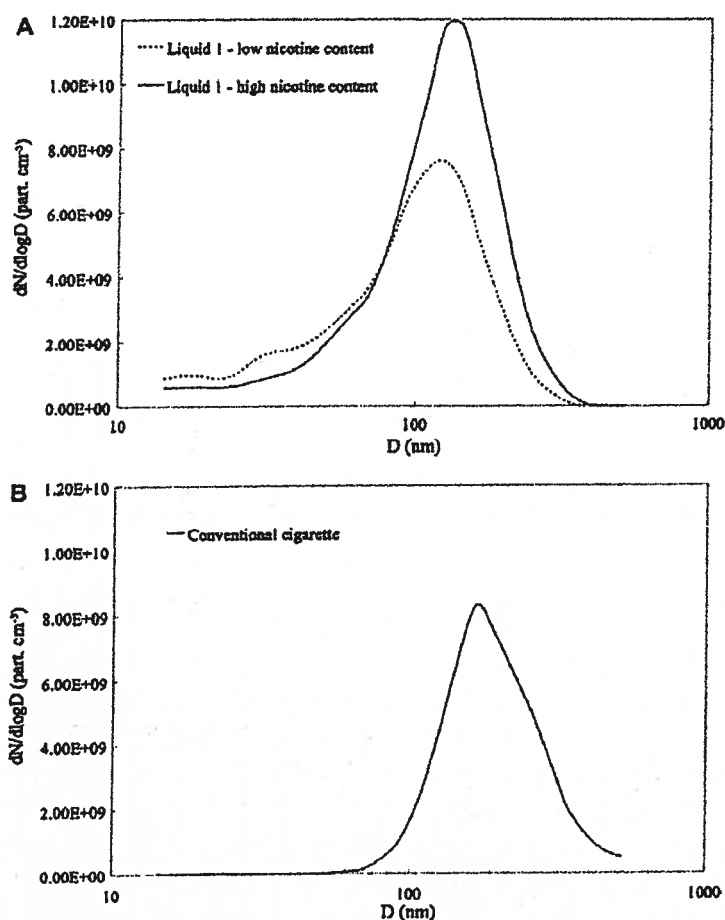


Figure 3. Particle number distribution from (A) mainstream aerosol in e-liquid 1 and from (B) conventional cigarette. Reproduced from Fuoco et al⁵⁵ with permission from the publisher. Copyright © 2013 Elsevier Ltd.

metals (tin, nickel, copper, lead, chromium). Williams et al⁵⁸ found heavy metals in samples of e-cigarette liquids and aerosol. Tin, which appeared to originate from solder joints, was found as both particles and tin whiskers in the fluid and Poly-fil, and e-cigarette fluid containing tin was cytotoxic to human pulmonary fibroblasts. E-cigarette aerosol also contained other metals, including nickel, 2 to 100 times higher than found in Marlboro cigarette smoke. The nickel and chromium nanoparticles (<100 nm) possibly originated from the heating element. It is likely that engineering features, including the nature of the battery, the heating temperature of the liquid, and the type of heating element and reservoir, will influence the nature, number, and size of particles produced. These metal nanoparticles can deposit into alveolar sacs in the lungs, potentially causing local respiratory toxicity and entering the bloodstream.

In summary, the particle size distribution and number of particles delivered by e-cigarettes are similar to those of conventional cigarettes, with most particles in the ultrafine range (modes, ≈ 100 –200 nm). Particle delivery appears to depend on the nicotine level in the e-cigarette fluid but not the presence of flavors. Smokers exhale some of these particles, which exposes bystanders to “passive vaping.” Like cigarettes, e-cigarette particles are small enough to reach deep into the

lungs and cross into the systemic circulation. At a minimum, these studies show that e-cigarette aerosol is not merely “water vapor” as is often claimed in the marketing for these products. Tests on e-cigarettes show much lower levels of most toxicants, but not particles, than conventional cigarettes. The thresholds for human toxicity of potential toxicants in e-cigarette vapor are not known, and the possibility of health risks to primary users of the products and those exposed passively to their emissions must be considered.

Nicotine Absorption

Early studies of nicotine absorption in 2010 found that e-cigarettes delivered much lower levels of plasma nicotine than conventional cigarettes,^{59,60} whereas a more recent study demonstrated that more experienced users using their own product who engaged in more puff intervals have nicotine absorption similar to that with conventional cigarettes,^{61–63} perhaps as a result of a combination of characteristics of the devices and user vaping topography.⁶³ Another study of smokers smoking e-cigarettes using a specified protocol found a similar rise in serum cotinine immediately after use (mean increase, ≈ 20 ng/mL).⁴⁷ Several studies reported that regardless of nicotine delivery, e-cigarettes can modestly alleviate some symptoms of withdrawal, and participants positively

appraised the use of e-cigarettes.⁶²⁻⁶⁵ In a study comparing the nicotine inhalator and e-cigarettes,⁶⁶ the nicotine inhalator delivered an amount of nicotine similar to that in the 16-mg e-cigarette; however, the authors noted that the e-cigarette malfunctioned and did not deliver any nicotine in a third of participants. These results highlight the need for product regulation in terms of drug delivery and effects, as well as device functioning and labeling.

Health Effects

Propylene glycol and glycerin are the main base ingredients of the e-liquid. Exposure to propylene glycol can cause eye and respiratory irritation, and prolonged or repeated inhalation in industrial settings may affect the central nervous system, behavior, and the spleen.⁶⁶ In its product safety materials, Dow Chemical Company states that "inhalation exposure to [propylene glycol] mists should be avoided,"⁶⁷ and the American Chemistry Council warns against its use in theater fogs because of the potential for eye and respiratory irritation.⁶⁸ When heated and vaporized, propylene glycol can form propylene oxide, an International Agency for Research on Cancer class 2B carcinogen,⁶⁹ and glycerol forms acrolein, which can cause upper respiratory tract irritation.^{70,71}

Major injuries and illness have resulted from e-cigarette use,⁷² including explosions and fires.^{73,74} Less serious adverse events include throat and mouth irritation, cough, nausea, and vomiting.⁷²

A study⁷⁵ of healthy smokers' pulmonary function after acute ad lib puffing of an e-cigarette (Nobacco, medium, 11 mg) for 5 minutes (after refraining from smoking tobacco cigarettes for 4 hours) found no effect on spirometry but did find significantly increased dynamic airway resistance (18%) and decreased expired nitric oxide (16%). Sham e-cigarette use had no significant effect. This study is limited by the small sample size, the short period of tobacco use abstinence before protocol execution, the short length of exposure to e-cigarette aerosol, and the lack of comparison with smoking conventional cigarettes. In addition, smokers in general have high airway resistance with dynamic testing and lower expired nitric oxide, likely as a result of oxidant stress. Despite these limitations, this study suggests that e-cigarette use constricts peripheral airways, possibly as a result of the irritant effects of propylene glycol, which could be of particular concern in people with chronic lung disease such as asthma, emphysema, or chronic bronchitis.

Flouris et al⁴⁷ assessed the short-term effects of e-cigarette use on pulmonary function in 15 cigarette smokers who puffed an e-cigarette (>60% propylene glycol, 11 mg/mL nicotine) and a conventional cigarette according to a specified protocol, and passive exposure to e-cigarette aerosol and conventional cigarette smoke with 15 never smokers. Active cigarette smoking resulted in a significant decrease in expired lung volume (forced expiratory volume in the first second of expiration/forced inspiratory vital capacity) that was not seen with active e-cigarette use or with passive tobacco cigarette or e-cigarette exposure. Additional analysis of the data collected in this study⁷⁶ found that white cell count increased after cigarette smoking, reflecting inflammatory process-associated risk for acute cardiovascular events. Active e-cigarette use and

passive exposure to e-cigarette vapor did not result in a significant increase in these biomarkers over 1 hour of exposure.

Schober et al³⁹ found elevated levels of exhaled nitric oxide in people using a nicotine e-cigarette (but not a nicotine-free e-cigarette), which the authors attributed to pulmonary inflammation.

National Vaper's Club, a pro-e-cigarette advocacy group, published a "risk assessment" of e-cigarette and cigarette use that concluded that "neither vapor from e-liquids or cigarette smoke analytes posed a condition of 'significant risk' of harm to human health via the inhalation route of exposure."⁷⁷ The authors failed to detect benzo(a)pyrene in conventional cigarette smoke despite the fact that it is an established carcinogen in cigarette smoke, and their assessment of conventional cigarettes concluded that they did not pose significant risk, both of which point to fatal errors in the data, data analysis, or both. Another report¹⁵ funded by the Consumer Advocates for Smoke-free Alternatives Association and published on the Internet used occupational threshold limit values to evaluate the potential risk posed by several toxins in e-cigarettes, concluding 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." Threshold limit values are an approach to assessing health effects for occupational chemical exposures that are generally much higher (often orders of magnitude higher) than levels considered acceptable for ambient or population-level exposures. Occupational exposures also do not consider exposure to sensitive subgroups such as people with medical conditions, children, and infants who might be exposed to secondhand e-cigarette emissions, most notably nicotine.

In summary, only a few studies have directly investigated the health effects of exposure to e-cigarette aerosol, but some demonstrate the ability of e-cigarette aerosol exposure to result in biological effects. Long-term biological effects are unknown at this time because e-cigarettes have not been in widespread use long enough for assessment.

Effects on Cessation of Conventional Cigarettes

E-cigarettes are promoted as smoking cessation aids, and many individuals who use e-cigarettes believe that they will help them quit smoking conventional cigarettes.^{7,29,30} The assumption that e-cigarettes will be as effective as or more effective than pharmaceutical NRTs has also motivated support for e-cigarettes among some public health researchers and policy makers⁷⁸ and (as discussed later) formed the basis for some public policies on the regulation of e-cigarettes.

Population-Based Studies

There are 4 longitudinal studies^{4,79-81} and 1 cross-sectional study⁸² of the association between e-cigarette use and quitting conventional cigarettes (Table 2).

Adkison et al⁴ studied current and former smokers in the *International Tobacco Control* study in the United States, Canada, the United Kingdom, and Australia at baseline and 1 year later and found that e-cigarette users had a statistically significant greater reduction in cigarettes per day (e-cigarette users, 20.1 to 16.3 cigarettes per day; nonusers, 16.9 to 15.0

Table 2. Population Studies of the Association Between E-Cigarette Use and Cessation of Conventional Cigarette Smoking

Study	Location and Study Design	Odds of Quitting (95% CI)
Longitudinal studies		
Adkison et al ⁴ (2013)	US, UK, Canada, Australia (ITC), surveyed, 1 y apart	0.81 (0.43–1.53)*
Vickerman et al ⁸⁰ (2013)	US quit-line callers from 6 states surveyed at enrollment and 7 mo later	0.50 (0.40–0.63)†
Grana et al ⁷⁹ (2014)	US sample drawn from a nationally representative internet panel, 1 y apart	0.76 (0.36–1.60)
Choi and Forster ⁸¹ (2014)	Midwestern young adults, 1 y apart	0.93 (0.19–4.63)
Cross-sectional study		
Popova and Ling ⁸² (2013)	US sample drawn from a nationally represented internet panel	0.69 (0.52–0.94)*
All studies		
Pooled‡		0.61 (0.50–0.75)

CI indicates confidence interval; E-cigarette, electronic cigarette; and ITC, International Tobacco Control.

*Odds ratios obtained by contacting authors.

†Computed by authors of this report on the basis of the numbers reported.

‡Estimated with a random-effects meta-analysis using Stata 12.1 metan. There was no evidence of heterogeneity ($P=0.28$) or evidence of publication bias with the use of a funnel plot.

cigarettes per day). Although 85% of e-cigarette users reported they were using the product to quit smoking at the initial wave, e-cigarette users were no more likely to have quit 1 year later than nonusers (OR, 0.81; 95% CI, 0.43–1.53; $P=0.52$).

Vickerman et al⁸⁰ found that ≈31% of quit-line callers surveyed 7 months after enrollment reported that they had ever tried e-cigarettes. The majority used them for <1 month (67.1%), and 9.2% were using them at the 7-month survey. The main reason for e-cigarette use was tobacco cessation (51.3%), but it is not known whether ever use occurred as part of a quit attempt in the preceding 7 months. Although quit-line callers represent a small population of smokers motivated to quit, these data present a real-world estimate of the potential effectiveness of using e-cigarettes for cessation in a population of smokers motivated to quit. Although this study had a low response rate (34.6%) and may be subject to recall bias because e-cigarette use and perceptions were assessed only at the 7-month follow-up, those who reported using e-cigarettes were statistically significantly less likely to quit than those who had not used e-cigarettes (21.7% among callers who used for ≥1 month, 16.6% among those who used for <1 month, and 31.4% among never users; $P<0.001$). The unadjusted odds of quitting were statistically significantly lower for e-cigarette users compared with nonusers (OR, 0.50; 95% CI, 0.40–0.63).

Grana et al⁷⁹ explored predictors of quitting among a national sample of smokers who participated in a study in 2011 and follow-up in 2012. Current e-cigarette use (past 30 days) at baseline did not predict a greater likelihood of having quit at the follow-up (OR, 0.71; 95% CI, 0.35–1.46). In a second logistic regression model that included baseline cigarettes per day, time to first cigarette, and intention to quit, in addition to baseline current e-cigarette use, only intention to quit (OR, 5.59; 95% CI, 2.41–12.98) and cigarettes per day (OR, 0.97; 95% CI, 0.94–0.99) were significant predictors of having quit at follow-up; current e-cigarette use remained nonsignificant (OR, 0.76; 95% CI, 0.36–1.60).

Choi and Forster⁸¹ followed up a cohort of young adults in Midwestern (recruited October 2010–March 2011 and followed up for 1 year). Among those who were smoking cigarettes at

baseline, 11% of those who used e-cigarettes at least 1 day in the past 30 days at baseline quit smoking at follow-up compared with 17% of smokers who never used e-cigarettes. In a logistic regression controlling for demographics and baseline cigarettes per day, baseline past 30-day e-cigarette use was not a significant predictor of having quit at follow-up (OR, 0.93; 95% CI, 0.19–4.63; $P=0.93$). There was also no significant change in the number of conventional cigarettes smoked per day between those who did and did not use e-cigarettes (difference, 0.2 cigarettes per day; 95% CI, –3.72 to 4.18; $P=0.91$).

In a national cross-sectional sample, Popova and Ling⁸² found that adult smokers who ever used e-cigarettes were significantly less likely to be former smokers compared to those who never used e-cigarettes (OR, 0.69; 95% CI, 0.52–0.94), controlling for demographics (Lucy Popova, personal communication). In an examination of only those who tried to quit, those who ever used e-cigarettes were significantly less likely to be former smokers than never users (adjusted OR, 0.61; 95% CI, 0.45–0.83).

Combining these results in a random-effects meta-analysis (Table 2) yields a pooled OR of 0.61 (95% CI, 0.50–0.75), indicating that e-cigarette use in the real world is associated with significantly lower odds of quitting smoking cigarettes. A limitation of 3 of these studies^{4,80,82} is that they did not control for level of nicotine dependence. It is possible that more dependent smokers, who would have more difficulty quitting in general, would be the ones who would be more likely to experiment with e-cigarettes, which could contribute to the finding that e-cigarette use is associated with a lower quit rate.

Clinical Trials

Four clinical trials (2 with very small samples) examined the efficacy of e-cigarettes for smoking cessation.^{83–86} Three trials^{83–85} did not have a control group who were not using e-cigarettes. The other study⁸⁶ compared e-cigarette efficacy to a standard-of-care regimen with a 21-mg nicotine patch. None of the trials were conducted with the level of behavioral support that accompanies most pharmaceutical trials for smoking cessation.

Polosa et al⁸³ conducted a proof-of-concept study in Italy in 2010 with smokers 18 to 60 years of age not intending to quit in the next 30 days. Subjects were offered Categoria e-cigarettes and instructed to use up to 4 cartridges (7.4-mg nicotine content) per day as desired to reduce smoking and to keep a log of cigarettes per day, cartridges per day, and adverse events. Six-month follow-up was completed with 68% of participants (27 of 40): 13 were using both e-cigarettes and tobacco cigarettes, 5 maintained exclusive tobacco cigarette smoking, and 9 stopped using tobacco cigarettes while continuing to use e-cigarettes. Cigarette consumption was reduced by at least 50% in the 13 dual users (25 cigarettes per day at baseline to 6 cigarettes per day at 6 months; $P<0.001$). Polosa et al⁸⁷ continued follow-up of this sample at 18 and 24 months with 23 subjects (58% of the original 40 enrolled). Among the 23 participants who completed a 24-month visit, 18 continued to smoke, and 11 had reduced cigarette consumption by $\geq 50\%$ with a statistically significant reduction from an average of 24 to 4 cigarettes per day ($P=0.003$). Five participants had quit tobacco cigarettes at 24 months. Study limitations included the use of a poor-quality product and the lack of a comparison or control group, which could make it difficult to determine whether quit rates achieved were not due to chance.

Caponnetto et al⁸⁵ conducted a similar study with 14 smokers with schizophrenia not intending to quit in the next 30 days. Participants were provided the same Categoria e-cigarette, and carbon monoxide, product use, number of cigarettes smoked, and positive and negative symptoms of schizophrenia were assessed at baseline and 4, 8, 12, 24, and 52 weeks. Seven of 14 participants (50%) sustained a 50% reduction in the number of cigarettes per day smoked at week 52, and the median of 30 cigarettes per day decreased to 15 cigarettes per day ($P=0.018$). Sustained abstinence from smoking occurred with 2 participants (14.3%) by week 52. Positive and negative aspects of schizophrenia were not increased after smoking cessation. The most common outcome was dual use of e-cigarettes with conventional cigarettes. Study findings are not generalizable to smokers with mental illness because of the very small sample size and lack of a control group.

Caponnetto et al⁸⁴ also conducted a randomized, quasi-controlled trial to examine the efficacy of e-cigarettes of different strengths for smoking cessation and reduction in 3 study arms: 12 weeks of treatment with the 7.2-mg nicotine e-cigarette, a 12-week nicotine-tapering regimen (6 weeks of treatment with a 7.2-mg e-cigarette and 6 weeks with a 5.4-mg e-cigarette), and a 12-week treatment with a nonnicotine e-cigarette. Similar reductions in the median cigarettes per day were seen at all study visits for all 3 treatment arms (7–10 cigarettes per day at 1 year). There was no statistically significant difference in 6-month or 1-year quit rate among the 3 conditions (1-year rates: 4% for placebo e-cigarette users, 9% for low-nicotine e-cigarette users, and 13% for high-nicotine e-cigarette users). The authors noted that those who initiated quitting in the first few weeks of the study stayed quitters, whereas those who did not remained dual users throughout the study. Twenty-six percent of quitters continued to use e-cigarettes at 1 year. Problems with the study include the lack of a control group not using e-cigarettes and noted lack of product quality (the devices malfunctioned often, and new

ones had to be sent frequently). An author on all of these studies, R. Polosa, served as a consultant for the Arbi Group SRL, the manufacturer of the Categoria e-cigarette used in the study, beginning in February 2011.

Bullen et al⁸⁶ conducted a randomized, controlled, clinical trial of e-cigarettes compared with medicinal NRT in Auckland, New Zealand. Adult smokers motivated to quit were randomized to the 3 study arms (16-mg e-cigarette, 21-mg NRT patch, no-nicotine e-cigarette). Voluntary telephone counseling was offered to all subjects. Subjects were observed at baseline, 1 week (quit day), 12 weeks, and 6 months. Fifty-seven percent of participants in the nicotine e-cigarettes group reduced their cigarettes per day by $\geq 50\%$ at 6 months compared with 41% in the patch group ($P=0.002$) and 45% in the nonnicotine e-cigarette group ($P=0.08$). Those randomized to the nicotine patch group were less adherent to the treatment (46%) than the 16-mg e-cigarette group (78%) and the no-nicotine e-cigarette group (82%). Of note, the study methodology may have introduced bias against success in the nicotine patch group because e-cigarettes were mailed for free directly to participants randomized to either the nicotine or no-nicotine e-cigarette group, whereas participants in the patch group were mailed cards redeemable for nicotine patches at a pharmacy and vouchers to cover the modest fee. Therefore, although the protocol for providing the patches represented "usual care" for New Zealand quit-line callers, this procedure may have introduced bias against NRT, making it difficult to view the study as a head-to-head comparison of e-cigarettes and NRT for cessation. There were no statistically significant differences in biochemically confirmed (breath CO) self-reported continuous abstinence from quit day to the 6-month follow-up between the nicotine e-cigarette (7.3%), nicotine patch (5.8%), and nonnicotine e-cigarette (4.1%).

Neither Caponnetto et al⁸⁴ nor Bullen et al⁸⁶ found effects of e-cigarette use on quitting beyond what is seen in unassisted or low-assistance studies of smokers using NRT to quit.⁸⁸ In determining the effectiveness of smoking cessation therapy, active drug is considered efficacious when it outperforms placebo; therefore, the evidence to date from clinical trials does not demonstrate that e-cigarettes are efficacious for cessation. However, it is possible that e-cigarettes even without nicotine act as substitutes for the sensory and behavioral effects of conventional cigarettes. If this is the case, the nonnicotine placebo e-cigarette would be considered an active treatment condition and, as discussed previously, has been shown to reduce withdrawal symptoms.^{59,60,63,89} Important limitations of the current research include the use of e-cigarettes that deliver relatively low levels of nicotine and the provision of minimal behavioral counseling. Another important limitation of studies assessing the effectiveness of e-cigarettes for smoking cessation is that, because they are not approved as cessation therapy, there are no therapeutic instructions for using them as replacements or to quit smoking (eg, dosage tapering, duration of use, how to combine them with behavioral strategies, guidance for discontinuation).

In contrast to the assumption that e-cigarettes would function as a better form of NRT, population-based studies that reflect real-world e-cigarette use found that e-cigarette use is not associated with successful quitting; all^{4,79,80,82} had point

estimates of the odds of quitting of <1.0 . The 1 clinical trial examining the effectiveness of e-cigarettes (both with and without nicotine) compared with the medicinal nicotine patch found that e-cigarettes are no better than the nicotine patch and that all treatments produced very modest quit rates without counseling.⁹⁶ Taken together, these studies suggest that e-cigarettes are not associated with successful quitting in general population-based samples of smokers.

Health Implications of Cigarette Reduction in the Context of Dual Use

Among adults, reductions in cigarettes per day were observed in several of the clinical studies^{83,84,86} and in 1 population-based study⁴ among those who did not quit. Reduction in cigarettes smoked per day could have benefit if it promotes subsequent cessation, as has been found with NRT,⁹⁰ but this pattern has not yet been seen with e-cigarettes. In the cigarette reduction analyses presented in some of the studies, many participants were still smoking about half a pack cigarettes per day at the end of the study.

Both duration (years of cigarette use) and intensity (cigarettes per day) determine the negative health effects of smoking.⁹¹ People who stop smoking at younger ages have lower age-adjusted mortality compared with those who continued to smoke later into adulthood.⁹² Findings for decreased smoking intensity have been less consistent, with some studies showing lower mortality with reduced daily cigarette consumption⁹³ and others not finding a significant overall survival benefit.⁹⁴ The 2014 report of the US Surgeon General concluded that "reducing the number of cigarettes smoked per day is much less effective than quitting entirely for avoiding the risks of premature death from all smoking-related causes of death."⁹⁵ Use of electronic cigarettes by cigarette smokers to cut down on the number of cigarettes smoked per day is likely to have much smaller beneficial effects on overall survival compared with quitting smoking completely.

This situation is particularly likely to exist for cardiovascular disease because of the highly nonlinear dose-response relationship between exposure to fine particles and the risk of cardiovascular disease.^{53,96} Light smoking, even 1 to 4 cigarettes per day, is associated with markedly elevated risk of cardiovascular disease.⁹⁷ In addition, e-cigarettes deliver loads of fine particles similar to those of conventional cigarettes.

The relative risk of death from lung cancer increases with years smoked and cigarettes per day,⁹⁸ as well as pancreatic cancer⁹⁹ and esophageal cancer.¹⁰⁰ The relative risk of both lung cancer and bladder cancer levels off after a certain number of cigarettes per day,¹⁰¹ suggesting that above a certain intensity, the specific levels of exposure may not cause significant differences in risk for these cancers. Doll and Peto¹⁰² found a dose-response relationship between duration of smoking and number of cigarettes smoked per day and risk of lung cancer, with models suggesting the impact of duration to be greater than that of intensity. Using participants from the Cancer Prevention Study II, Flanders et al¹⁰³ found a greater increase in lung cancer mortality with a greater duration of cigarette smoking compared with a greater intensity of smoking. Overall, these data suggest that lung cancer mortality increases more with additional years of smoking than

additional cigarettes per day. Thus, if dual use of e-cigarettes and cigarettes results in reductions in the number of cigarettes per day for current smokers, any reduction malignancy risk will be less than proportional to the reduction in cigarette consumption because of the (likely larger) importance of duration of smoking.

What to Tell Patients About E-Cigarettes and Cessation

First and foremost, clinicians must support a smoker's quit attempt and try to ensure any that advice given does not undermine their motivation to quit. Clinicians should follow the 5 A's of evidence-based treatment: ask, advise, assess, assist, and arrange.¹⁰⁴ They should assess their patient's motivation and readiness to quit and recommend a treatment plan that should include setting a quit date and obtaining cessation counseling and, if appropriate, conventional smoking cessation medications. The safest and most proven smoking cessation pharmacotherapies are the nicotine replacement medications varenicline and bupropion, which have been approved by the US Food and Drug Administration (FDA). Referral to a free telephone quit line (eg, 1-800-QUIT-NOW) or another counseling support program enhances the effectiveness of smoking cessation medications.¹⁰⁴

If a patient has failed initial treatment, has been intolerant of or refuses to use conventional smoking cessation medication, and wishes to use e-cigarettes to aid quitting, it is reasonable to support the attempt. However, subjects should be informed that, although e-cigarette aerosol is likely to be much less toxic than cigarette smoking, the products are unregulated, contain toxic chemicals, and have not been proven as cessation devices. The patient should also be advised not to use the product indoors or around children because studies show that bystanders may be exposed to nicotine and other toxins (at levels much lower than cigarettes) through passive exposure to the e-cigarette aerosol. Because there are no long-term safety studies of e-cigarette use, patients should be urged to set a quit date for their e-cigarette use and not plan to use it indefinitely. It is also important to stress that patients should quit smoking cigarettes entirely as soon as possible because continued cigarette smoking, even at reduced levels, continues to impose tobacco-induced health risks (particularly for cardiovascular disease).

Tobacco Industry and Involvement

By 2013, the major tobacco companies had purchased or developed e-cigarette products (Table 3).

There is no evidence that the cigarette companies are acquiring or producing e-cigarettes as part of a strategy to phase out regular cigarettes, even though some claim to want to participate in "harm reduction." Lorillard CEO Murray Kessler stated in an interview with the *Wall Street Journal* that e-cigarettes will provide smokers an unprecedented chance to reduce their risk from cigarettes.¹⁰⁵ He also published an op-ed in *USA Today* on September 23, 2013, stating: "E-cigarettes might be the most significant harm-reduction option ever made available to smokers."¹⁰⁶ Shortly before this op-ed was published, however, Lorillard won approval from the US FDA to market new nonmentholated Newport conventional

Table 3. Tobacco Companies That Have Acquired or Created E-Cigarette Companies and Brands (as of January 2014)

Tobacco Company	Acquired E-Cigarette Company	E-Cigarette Brand(s)
Altria Inc	GreenSmoke	Mark Ten
Reynolds American Inc	No	Vuse
Lorillard	Blu Cigs, Inc	Blu
British American Tobacco	CN Creative	Vype
Imperial Tobacco	Dragonite Holdings Ltd	Ruyan
Swisher	No	E-Swisher

E-cigarette indicates electronic cigarette.

cigarettes, expanding their cigarette line while touting their ability to offer a product they claim reduces harm from cigarettes. This allows the cigarette companies to have it both ways. (Likewise, after evaluating the cigarette companies' internal documents and public positions on snus [a form of moist snuff tobacco in a pouch popular in Sweden] as "harm reduction" in Europe, Gilmore et al¹⁰⁷ found that they were entering the snus market¹⁰⁷ and adopting "harm reduction" rhetoric¹⁰⁸ to protect their cigarette business as long as possible.) As noted in the 2010 Surgeon General's report,¹⁰⁹ the tobacco industry has used every iteration of cigarette design to undermine cessation and prevention.

The tobacco companies address e-cigarette issues as part of their policy agenda. As they did beginning in the 1980s,^{110,111} they continue to engage in creating and supporting "smokers' rights" groups, seemingly independent groups that interact with consumers directly on political involvement in support of their agenda.¹¹¹ Altria and R.J. Reynolds Tobacco Company maintain Web sites called Citizens for Tobacco Rights and Transform Tobacco. E-cigarette news and action alerts are featured on the home pages of these websites and include instructions for taking action against bills designed to include e-cigarette use in smoke-free laws. E-cigarette companies engage in similar tactics, using the same political and public relations strategies as the tobacco companies (most notably featuring organized "vapers" like the organized smokers). They also use social media that is tightly integrated with their product marketing campaigns to press their policy agenda.²² These strategies were successfully deployed in Europe to convince the European Parliament to substantially weaken the proposed EU Tobacco Product Directive in October 2013.¹¹²

Current State of Global Regulation (March 2014)

Like e-cigarette products, the policy environment related to e-cigarettes is rapidly developing despite the fact that the science is just emerging. Policy makers in many countries are under considerable pressure to provide regulatory guidance regarding e-cigarettes, often on the basis of the assumption that e-cigarettes will contribute to reducing the harms of smoking either by serving as a smoking cessation aid or by replacing combusted cigarettes. The data reviewed here, together with evidence of dual use and youth initiation of e-cigarette use, do not demonstrate any hypothesized harm-reducing effect.

Some countries (including Brazil, Singapore, Canada, the Seychelles, and Uruguay) have prohibited the sale of e-cigarettes, and many others are developing policies.¹ The United States, European Union, and United Kingdom illustrate the range of regulatory approaches being developed.

The United States

In the United States, as of March 2014, e-cigarette products remained unregulated by any federal authority, particularly the US FDA. The Sottera Inc case ruling that was upheld on appeal in the US court found that e-cigarettes could be regulated as tobacco products unless they are marketed with health and therapeutic claims.¹¹³ The US FDA has stated its intent to assert ("deem") authority over e-cigarettes but has yet to act. The US FDA does not have the authority to regulate where e-cigarettes are used; that is the domain of state and local governments, where almost all activity on smoke-free laws has occurred.

Since e-cigarettes entered the US market in 2008, there has been a rapid increase in the number of municipalities and states that have adopted legislation regulating where e-cigarettes can be used and laws restricting sales to minors. As of March 2014, 27 states had laws restricting sales to minors, 1 state (Minnesota) taxed e-cigarettes as tobacco products, and 3 states (New Jersey, North Dakota, and Utah) and >100 municipalities (including New York, Los Angeles, San Francisco, and Chicago) prohibited the use of e-cigarettes in 100% smoke-free indoor environments.¹¹⁴ An additional 9 states restricted e-cigarettes in other venues such as school district property, Department of Corrections/prisons, public educational facilities and grounds, and commuter transit systems.¹¹⁴ Some local and statewide smoke-free laws enacted before the introduction of e-cigarettes include language that could be interpreted as including e-cigarettes.

European Union Tobacco Product Directive

In February 2014, the European Parliament approved a revised European Union Tobacco Product Directive that regulates e-cigarettes with nicotine concentrations up to 20 mg/mL (an amount equal to that in a pack of cigarettes) as tobacco products.¹¹⁵ E-cigarettes with higher nicotine concentrations or intended therapeutic uses will be regulated as medical devices.¹¹⁶ The directive stipulates that e-cigarettes must be childproof and that packaging must include information about ingredients, adverse effects, and health warnings.¹¹⁵ Refillable cartridges are allowed as long as their volume does not exceed 2 mL (but could be banned by the European Commission if at least 3 member states prohibit them on the basis of risks to human health).¹¹⁵ Marketing and advertising restrictions will mirror those of tobacco products.¹¹⁵

The United Kingdom

In the United Kingdom, the Medicines and Healthcare Products Regulatory Agency announced a plan to regulate e-cigarettes as medicines on the basis of the assumption that e-cigarettes function like NRTs for smokers wishing to cut down or quit.⁷⁸ As of January 2014, Medicines and Healthcare Products Regulatory Agency policies did not include any restrictions on e-cigarette marketing.¹¹⁷ The antismoking advocacy group Action on Smoking and Health UK has announced that it "does not

consider it appropriate to include e-cigarettes under smokefree regulations,"¹¹⁸ supporting one of the e-cigarette companies' key marketing messages that e-cigarettes can be used everywhere without the restrictions and social stigma of smoking.^{3,119}

Policy Recommendations

E-cigarettes deliver lower levels of some of the toxins found in cigarette smoke. Main concerns about the potential of e-cigarettes to make a contribution to reducing the harm caused by cigarette smoking arise from effects on youth, dual use with cigarettes resulting in delayed or deferred quitting (among both adults and youth), and renormalization of smoking behavior.

The ultimate effect of e-cigarettes on public health will depend on what happens in the policy environment. These policies should be implemented to protect public health:

- Prohibit the use of e-cigarettes anywhere that use of conventional cigarettes is prohibited.
- Prohibit the sale of e-cigarettes to anyone who cannot legally buy cigarettes or in any venues where sale of conventional cigarettes is prohibited.
- Subject e-cigarette marketing to the same level of restrictions that apply to conventional cigarettes (including no television or radio advertising).
- Prohibit cobranding e-cigarettes with cigarettes or marketing in a way that promotes dual use.
- Prohibit the use of characterizing flavors in e-cigarettes, particularly candy and alcohol flavors.
- Prohibit claims that e-cigarettes are effective smoking cessation aids until e-cigarette manufacturers and companies provide sufficient evidence that e-cigarettes can be used effectively for smoking cessation.
- Prohibit any health claims for e-cigarette products until and unless approved by regulatory agencies to scientific and regulatory standards.
- Establish standards for regulating product ingredients and functioning.

In addition to being important in their own right, should these policies be put in place together with policies designed to make combustible tobacco products (eg, cigarettes, cigars, cigarillos) less desirable and available, it is possible that current conventional cigarette smokers who will not quit nicotine would shift to e-cigarettes without major dual use or youth initiation to nicotine addiction with e-cigarettes. Absent this change in the policy environment, it is reasonable to assume that the behavior patterns that have been observed for e-cigarettes will persist, which makes it unlikely that they will contribute to reducing the harm of tobacco use and could increase harm by perpetuating the life of conventional cigarettes.

Conclusions

Although most of the discussion of e-cigarettes among health authorities has concentrated on the product itself, its potential toxicity, and use of e-cigarettes to help people quit smoking, the e-cigarette companies have been rapidly expanding using aggressive marketing messages similar to those used to promote cigarettes in the 1950s and 1960s. E-cigarette advertising is on

television and radio in many countries that have long banned similar advertising for cigarettes and other tobacco products and may be indirectly promoting smoking conventional cigarettes. Although it is reasonable to assume that, if existing smokers switched completely from conventional cigarettes (with no other changes in use patterns) to e-cigarettes, there would be a lower disease burden caused by nicotine addiction, the evidence available at this time, although limited, points to high levels of dual use of e-cigarettes with conventional cigarettes, no proven cessation benefits, and rapidly increasing youth initiation with e-cigarettes. Although some cite a desire to quit smoking by using the e-cigarette, other common reasons for using the products are to circumvent smoke-free laws and to cut down on conventional cigarettes, which may reinforce dual use patterns and delay or deter quitting.

The trajectory of the dual use pattern among adults or children is unclear, but studies of youth find that as many as one third of youth who use e-cigarettes have never smoked a conventional cigarette. Nicotine is a highly addictive substance with negative effects on animal and human brain development, which is still ongoing in adolescence.¹²⁰⁻¹²³ Furthermore, high rates of dual use may result in greater total public health burden and possibly increased individual risk if a smoker maintains an even low-level tobacco cigarette addiction for many years instead of quitting.

Although data are limited, it is clear that e-cigarette emissions are not merely "harmless water vapor," as is frequently claimed, and can be a source of indoor air pollution. Smoke-free policies protect nonsmokers from exposure to toxins and encourage smoking cessation.¹²⁴ One hundred percent smoke-free policies have larger effects on consumption and smoking prevalence,¹²⁵ as well as hospital admissions for myocardial infarction, stroke, and other cardiovascular and pulmonary emergencies,¹²⁶ than weaker policies. Introducing e-cigarettes into clean air environments may result in population harm if use of the product reinforces the act of smoking as socially acceptable or if use undermines the benefits of smoke-free policies.

Acknowledgments

We thank the following individuals for their advice and feedback: Cort Anastasio, PhD; John Balmes, MD; Cynthia Hallett, MPH; Sara Kalkhoran, MD; Lauren Lempert, JD, MPH; C. Arden Pope III, PhD; Martina Pötschke-Langer, MD, MA; Prudence Talbot, PhD; Michael Thun, MD; Gemma Vestal, JD, MPH, MBA; and the reviewers solicited by the World Health Organization Tobacco Free Initiative of the longer report prepared for it.

Sources of Funding

This article is a greatly condensed version of a report prepared for (and supported by) the World Health Organization Tobacco Free Initiative. Additional support came from the University of California Tobacco Related Disease Research Program 21FT-0040 and grant 1P50CA180890 from the National Cancer Institute and Food and Drug Administration Center for Tobacco Products. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health, the US FDA, or the World Health Organization. Dr Glantz is an American Legacy Foundation Distinguished Professor in Tobacco Control.

Disclosures

Dr Benowitz is a consultant to several pharmaceutical companies that market smoking cessation medications and has been a paid expert witness in litigation against tobacco companies. Drs Grana and Glantz report no conflicts.

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KEY WORDS: adolescent ■ particulate matter ■ public policy ■ smoking

EXHIBIT 6

Electronic Cigarettes: A Policy Statement From the American Heart Association

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on behalf of the American Heart Association Advocacy Coordinating Committee, Council on Cardiovascular and Stroke Nursing, Council on Clinical Cardiology, and Council on Quality of Care and Outcomes Research

Circulation. published online August 24, 2014;

Circulation is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231

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Print ISSN: 0009-7322. Online ISSN: 1524-4539

The online version of this article, along with updated information and services, is located on the World Wide Web at:

<http://circ.ahajournals.org/content/early/2014/08/22/CIR.000000000000107.citation>

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AHA Policy Statement

Electronic Cigarettes

A Policy Statement From the American Heart Association

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For decades, advocacy for tobacco control has been a priority of the American Heart Association (AHA). In partnership with major public health organizations, the association has made major strides in tobacco use prevention and cessation by prioritizing evidence-based strategies such as increasing excise taxes; passing comprehensive smoke-free air laws; facilitating US Food and Drug Administration (FDA) authority to regulate tobacco, including comprehensive tobacco cessation treatment within healthcare plans; and supporting adequate funding of comprehensive tobacco control programs in different states. These tobacco control efforts have cut in half the youth smoking rate from 1997 to 2007 and have saved >8 million lives in the past 50 years.¹ However, the work is far from done and has stalled, especially for people living below the poverty line, those with mental illnesses,² and those with low educational attainment.³ Unless current trends reverse, ≈5.6 million children alive today in the United States will die prematurely of smoking-related diseases.¹ Even now, cigarette smoking kills nearly half a million Americans each year, and an additional 16 million individuals suffer from smoking-related illness, which costs the United States \$289 billion dollars annually in direct medical care and other economic costs.¹

This statement reviews the latest science concerning one of the newest classes of products to enter the tobacco product landscape—electronic cigarettes (e-cigarettes), also called electronic nicotine delivery systems (ENDS)—and provides an overview on design, operations, constituents, toxicology, safety, user profiles, public health, youth access, impact as a cessation aid, and secondhand exposure. On the basis of

the current evidence, we provide policy recommendations in key areas of tobacco control such as clean indoor air laws, taxation, regulation, preventing youth access, marketing and advertising to youth, counseling for cessation, surveillance, and defining e-cigarettes in state laws. The statement concludes by outlining a future research agenda to further our understanding of this emerging area of tobacco control and the impact of e-cigarettes on public health.

E-Cigarettes or ENDS

The first concept of an electric cigarette was patented in 1965 by Herbert A. Gilbert.⁴ Subsequently, an aerosolized, high-frequency e-cigarette was patented in China by Mr. Hon Lik and Ruyan Technology; it entered the marketplace in 2003⁵ and was patented internationally in 2007.⁶ Ruyan has since registered patents in >40 countries, including the United States,⁷ and has already brought patent infringement lawsuits against several e-cigarette manufacturers.⁸ E-cigarette design and manufacturing processes continue to evolve, and most products on the market today use a simpler, battery-powered heating element instead of the high-frequency, ultrasonic technology patented by Ruyan.⁷

As of early 2014, there were 466 brands and 7764 unique flavors of e-cigarette products.⁹ These products are now widely available online¹⁰ and in retail outlets in many countries across the world.^{11,12} In contrast to combustible products, e-cigarette availability in retail outlets in the United States is currently more likely in neighborhoods with higher median household income and a lower percentage of black and

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This statement was approved by the American Heart Association Advocacy Coordinating Committee on July 28, 2014. A copy of the document is available at <http://my.americanheart.org/statements> by selecting either the "By Topic" link or the "By Publication Date" link. To purchase additional reprints, call 843-216-2533 or e-mail kelle.ramsay@wolterskluwer.com.

The American Heart Association requests that this document be cited as follows: Bhatnagar A, Whitsel LP, Ribisl KM, Bullen C, Chaloupka F, Piano MR, Robertson RM, McAuley T, Goff D, Benowitz N; on behalf of the American Heart Association Advocacy Coordinating Committee, Council on Cardiovascular and Stroke Nursing, Council on Clinical Cardiology, and Council on Quality of Care and Outcomes Research. Electronic cigarettes: a policy statement from the American Heart Association. *Circulation*. 2014;130:•••-•••.

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(*Circulation*. 2014;130:00-00.)

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Circulation is available at <http://circ.ahajournals.org>

DOI: DOI: 10.1161/CIR.0000000000000107

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Hispanic residents.¹² E-cigarette availability in retail outlets is also higher in states with weak or nonexistent laws for clean indoor air and low cigarette taxes.¹²

Although the sale of e-cigarettes is prohibited in some countries (Australia, Brazil, Canada, Mexico, Panama, Singapore, and Switzerland), it is allowed in most others, including the United States.¹³ The number of e-cigarettes sold has increased exponentially year by year. Wells Fargo has predicted that sales margins for e-cigarettes could grow to \$10 billion by 2017, surpassing conventional cigarette sales margins.¹⁴ The big 3 major tobacco companies have been purchasing independent e-cigarette companies and may share 75% of the profit pool in 10 years.¹⁴

E-cigarettes are battery-powered devices that have cartridges or refillable tanks containing a liquid mixture composed primarily of propylene glycol and/or glycerol and nicotine, as well as flavorings and other chemicals.⁵ During use, inhalation activates a pressure-sensitive circuit that heats the atomizer and turns the liquid into an aerosol that is inhaled by the user through the mouthpiece and exhaled as a fine mist.⁵ Some e-cigarettes have buttons that allow the user to manually activate the heating element. The exhaled aerosol does not contain smoke, tar, or carbon monoxide. Studies of specific types of e-cigarettes have shown that compared with conventional cigarettes, the byproducts from their aerosols produce very low levels of air toxins.^{15–17} Proponents of e-cigarettes maintain that these products emulate smoking behavior without exposing the user to the toxic smoke constituents of conventional cigarettes that are deleterious to health, so there would be a public health benefit if individual smokers completely switched or substantially reduced their cigarette smoking habit.^{18–20} However, the use of e-cigarettes could be a problem at the population level. For instance, e-cigarettes could fuel and promote nicotine addiction, especially in children, and their acceptance has the potential to renormalize smoking behavior. E-cigarette use could also potentially serve as a gateway to other drugs and harmful substances.²¹

E-Cigarettes: Design and Operation

Since their initial manufacturing in 2003, there has been a rapid growth and evolution in the types, design, and overall engineering characteristics of e-cigarettes.^{22,23} This has resulted in a large degree of product variability in size, potential nicotine concentrations, and e-liquid formulations. There have also been changes in electrical circuitry (eg, heating element or atomizer) and battery life that allow for more e-liquid delivery, adjustments in flavor, and longer device use.

Different types of e-cigarettes are being developed continuously. Table 1 lists some of the different e-cigarette types and name brands on the market today. Newer second- and third-generation devices allow for multiple types of user customization. This has resulted in cross-product and within-product differences in aerosol production, nicotine delivery, and product use risk.²² These developments significantly complicate the ability to assess the impact of e-cigarettes on individual and population health.^{22,23}

Regardless of type, there are 3 basic e-cigarette components: a battery, an e-liquid-containing cartridge, and an atomizer (ie, a vaporization chamber with heating element).²¹

Other components include an airflow sensor (sensing inhalation), a microchip for controlling the heating element, and a light-emitting diode light at the tip that simulates a burning cigarette tip.²¹ All devices have air holes, which control the pressure drop and facilitate the flow of air required for puffing.²² E-cigarettes are available with automatic or manual button-activated batteries. The battery in an automatic device is activated by inhalation or the drag, whereas manual devices require the depression of a button for battery activation.²² The smokelike aerosol produced by these devices is not because of the combustion of organic material; rather, it is an aerosol of the e-liquid. As noted, the “atomizers” contain the heating elements that convert the fluid into an aerosol. Such atomizers are an essential component of all vaporizers, and they consist of a small heating element that evaporates the fluid and a wicking device that draws in the fluid. Since the inception of e-cigarettes, the atomizers have undergone dramatic engineering changes. Developments include the evolution of the atomizer into “cartomizers” (cartridge plus atomizer), which is a combination of an e-liquid distribution system and a wick/fiber and heating element.²³

Second- and third-generation e-cigarettes models, which are larger than the first “cigarette-like” e-cigarettes (cigalikes), are referred to as “clearomizers,” “tankomizers,” or “cartotanks” because they can hold several milliliters of fluid in refillable reservoirs. Some second- and third-generation e-cigarette batteries are available in different voltages (3.0 to 7.0 V) and with greater battery life (greater milliampere-hour) than earlier models. Within the atomizer, a resistance wire is encircled around the wicking device that draws the fluid in. When activated by the sensing device, the resistance wire rapidly heats up, turning the fluid into an aerosol, which is then inhaled by the user. The resistance and voltage applied to the heating element, as well as the material from which the heating element is made, are important determinants of the temperature achieved, which determines in part the amount and quality of the aerosol produced by the atomizer.

Some second- and third-generation e-cigarettes have programmed pumps, diaphragms, or micropumps on microelectromechanical systems. These allow for a specific programmed amount or a combination of e-liquid delivery to the aerosol generator.²² Some e-cigarettes contain programmable logic units, integrated circuits, and other electronic components that are used to display average use cycle and safety warnings.²² Ongoing product development and evolution are likely to continue, and therefore, new regulatory policies will be important to ensure appropriate quality control.

Profile of Users

The number and duration of surveys are increasing and variably include current, former, and nonsmoker categories.^{24,25} These surveys are difficult to consolidate because they have been undertaken in different populations and jurisdictions, using different sampling methods and definitions, over a number of years while e-cigarette types, visibility, and use have increased dramatically. Generally, non-Hispanic whites, current smokers, young adults, and those with a higher education and higher income perceive e-cigarettes as less harmful than combustible tobacco products and are more likely to use

Table 1. Types of E-Cigarettes

Generation	Examples
First generation	
First generation e-cigarettes were designed to look and feel like tobacco cigarettes. Although there is some variation in size, most resemble cigarettes and therefore have also been referred to as "cigalikes." These battery-operated devices were initially composed of 3 pieces: a battery, atomizer, and cartridge. Now, the atomizer and cartridge have been replaced by a combined "cartomizer," which screws into and connects with a battery, some of which are rechargeable. The disposable e-cigarettes are designed for 1-time use and are discarded after use. These cigalike devices are all available in various nicotine concentrations and with different flavorings.	Halo White Cloud Green Smoke Apollo Blu South Beach V2 Cigs Atlantic
Second generation	
These e-cigarette devices are larger and typically do not resemble a cigarette. These medium-battery (rechargeable)-style e-cigarettes are also referred to as "tank-styled" e-cigarettes. Sizes, shapes, and colors can resemble pens, small screwdrivers, or the tip of a hookah pipe. These larger e-cigarette devices have the basic e-cigarette components: the battery, the atomizer, and the cartridge. However, there are some key differences between these devices and the first-generation e-cigarette devices: second-generation e-cigarette devices have larger-capacity batteries (greater milliampere-hours) and therefore stay charged longer, have larger atomizers and electronic circuits that deliver greater energy (which enhances nicotine delivery to the user), and have large, separate cartridges ("tanks") that the user can fill up using different purchased e-liquids and flavorings. Some also have a manual switch that allows modulation of both puff length and frequency.	eGo Riva Tornado KGo
Third generation	
These devices are similar to the second generation but are larger and allow for more personal and custom modifications; therefore, they are sometimes referred to as "personalized vapors" or aerosols. Similar to the second-generation devices, these devices come with a range of different cartridge and atomizer options (eg, cartomizer, clearomizer, tankomizer) and batteries (greater milliampere-hours coupled with a certain voltage [3.0–6.0 V]). Some e-cigarettes devices allow the user to adjust the resistance on the atomizer/cartomizer. A low-resistance cartomizer produces higher heating element temperatures, thus generating more heat and affecting the amount and quantity of the aerosol. Users of these devices can pair different atomizers (that allow different resistances) with high-capacity batteries to maximize both aerosol production and battery life.	Companies with personal vapors: Apollo Henly Vapor Zone Volcano
E-cigs could either be classified as a second- or third-generation e-cigarette device. Available in disposable and rechargeable forms. Designed to simulate a cigar in terms of size. Some e-cigs have an LED tip that is partially hidden behind some type of screen to mimic a real cigar's ash.	E-cigar: Cuvana Marcella-rechargeable Vapor Zeus Royale premium

E-cigs indicates electronic cigars; e-cigarettes, electronic cigarettes; LED, light-emitting diode.

them.^{24,26–29} European and North American surveys conducted in 2012 and 2013 report that most e-cigarette users are current or former smokers³⁰; 40% to 70% of all adults have heard about them, with awareness highest in smokers and growing.^{26,31–33} Such surveys also report that ≈3% to 7% of the adult population has ever used e-cigarettes.^{26,34} Among smokers in the United States and Great Britain, ≈11% report ever having used e-cigarettes, whereas the use of e-cigarettes is significantly lower (0.5%–1.0%) in nonsmokers.^{25,26,35} A study conducted in the Czech Republic in 2012 revealed that almost 20% of smokers who try e-cigarettes go on to become regular users.³⁶

It is uncertain how many e-cigarette users are smokers who really want to stop cigarette smoking or ex-smokers but persistent e-cigarette users, or who want to be dual users. At present, there are few longitudinal studies to assess how many smokers are able to completely quit cigarette use, whether they continue e-cigarette use after quitting or whether they continue dual use, that is, using them concurrently with combustible products.³⁶ Epidemiological studies and population surveys also indicate that although many e-cigarette users plan to use the devices to quit or reduce their smoking, they are usually using them in a dual-use capacity, especially in places where smoking is restricted.^{35–40} A survey conducted in 2012 showed that >80% of current e-cigarette users do not use them on a daily basis, and almost half of all smokers indicated they may use e-cigarettes in the future.³⁵ Finally, among college students, another e-cigarette user group, e-cigarette use may

not be motivated by the desire to quit smoking, nor may it lead to quitting.⁴¹ In conclusion, the overall use patterns are unclear and constantly changing, which makes it difficult to draw firm conclusions about the prevalence, preference, and purpose of e-cigarette use.

Youth

Concerned public health advocates see e-cigarettes as a route to nicotine addiction and possibly as a potential gateway to tobacco use in youth or nonsmokers and to reinitiation of tobacco product use by former users.⁴² Data from the 2011 to 2012 National Youth Tobacco Survey⁴³ showed that among students in grades 6 through 12, current e-cigarette use (≥1 day in the past 30 days) increased from 1.1% in 2011 to 2.1% in 2012 and any use of e-cigarettes (ever use) increased from 3.3% to 6.8% in the same corresponding years. Overall, by 2012, 1.78 million high school and middle school students nationwide had tried e-cigarettes. For those students who had ever used e-cigarettes, 9.3% reported never smoking conventional cigarettes, whereas 76.3% of current e-cigarette users responded that they also smoke conventional cigarettes. Among never-smokers, 0.7% were currently users (past 30 days), which indicates that few never-smokers who try e-cigarettes continue their use.⁴⁴ A survey of 40 000 middle school and high school students from ≈200 schools has shown that e-cigarette use is higher in current smokers and ever-smokers

and among those intending to quit.⁴³ This surveillance does not address whether adolescents are using e-cigarettes as a gateway to smoking cigarettes, but adolescents do consider e-cigarettes as high-tech, accessible, and convenient, especially in places where smoking cigarettes is not allowed.⁴⁵ Increasingly, there is robust marketing and advertising using celebrities and appealing flavors (eg, chocolate, strawberry, and vanilla) to make e-cigarettes especially more attractive and appealing to children and adolescents.⁴⁵ Much of the marketing for e-cigarettes has been through the Internet and social media outlets such as YouTube,⁴⁶ but increasingly, e-cigarettes are advertised on television, radio, and in the print media, where broadcast cigarette ads have been banned since 1971.⁴⁷ Data from a US population survey indicated that for those reporting they have heard about e-cigarettes, the majority (48%) reported television as their primary source, followed by “in-person conversation” and the Internet.³⁵ Another study found that youth exposure to television advertisements for e-cigarettes increased 256% between 2011 and 2013, with 24 million youth reached.⁴⁸ Online searches for e-cigarettes have surpassed those for nicotine replacement therapies (NRTs) and snus, products that have been on the market much longer.⁴⁹

E-Cigarettes and Public Health

The major public health issues regarding e-cigarettes include whether or not they may contribute to reducing overall tobacco-related harm through complete cessation or possibly through reduction of the number of cigarettes smoked, denormalization of smoking, reduction in prevalence of use of combustible products (especially cigarettes), reduction of second-hand smoke exposure, and diminishing the influence of the tobacco industry. Although some believe that acceptance of e-cigarettes has the potential to reverse the social norm for prohibiting smoking in public places achieved over decades of advocacy work, others see these products as a way to denormalize smoking because they are a potential mechanism for quitting.²⁰ It is not known whether the emerging e-cigarette technology will shift people from combustible products to the exclusive use of e-cigarettes or whether dual use will persist.⁵⁰

E-Cigarettes as a Cessation Aid

Current evidence evaluating the efficacy of these products as a cessation aid is sparse, confined to 2 randomized controlled trials and 1 large cross-sectional study, anecdotal reports, and Internet-based surveys. A large cross-sectional study showed that smokers who wanted to quit without professional help were significantly more likely to report abstinence using e-cigarettes than with traditional cessation aids or going “cold turkey.”⁵¹ The adjusted odds ratio for self-reported cigarette abstinence in e-cigarette users was 1.63 (95% confidence interval 1.17–2.27) higher than with NRT use and 1.61 (95% confidence interval 1.19–2.18) higher than for those using no aid. In a survey in the United Kingdom, 67.8% of e-cigarette users “completely replaced tobacco cigarettes with electronic cigarettes”; however, these reports are confounded by a self-selection bias in that the respondents are often e-cigarette enthusiasts.³⁹ In contrast, other surveys suggest that compared with never-users, e-cigarette users are less likely to be tobacco

abstinent⁵² and that e-cigarette users were no more likely than cigarette smokers to have quit permanently despite having reduced their cigarette consumption.²⁴

The largest randomized controlled trial conducted to date, which used e-cigarettes available on the market in 2010 that are now obsolete, had cartridges labeled as containing 16 mg of nicotine and showed that the study e-cigarettes were modestly effective with or without nicotine at helping smokers quit, on par with the abstinence achieved with nicotine patches.⁵³ At 6 months, the verified quit rates were 7.3% with nicotine e-cigarettes, 5.8% with nicotine patch, and 4.1% with placebo e-cigarette treatment. This study also found that dual use persisted at 6 months at moderately high levels (approximately one third of participants); dual use also occurred with patch users but at much lower levels (7%).

Health Effects and Safety

The overall health effects of e-cigarettes should be considered both in the context of the intrinsic toxicity of e-cigarettes and with regard to their relative toxicity compared with the well-known injurious effects of smoking conventional cigarettes. Even if there are some intrinsic adverse health effects of e-cigarettes, there would be a public health benefit if e-cigarettes proved to be much less hazardous than combustible cigarettes and if smokers could switch entirely from conventional cigarettes to e-cigarettes. However, in general, the health effects of e-cigarettes have not been well studied, and the potential harm incurred by long-term use of these devices remains completely unknown. Nevertheless, some studies have examined the health effects of e-cigarettes by considering the constituents of their aerosol and their known toxicities and through toxicological evaluation of e-cigarette liquids and aerosols. Current data from human exposures, including experimental studies, and surveys of adverse effects and accidental exposure are discussed below. Available data on the safety and health effects of e-cigarettes have been reviewed elsewhere.^{54–56}

The constituent and toxicant levels within the e-liquid and aerosol vary depending on the type of e-liquid (or e-juice) formulation and the specific design of the device.⁵⁷ Typically, e-liquid formulations contain nicotine, flavors, water, glycerin, and propylene glycol.⁵⁷ Exposure to levels and types of metals or other materials within the aerosol depends on the material and other engineering features of the heating coils.⁵⁷ Potential metallic and nanoparticles derived from the heating coils can include tin, iron, nickel, and chromium.^{22,58} Other materials in e-cigarettes could include ceramics, plastics, rubber, filament fibers, and foams. Some of these materials can be aerosolized and inhaled. Importantly, low levels of harmful or potentially harmful metals such as lead, nickel, and chromium are listed as having been detected.^{22,59} The e-liquids typically contain many flavorings, including tobacco flavoring. In tobacco-flavored products, other tobacco “contaminants” may be present. Trace levels of tobacco-specific *N*-nitrosamines, polycyclic aromatic hydrocarbons, and volatile organic compounds in the e-liquid and vapor have been reported; however, the amounts are deemed too low to cause human risk.^{57,60} Other flavorings include fruit and spices (eg, strawberry, black cherry, and Ceylon cinnamon) or flavorings such as “bubble gum” or “chocolate truffle.”

Propylene glycol is a major ingredient in e-cigarettes. It is approved by the FDA as a solubilizing agent for different types of medications and is considered generally nontoxic.⁵⁹ However, in 1 product, small amounts of diethylene glycol, a potential byproduct of nonpharmaceutical grade propylene glycol, have been detected.⁶¹ Other contaminants found in particular products have included the weight-loss chemical rimonabant (Zimulti) and the erectile dysfunction medication tadalafil (the active ingredient in Cialis). As a result, the FDA has issued warnings to several e-cigarette companies for selling e-cartridges with these contaminants.⁶¹

Nicotine

Nicotine is delivered by most but not all e-cigarette products. Most e-liquids contain 24 mg/mL, 18 mg/mL, 12 mg/mL, or 6 mg/mL nicotine and are qualified by the manufacturers as high, medium, or low nicotine strength.⁶² Some e-liquids are available in 36 mg/mL concentrations.⁶² Nicotine solutions of 100 mg/mL for use in making e-cigarette refill liquids are available over the Internet. As a point of context, 1 regular cigarette contains ≈ 10 to 15 mg of nicotine and delivers a systemic dose of ≈ 1 mg of nicotine. Testing has revealed that the nicotine content noted in some e-cigarette products and refill solutions has been incorrect and either overestimates or underestimates the amount of nicotine,⁶¹ which indicates a need for regulatory oversight.⁶¹ The overall total amount of nicotine in the e-liquid depends on the size of the refill vial; for example, a 10-mL bottle of 24 mg/mL contains a total of 240 mg of nicotine.

Blood levels of nicotine are generally lower from e-cigarette use than from conventional cigarettes, but users of some e-cigarette tank systems with more powerful batteries that heat liquids to higher temperatures may achieve blood nicotine levels comparable to those of cigarette smokers.^{63,64} The extent to which nicotine inhaled from an e-cigarette is absorbed through the lungs or via the throat and upper airway has not been determined. The size distribution of particles generated by e-cigarettes, discussed later in this report, suggests that at least some pulmonary absorption is likely. In 1 study,⁵⁸ it was found that absorption of nicotine from e-cigarettes was lower than from tobacco cigarettes even with the new-generation cartomizers, which suggests that most absorption from the devices occurs in the buccal mucosa or upper airways. Compared with smoking 1 tobacco cigarette, the electronic devices and liquid used in this study delivered one third to one fourth the amount of nicotine after 5 minutes of use. New-generation e-cigarette devices were more efficient in nicotine delivery but still delivered nicotine much more slowly than tobacco cigarettes.

The main health concern for nicotine in cigarette smokers is maintenance of addiction. Most of the adverse health effects of smoking are caused by tobacco combustion products,⁶⁵ but there are some health concerns that are related to nicotine per se. Many of these concerns are related to the ability of nicotine to release catecholamines, including hemodynamic effects (increase in heart rate, a transient increase in blood pressure, vasoconstriction of coronary and other vascular beds), adverse effects on lipids, and induction of insulin resistance.⁶⁵ Nicotine has also been reported to produce endothelial dysfunction and to cause fetal teratogenicity, operating

by different mechanisms.⁶⁶ Nicotine in vitro and in animals can inhibit apoptosis and enhance angiogenesis, effects that raise concerns about a role of nicotine in promoting the development and spread of cancer and in the acceleration of atherosclerotic disease.⁶⁷

Because most people use nicotine in the form of tobacco products, there are relatively few data on the health effects of prolonged exposure to pure nicotine. There are some studies of prolonged NRT in smokers who have quit smoking.^{68,69} In these studies, no adverse effects have been found when nicotine medication was administered for months to several years. Other studies indicate that patients with known cardiovascular disease tolerate NRT well for periods up to 12 weeks.⁶⁵

Because most of the toxicity from cigarette smoking derives from combustion products, the health effects of smokeless tobacco could be examined to assess potential long-term adverse effects of nicotine without exposure to combustion products. Smokeless tobacco users take in as much nicotine as cigarette smokers, although not by the pulmonary route.⁷⁰ The most extensive and rigorous epidemiological studies on smokeless tobacco use come from Scandinavia, where a large percentage of men use snus, a smokeless tobacco product that contains nicotine but relatively low levels of carcinogens and other toxins. These studies report only a very small cardiovascular disease risk in snus users compared with tobacco smokers.⁷¹ However, discontinuation of snus use after MI has been found to be associated with nearly halved mortality risk, which is similar in magnitude to the benefit associated with smoking cessation.⁷² Thus, although the adverse health effects of e-cigarettes are not known, they are likely to be much less than those of cigarette smoking, but could be significant in individuals with heart disease.

Acute nicotine toxicity is a concern if e-cigarette liquids are ingested, which may occur accidentally by children or intentionally by adults as a suicidal overdose, or with dermal exposure. Nicotine is well absorbed through the skin when in an alkaline solution, and e-cigarette liquids are alkaline. Nicotine intoxication commonly causes dizziness, nausea, vomiting, pallor, tachycardia, and sweating. Abdominal pain, salivation, lacrimation, and diarrhea have also been noted. Confusion, agitation, lethargy, convulsions, and possibly death are seen in cases of severe poisonings that cause hypotension and respiratory muscle weakness.⁷³ In such cases, respiratory arrest is the most likely the cause of death.⁷³ Symptoms usually begin within 15 minutes of acute liquid nicotine exposure and resolve within 1 to 2 hours.⁷³ Cutaneous exposure may lead to delayed onset and prolonged symptoms. A number of cases of accidental exposure in children and adults have been reported by poison control centers.^{74,75} The concentrations of nicotine in e-cigarette liquids are high enough to be fatal to a child if even a few milliliters is ingested.^{76,77} There are isolated reports of severe toxicity, including death, in children who ingested e-cigarette liquids. Nationally, calls to poison control centers attributable to accidental exposure to e-cigarettes have increased dramatically (161%–333%), mostly involving children who were exposed to the replacement cartridges and liquids containing nicotine.^{78,79}

Minor Tobacco Alkaloids and Tobacco-Specific Nitrosamines

Some but not all e-cigarette liquids contain minor tobacco alkaloids (such as nornicotine, anabasine, or anatabine) and tobacco-specific nitrosamines, such as *N*'-nitrosonornicotine and 4-(methylnitrosamine)-1-(3-pyridyl)-1-butanone (NNK).⁷⁶ These may be present in the liquids because nicotine is extracted from tobacco, and these compounds are present in tobacco. Several minor tobacco alkaloids have nicotine-like actions, although they are less potent than nicotine. Extensive evidence has shown that tobacco-specific nitrosamines are highly carcinogenic⁸⁰; however, the levels of both minor alkaloids and nitrosamines present in most e-cigarette products are low and are unlikely to pose a significant human health risk.⁸¹ Minor alkaloids and tobacco-specific nitrosamine are undetectable in nicotine medications.⁸²

Carbonyls and Other Volatile Chemicals

Thermal degradation of propylene glycol can generate propylene oxide, which is classified by the International Agency for Research on Cancer as a class 2B carcinogen. The heating of glycerol can form acrolein, which is an irritant and oxidizing agent thought to contribute to adverse pulmonary and cardiovascular effects of cigarette smoking.^{83–85} Analyses of emissions from cigarettes have found primarily formaldehyde, acetaldehyde, and acrolein, along with low levels of toluene, xylene, benzene, and butadiene.⁸⁶ Although these compounds are potentially toxic, the levels in e-cigarette emissions are many-fold lower than those found in cigarette smoke and in some cases similar to those found in the mist of medicinal nicotine inhalers. The risk of exposure to low levels of these compounds is unknown. With intense heating, such as from the use of tank models with large batteries, higher amounts of formaldehyde are generated, in some cases similar to levels found in cigarettes smoke.^{60,87} Formaldehyde is a carcinogen and an irritant, but the risks of prolonged inhalation of formaldehyde at the levels found in e-cigarette aerosols are unknown.

Propylene glycol and glycerol are added in e-cigarette liquids to generate an aerosol that resembles cigarette smoke. Animal studies of propylene glycol inhalation for up to several months have revealed little or no toxicity.^{88,89} Propylene glycol is used to generate theater fog and is used in aviation industries. It can cause eye and respiratory irritation, and there have been concerns about respiratory irritation in the theater.⁹⁰ Thus, there are concerns about potential harm from the inhalation of propylene glycol from e-cigarettes, particularly for people with asthma or chronic obstructive lung disease, although there is little research on the effects in susceptible populations.

Metals

Detectable levels of metals such as tin, silver, iron, nickel, cadmium, and copper have been detected in some but not all e-cigarettes in which they could be generated from the heating element.⁵⁸ Some e-cigarette solutions contain tin “whiskers,” microscopic crystals that emanate from tin in the solder joints.⁵⁸ The nature and amount of metals generated depend on the design of the e-cigarette product, and some generate few or no metals. The levels of metals in e-cigarette emission

are generally low, but little is known about the toxicity of prolonged inhalation of low levels of metals.

Particles

E-cigarettes generate an aerosol that consists of fine and ultra-fine particles in a gas phase. These particles are likely generated from supersaturated 1,2-propanediol vapor. Nanoparticles present in some e-cigarette aerosols have been reported also to contain trace levels of tin, chromium, and nickel.⁵⁸ It has been reported that particle number concentration of the mainstream aerosol generated by e-cigarettes, averaged across several liquids and types of e-cigarettes, was similar to that of conventional tobacco cigarettes.^{91,92} The number of particles in e-cigarette aerosol has been found to be influenced by the liquid nicotine content and puffing time, and higher levels of particles were generated by e-cigarettes that contained higher nicotine concentrations.⁹¹ The particle size distribution from the few e-cigarette devices that have been tested has been reported to be similar to that of conventional cigarettes.⁹² Particles such as those generated by e-cigarettes can reach deep into the lungs and potentially cross into the systemic circulation. Carbonaceous particles present in cigarette smoke and ambient air have been demonstrated to have adverse cardiovascular and respiratory effects in both human and animal models.^{93,94} It is not known whether the type of particles generated by e-cigarettes have the same toxicity as particles present in ambient air or those generated by conventional cigarettes, but this is an important question for determining the long-term safety of e-cigarettes.

Toxicology Studies

Results of several toxicology studies with e-cigarette liquids and aerosols have been published. These studies show that e-cigarette liquids and aerosols affect the viability of established cultured cell lines, such as human or mouse fibroblasts, human embryonic stem cells, mouse neural stem cells, and cardiomyoblasts.^{95–97} For example, using 3 different cell types (ie, human embryonic stem cells, mouse-derived neural stem cells, and human pulmonary fibroblasts), Bahl et al⁹⁵ examined the cytotoxicity of several flavored e-cigarette refill extracts from 4 different manufacturers. They reported that extract flavorings such as Ceylon cinnamon were toxic to all 3 cell types tested. In addition, 1 butterscotch sample was highly toxic, whereas 2 other butterscotch samples from the same company had low toxicity, which shows the within-product and between-product variability.⁹⁵ Overall, the human embryonic and neonatal mouse-derived stem cells were more sensitive than adult lung fibroblasts to the cytotoxic effects of the extracts. Cytotoxicity was not caused by nicotine but was correlated with the number and concentrations of flavoring chemicals. In general, cytotoxicity appeared to be related to the concentrations and numbers of flavorings used and unrelated to nicotine. Of particular concern with respect to cytotoxicity of flavorings are the effects of cinnamaldehyde, a flavoring that is approved for use in food but can be dangerous when inhaled.⁹⁸ Aerosols of some but not all e-cigarettes have also been reported to be mildly cytotoxic.⁹⁸

Although the nature, concentration, and time course of exposure to e-cigarette constituents are likely to be quite different from those present in tobacco cigarette smoke, in

general, the few studies conducted so far suggest that e-cigarette emissions are much less toxic than cigarette smoke in cytotoxicity tests. The significance of these findings to the *in vivo* toxicity of e-cigarette liquid constituents is not clear, and additional research is needed to establish the potential toxicity of flavors and other e-cigarette constituents.

Human Health Effects

To date, relatively little research has been conducted on the human health effects of e-cigarettes. Spontaneous reports and clinical trial data have reported common minor side effects of throat and mouth irritation, dry cough, nausea, and vomiting. No serious adverse effects have been reported in clinical trials with >6 months of use compared with nicotine patches, with no difference between groups.^{53,99} Because propylene glycol as a constituent of theater fog is known to cause respiratory irritation, pulmonary toxicity has been a reasonable concern. One study of 10 healthy smokers using 1 brand of e-cigarette (Nobacco, 11 mg of nicotine, >60% propylene glycol) as desired for 5 minutes found no significant effect on conventional spirometry measures but did find a small but significant increase in dynamic airway resistance (18%) and a significant decrease in exhaled nitric oxide (16%).¹⁰⁰ Smokers in this study had abstained from cigarette smoking for only 4 hours before using e-cigarettes, and there was no comparison with the effects of a conventional cigarette. Another study examined pulmonary function in 15 cigarette smokers and 15 never-smokers who used the same brand of e-cigarette (60% propylene glycol, 11 mg of nicotine).¹⁰¹ Cigarette smoking caused a significant decrease in forced expiratory volume in the first second of expiration/forced vital capacity (FEV₁/FVC), which was not seen with e-cigarette use. This study also reported that cigarette smoking increased white blood cell count, which reflects an inflammatory response, whereas there was no significant change with the use of e-cigarettes.¹⁰¹ A small retrospective study of pulmonary function and symptoms in smokers with asthma who switched to e-cigarettes found no adverse effects of e-cigarettes, but rather, the e-cigarette users had improved pulmonary function and reduced severity of asthma symptoms.¹⁰² Eighteen heavy smokers with mild to moderate asthma who were taking a stable dose of inhaled corticosteroids and long-acting β -agonists had pulmonary function tests before and 6 and 12 months after beginning e-cigarette use. These individuals mostly started with e-cigarettes that were cigarette-like, but most switched later to tank-type devices. Ten individuals quit smoking entirely, whereas 8 continued dual use. Dual users decreased their number of cigarettes smoked per day from an average of 22.4 at baseline to 3.9 per day at 12 months. These subjects showed a small but significant improvement in FEV₁ and forced mid-expiratory flow (25%–75%) and reduced airway responsiveness to inhaled methacholine, as well as an improved score on an asthma control questionnaire. The authors comment that the improvement in asthma symptoms may be related to stopping smoking or smoking fewer cigarettes, which could have led to less severe inflammation or a reduction in corticosteroid insensitivity. Although it was small, retrospective, and not controlled, this study does provide evidence that e-cigarette use is not harmful to people with mild to moderate asthma, but

more extensive studies are required to establish the safety of e-cigarette use in this population.

Few studies have reported the cardiovascular effects of e-cigarettes. The results of these studies suggest that e-cigarettes can increase heart rate and blood pressure, as expected with systemic absorption in nicotine. The use of e-cigarettes for 7 minutes did not cause diastolic dysfunction, which was seen with conventional cigarette smoking.⁵⁵ Another study found that e-cigarette use had no effect on flow velocity reserve of the left anterior descending coronary artery assessed by echocardiography, whereas cigarette smoking caused a decline in flow reserve (16%) and an increase in coronary vascular resistance (19%).⁵⁵ A case of atrial fibrillation in an elderly person after e-cigarette use has been reported, an effect that could have been caused by the autonomic nervous system effects of nicotine.¹⁰³ One case of lipid pneumonia has been reported in an e-cigarette user, but the causation is questionable because there is no clear biological plausibility.¹⁰²

In summary, the data on health effects to date, studied primarily in healthy people with short-term exposure, reveal little or no evidence of severe adverse events. Respiratory irritation and the bronchial constriction from a propylene glycol aerosol raise concerns about harm to people with asthma and chronic obstructive pulmonary disease, but 1 small study reports no harm but rather benefit when users quit smoking or smoke fewer cigarettes per day. There are no reports of e-cigarette safety in patients with known cardiovascular disease.

Secondhand E-Cigarette Aerosol Exposure

Passive cigarette smoke exposure is hazardous. It is associated with an increased risk of respiratory disease, including asthma; a variety of infectious diseases; lung cancer; acute coronary events; and stroke.¹⁰⁴ Acute exposure to secondhand smoke produces endothelial dysfunction and platelet activation. Most or all of the acute adverse effects of secondhand smoke are thought to result from exposure to the combustion products of tobacco, including many oxidants and other reactive chemicals.

Most of the secondhand smoke generated from conventional cigarettes results from sidestream smoke, which accounts for 75% of the burning cigarette mass. E-cigarettes do not generate sidestream aerosol. The secondhand emissions from e-cigarettes consist entirely of what is exhaled after inhalation by the user. We focus on data from studies in which aerosol generated by e-cigarette users was evaluated.

Schripp et al¹⁰⁵ studied secondhand emissions by asking a volunteer to use e-cigarettes in a closed chamber. Analysis of the air revealed the presence of formaldehyde, acrolein, isoprene, acetaldehyde, and acetic acid, but at levels 5 to 40 times lower than those generated by a combusted cigarette. Schober et al¹⁰⁶ conducted 6 sessions, each of which consisted of 3 subjects using e-cigarettes as desired for 2 hours in a 45-m³ ventilated room. The e-cigarettes were refillable tank devices with a liquid that contained both propylene glycol and glycerin and either 22 mg of nicotine per milliliter or zero nicotine. E-cigarette use significantly increased PM_{2.5} (particulate matter <2.5 μ m in size), propylene glycol, glycerin, and nicotine, but not formaldehyde, benzene, acrolein, or acetone. There was a 30% to 90% increase in the sum of 16 measured polycyclic aromatic hydrocarbons

and a 2.4-fold increase in ambient aluminum concentration. No comparisons were made to secondhand cigarette smoke. Czogala et al¹⁷ compared ambient levels of nicotine in a ventilated room in which people had either smoked conventional cigarettes or used e-cigarettes. Five subjects generated the aerosol over 1 hour using either pen or tank-type e-cigarettes. With e-cigarette use, the ambient level of nicotine was $\approx 10\%$ of that seen with smoking conventional cigarettes (3.3 versus 31.6 $\mu\text{g}/\text{m}^3$). The ambient $\text{PM}_{2.5}$ concentration after e-cigarette use was $\approx 18\%$ of that seen with cigarette smoking. In another study by Flouris et al,¹⁰¹ 15 nonsmokers were exposed in a 60- m^3 ventilated chamber to 1 hour of secondhand cigarette smoke (at a concentration simulating that of a smoky bar) or to e-cigarette aerosol generated by a smoking machine. The study found that serum cotinine was similar in nonsmokers after secondhand tobacco smoke and e-cigarette aerosol exposure (2.6 versus 2.4 ng/mL). Exposure to e-cigarette aerosol had no effect on pulmonary function or white blood cell count. Thus, secondhand exposure to e-cigarette aerosol exposes a nonsmoker to nicotine, particulates, and several potentially toxic organic chemicals, but at much lower levels than from conventional cigarette smoke. The biological effects of such an exposure are expected to be much less than that of secondhand smoke, but nonsmokers are exposed to some nicotine, and the regular use of e-cigarettes has the potential to substantially contaminate the environment with nicotine.

Policy Guidance

Summary Position

The AHA recognizes the increase in e-cigarette use and the need to develop a clear policy position on their use and their impact on the tobacco control movement. E-cigarettes either do not contain or have lower levels of several tobacco-derived harmful and potentially harmful constituents compared with cigarettes and smokeless tobacco. In comparison with NRTs, e-cigarette use has increased at an unprecedented rate, which presents an opportunity for harm reduction if smokers use them as substitutes for cigarettes. However, although firm evidence is lacking, there are concerns that e-cigarette use and acceptance of e-cigarettes has the potential to renormalize smoking behavior, sustain dual use, and initiate or maintain nicotine addiction. Their use also could serve as a gateway to reinitiation of smoking by ex-smokers. Unregulated e-cigarette use also has the potential to erode gains in smoking cessation and smoke-free laws. The AHA considers e-cigarettes that contain nicotine to be tobacco products and therefore supports their regulation under existing laws relating to the use and marketing of tobacco products. To prevent the potential negative public health impact of e-cigarettes, we strongly support laws and regulation that prohibit the sale and marketing of e-cigarettes to youth. We support effective regulation that addresses marketing, labeling, quality control of manufacturing, and standards for contaminants. We also support the inclusion of e-cigarettes in smoke-free air laws. Moreover, we consider it important to monitor and prevent these products from serving as gateway products or as an initiation to nicotine addiction in nonsmokers and reinitiation in smokers. We will continue to assess the scientific evidence relating to their long-term health effects and their efficacy as a smoking cessation aid

and encourage the development of a robust research agenda to understand the public health impact of e-cigarettes, especially in at-risk populations.

Below, we summarize the association's current policy guidance on specific issues related to tobacco control, as well as the rationale underlying the policy recommendation. This policy guidance was developed by an expert advisory group and leading researchers in the field of tobacco control and prevention and e-cigarettes, in tandem with a comprehensive review of the literature. The association's policy guidance will continue to be updated as rapidly evolving evidence emerges.

Inclusion of E-Cigarettes in Smoke-Free Air Laws

The AHA supports the inclusion of e-cigarettes in smoke-free air laws.

Although the levels of toxic constituents in e-cigarette aerosol are much lower than those in cigarette smoke,¹⁵ there is still some level of passive exposure to organic compounds, nicotine, and fine particles.^{58,105,107} To date, there is insufficient evidence to support the notion that exposure to exhaled aerosol has a deleterious impact on bystanders.²⁶ Some studies have found very low concentrations of air pollutants across different types, liquids, puff durations, and nicotine concentrations.^{15,105} The levels of particle and nicotine exposure vary with the composition of the liquids, the type of e-cigarette, size of the room, puff duration, interval between puffs, and the number of users.¹⁰⁵ Nevertheless, there is concern that nonsmokers will be involuntarily exposed to nicotine, which could be substantial where there is heavy e-cigarette use in confined spaces. Moreover, unregulated e-cigarette use has the potential to recreate a social norm around tobacco product use in public places,^{108–110} unraveling decades of work on comprehensive smoke-free air laws. It is not always easy to identify that a person is using an e-cigarette, because there is not the large plume of smoke or the strong detectable odor that comes from conventional cigarettes. Therefore, the use of e-cigarettes creates enforcement issues for employees in restaurants, bars, airport terminals, planes, and other smoke-free public places. E-cigarette companies are marketing their products to be used in all the places where smoking is banned, including bars, restaurants, hotels, offices, and airplanes, which promotes unregulated use.

Although the AHA supports the inclusion of e-cigarettes in new smoke-free laws, the AHA only supports changing existing smoke-free laws to include e-cigarettes when it can be ensured there will be no amendments attached to the legislation that would weaken existing laws.

Preventing Youth Access

The AHA supports the inclusion of e-cigarettes in state and federal laws and regulations that prohibit the sale of e-cigarettes to minors.

There is concern among public health advocates that e-cigarettes could increase nicotine addiction and serve as a gateway for the use of tobacco products, particularly among youth. As discussed above, adolescents view e-cigarettes as safer than conventional cigarettes, more convenient to use, and more readily accessible.⁴⁵ Their attraction to these "high-tech" devices is

fuéled further by the marketing practices of the tobacco industry, which is manufacturing flavored e-cigarettes that are likely to be more appealing to a younger population. To reduce the availability of e-cigarettes among youth, 22 states have enacted e-cigarette youth access laws and 6 states have youth access laws for tobacco-derived or nicotine-containing products without explicitly using “e-cigarette” or similar terms in their law.¹¹¹ For instance, Arizona, California, New Jersey, and New Hampshire have now banned e-cigarette sales to minors. In its proposed rule on “Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act” the FDA proposed to ban the sales of e-cigarettes to consumers under the age of 18, which is similar to the existing federal ban on the sale of cigarettes and smokeless tobacco products to minors under the Family Smoking Prevention and Tobacco Control Act. Given that e-cigarettes are actively sold via Websites across state lines,¹⁰ it is essential to develop a comprehensive federal law or regulation banning e-cigarette sales to minors because state laws are a temporary patchwork approach¹¹² and only the federal government can regulate interstate commerce.^{113–115}

Marketing and Advertising to Youth

The AHA supports the inclusion of e-cigarettes in laws that restrict the marketing and advertising of e-cigarettes to minors.

There is robust marketing and advertising of e-cigarettes on television and in magazines using celebrities as well as flavorings to make these products particularly attractive to children and adolescents.¹⁰ Many of these advertisements have themes that promote rebelliousness and glamorize e-cigarette use, which conveys the message to youth that e-cigarette use is fun, socially acceptable, and desirable. Youth exposure to e-cigarette advertising increased more than 250% from 2011 to 2013, with e-cigarette advertisements reaching >24 million youths during this period.⁴⁸ Such marketing practices are likely to recruit a new generation of nicotine addicts. The public health community is unified in developing regulation and passing legislation that restricts the marketing and access of e-cigarettes to minors, similar to existing laws restricting marketing and youth access to combustible products.

Taxing E-Cigarettes

The AHA supports taxing e-cigarettes at a rate high enough to discourage youth use, while retaining or increasing differentials with combustible products by increasing taxes on combustibles. Any revenue generated through taxation ideally should support tobacco cessation and prevention programs.

The diversity of products makes it difficult to develop a uniform tax policy for various devices and refills, and it also creates opportunities for avoidance. An ad valorem tax, one levied as a percentage of price, preferably at the retail level, could include all components of e-cigarettes and related devices. However, a tax that is too high would create a barrier to switching to e-cigarettes among low-income users of combustible tobacco. Growing evidence shows that e-cigarette users are more responsive to price than cigarette use, with 1 study estimating that a 10% increase in e-cigarette prices would reduce sales of reusable e-cigarettes by ≈19% and sales of disposable e-cigarettes by ≈12%.¹¹⁶ Similarly, data from a survey with adult tobacco users

show that their low prices relative to other tobacco products is a key reason for use among many current e-cigarette users (F. Chaloupka, written communication, June 6, 2014).¹¹⁶ The initial cost of a reusable e-cigarette is higher, although over the long-term, they are cheaper because the reusable devices can be used over and over again. Hence, although a tax on the initial product could be punitive, especially for the low-income users, it is critical that the tax be high enough to deter youth access, because it has been demonstrated repeatedly that youth are especially price sensitive.^{118,119} At the same time, increasing taxes on combustible tobacco products would prevent youth uptake, encourage some adult users to quit or cut back, and likely increase interest in switching from combustible products to e-cigarettes.

FDA Regulation of E-Cigarettes

The AHA supports effective FDA regulation of e-cigarettes that addresses marketing, youth access, labeling, quality control over manufacturing, free sampling, and standards for contaminants. The regulation should allow for quality-controlled products for adults who want to transition from conventional cigarettes to e-cigarettes or to quit or reduce smoking. Bottles containing nicotine refill liquids can be toxic if swallowed, so cartridges and bottles should have proper warning labeling and child-proof packaging.¹²⁰ It is important that the relevant government agency monitor whether these devices are used for delivery of other drugs and medications. Companies should not be able to claim that e-cigarettes are a cessation aid unless they are approved by the FDA for that purpose.

The FDA has currently issued its proposed rule to give the agency oversight over e-cigarettes, addressing youth access, sampling, ingredient listing, manufacturing, and warning labels, but not addressing marketing and advertising or flavorings. Some products currently on the market are unreliable and poorly designed, and there is inadequate and inaccurate labeling of constituents.^{121,122} Several companies are moving their manufacturing processes from China to the United States to prepare for the standardization and quality control that will be required under FDA oversight.¹²³ Adverse event reports regarding e-cigarette use are being monitored in many countries across the globe. In the United States, the Center for Tobacco Products under the FDA is developing a tobacco-specific adverse event reporting system for e-cigarettes. Consumers or healthcare providers can report adverse events for any tobacco products through the Department of Health and Human Services’ Safety Reporting Portal.¹²⁴ The FDA would regulate e-cigarettes for tobacco cessation under current rules via the Center for Drug Evaluation Research, and as is the case for all other approved cessation aides, this would require rigorous safety and efficacy studies. FDA oversight is critically important to ensure that e-cigarettes and similar products are not harmful to public health.

The entry of the major US cigarette manufacturers (Altria Group, Reynolds American, and Lorillard) into the marketplace raises a number of potential public health concerns. Rather than encouraging cessation, the tobacco industry could promote e-cigarettes as a way to circumvent clean indoor air policies, thereby promoting dual use to sell more conventional cigarettes. The industry could also steer e-cigarette users to combustible products and thereby increase rather than

decrease nicotine and tobacco addiction.¹²⁵ E-cigarette manufacturers are spending millions of dollars and working with major lobbying firms to pass legislation or influence regulation to exempt e-cigarettes or carve out a special classification.¹²⁶

In the European Union, starting in 2016, advertisements for e-cigarettes will be banned in all 28 nations, the packaging must be childproof and have graphic warning labels, and the nicotine content will be limited to 20 mg/mL.¹²⁷ The new regulations are part of a larger regulatory package that will impose even stricter rules on combustible tobacco products. The European Parliament backed off of its original proposal, which would have treated e-cigarettes as a medical or drug-delivery device, but allows member states to categorize them as a cessation aid if member states choose to do so.¹²⁷

E-Cigarettes and the Potential to Regulate Nicotine Content of Conventional Cigarettes

The public health benefit of e-cigarettes competing with conventional cigarettes in a free marketplace is uncertain. Some potential harms, such as toxicity of unregulated products and marketing to youth, could be mitigated by effective FDA regulation. Possibly in the context of free market competition and perhaps with improved e-cigarette products, smokers would find e-cigarettes sufficiently attractive to use them to quit smoking. On the other hand, the permissive availability of e-cigarettes could result in an increase in nicotine addiction without a reduction in overall use of conventional cigarettes. A broader public health strategy could be developed that would combine regulation for combustible products, including regulation of characteristics and pricing, with the regulation of e-cigarettes or other electronic nicotine devices that appeal to smokers.¹²⁸ In 1994, the idea of reducing the nicotine content of cigarettes to make cigarettes less addictive was proposed, but the strategy was not implemented.¹²⁹ In 2009, the FDA gained regulatory authority over tobacco, which includes the authority to reduce nicotine in cigarettes to make them less addictive, as long as the nicotine level is not reduced to zero. Such a nicotine reduction regulatory policy could mandate nicotine reduction in all manufactured tobacco products so that they would not sustain addiction. Research is ongoing on the safety and the effects of smoking behavior with cigarettes with reduced nicotine content.^{130,131} If

a reduced nicotine content regulatory strategy becomes policy, cigarettes could become less addictive because of limited nicotine availability, and therefore, less attractive to the smoker. If at the same time, e-cigarettes are widely available, it could potentially help the cigarette smoker to transfer their nicotine addiction from tobacco to a cleaner form of nicotine delivery. This transition could be facilitated by differential taxation and could reduce the burden of cigarette-induced disease. Nevertheless, at present, it remains unclear whether society would be accepting of recreational nicotine addiction if associated with minimal health consequences. Modeling the health effects of reducing the nicotine content of cigarettes to nonaddictive levels, Tengs et al¹³² concluded that "Policy makers would be hard-pressed to identify another domestic public health intervention, short of historical sanitation efforts, that has offered this magnitude of benefit to the population."

Cessation Counseling

The AHA maintains that e-cigarette use should be part of tobacco screening questions incorporated into clinical visits and worksite/community health screenings that are tied to healthcare delivery. Clinicians should be educated about e-cigarettes and should be prepared to counsel their patients regarding comprehensive tobacco cessation strategies. There is not yet enough evidence for clinicians to counsel their patients who are using combustible tobacco products to use e-cigarettes as a primary cessation aid. The association will continue to monitor the evidence concerning e-cigarettes as cessation devices to determine whether they might be integrated into comprehensive cessation strategies. For patients with existing cardiovascular disease and stroke, or at risk of a cardiovascular disease event, intensive cessation counseling should be offered as soon as possible. (See Table 2 for a summary of recommended clinical guidance.)

The efficacy of e-cigarettes as a primary smoking cessation aid has not been established as being better than other cessation modalities. Current evidence^{50,53,134} suggests at best a modest effect on cessation, likely equal to or slightly better than that of nicotine patches without behavioral support. If a patient has failed initial treatment, has been intolerant to

Table 2. Summary of Current Recommendations for Clinical Guidance

E-cigarette use should be included in tobacco screening questions that are part of every health examination.

Clinicians should be educated about e-cigarettes and should be prepared to counsel their patients regarding comprehensive tobacco cessation strategies.

Patients should be separated into 3 treatment categories based on their tobacco/e-cigarette use status¹³³:

1. Tobacco product users who are willing to quit should receive intervention to help them quit
2. Tobacco product users unwilling to quit at the time should receive interventions to increase their motivation to quit
3. Those who recently quit using tobacco products should be provided relapse prevention treatment

There is not yet enough evidence for clinicians to counsel their patients who are using tobacco products to use e-cigarettes as a primary cessation aid.

If a patient has failed initial treatment, has been intolerant to or refuses to use conventional smoking cessation medication, and wishes to use e-cigarettes to aid quitting, it is reasonable to support the attempt. However, patients should be informed that although e-cigarette aerosol is likely to be much less toxic than cigarette smoking, the products are unregulated, may contain low levels of toxic chemicals, and have not been proven to be effective as cessation devices.

In the absence of long-term safety studies of e-cigarette use, it may be appropriate to advise the patient to consider setting a quit date for their e-cigarette use and not to plan to use it indefinitely (unless needed to prevent relapse to cigarettes).

It is also important to stress that patients should quit smoking cigarettes entirely as soon as possible, because continued cigarette smoking, even at reduced levels, continues to impose tobacco-induced health risks.

For patients with existing CVD or stroke, or at risk of a CVD event, intensive cessation counseling and pharmacotherapy should be offered as soon as possible.

CVD indicates cardiovascular disease; e-cigarette, electronic cigarette.

or refused to use conventional smoking cessation medication, and wishes to use e-cigarettes to aid quitting, it is reasonable to support the attempt. However, subjects should be informed that although e-cigarette aerosol is likely to be much less toxic than cigarette smoking, the products are unregulated, may contain low levels of toxic chemicals, and have not been proven as cessation devices. Because there are as yet no long-term safety studies of e-cigarette use, it may be appropriate to advise the patient to consider setting a quit date for their e-cigarette use and not plan to use it indefinitely (unless needed to prevent relapse to cigarettes). It is also important to stress that patients should quit smoking cigarettes entirely as soon as possible, because continued cigarette smoking, even at reduced levels, continues to impose tobacco-induced health risks.

Employers will have to decide whether employees who use e-cigarettes exclusively will be considered tobacco users. Within the context of incentive design within healthcare plans associated with a worksite wellness programs, employers may charge tobacco users up to 50% more for their health insurance under the new Affordable Care Act regulations. There is no significant evidence that these tobacco surcharges increase quit rates, although 1 study showed that self-reported quit rates did increase more than the national average in Georgia State Health Benefit Plan employees.¹³⁵ With currently available methods, it is not possible to distinguish between a cigarette smoker and an e-cigarette user, because only the levels of cotinine are measured. Because cotinine is a metabolite of nicotine, it is likely to be present in the blood or urine of a user of e-cigarettes, combustible cigarettes, other tobacco products, and even nicotine patches. Hence, until newer methods are developed to distinguish between e-cigarettes and conventional cigarette use, employers would have to base their decisions primarily on self-report. Whether or not employers choose to penalize employees who are using e-cigarettes, employers should provide comprehensive cessation benefits to employees that include behavioral counseling and pharmacotherapy with a minimal copay or deductible for all users of tobacco products.

Insurance companies may also assess the 50% penalty in the individual market, although 10 states prohibit or restrict the ability of insurance companies to do that.^{136,137} Along with age, geographic location, and family size, tobacco use is 1 of 4 variables that insurers can take into account when selling plans on the individual market. The AHA is concerned that the tobacco surcharge will make it difficult for tobacco users to access the cessation services they need. At minimum, insurers in the individual marketplace, like employers, should provide comprehensive tobacco cessation benefits with minimal copays or deductibles for all e-cigarette and tobacco users.

Surveillance for E-cigarette Use and Health Impact

The AHA recognizes the need to improve and increase surveillance on e-cigarette use throughout the US and global population and establish a research agenda to elucidate the longitudinal public health impact of e-cigarette use.

There is a need to increase or maintain surveillance using high-quality longitudinal studies on the prevalence of e-cigarette use in adults, children, and adolescents; quit attempts; quit rates; e-cigarette rates versus smoking rates; dual use (with combustible tobacco or other tobacco products); and reinitiation of ex-smokers

to e-cigarettes and then perhaps back to tobacco. Current surveillance should also include adequate reference to the emerging products entering the marketplace to ensure there is a thorough understanding of the true prevalence of use of these alternatives to combustible products. Surveillance should also capture how these devices are being used for delivery of other legal or illicit drugs. There must be further experimental research and surveillance on the short-, medium-, and long-term physiological effects of deep lung inhalation of not only the nicotine but also propylene glycol and glycerol, flavorings, and other ingredients. Experimental research and surveillance also needs to capture the long-term population health impact, effect on fetal development, and physiological and behavioral effects of these ingredients, as well as the health impact of secondhand and thirdhand exposure.

Defining E-Cigarettes in State Law

The AHA supports including e-cigarettes in the definition of tobacco products (or tobacco-derived products) and smoking, not by creating a separate definition for e-cigarettes, because a separate definition can create a risk of e-cigarettes being exempted from other tobacco control laws, including smoke-free laws. E-cigarettes defined as tobacco products could still be treated differently within taxation legislation and regulation.

Bringing e-cigarettes within a general definition of "tobacco products" in state or local law is also entirely consistent with their treatment under federal law. In *Sottera, Inc. (dba NJOY) v FDA* (627 F2d 891 [DC Cir 2010]), an e-cigarette manufacturer argued that its products could only be regulated by the FDA as tobacco products under the Family Smoking Prevention and Tobacco Control Act of 2009, not under the drug/device provisions of the Food, Drug, and Cosmetic Act.¹³⁸ The court agreed with the manufacturer, holding that e-cigarettes fit within the broad definition of *tobacco product* in the Tobacco Control Act ("any product made or derived from tobacco that is intended for human consumption"). The court further held that e-cigarettes could be regulated only under the Food, Drug, and Cosmetic Act if marketed with therapeutic claims. Thus, in *Sottera*, an e-cigarette manufacturer sought to be regulated by the FDA as a manufacturer of a "tobacco product," and the court agreed that such regulation was within the FDA's authority as a matter of federal law.^{138,139} These decisions were made although e-cigarettes do not actually contain tobacco, only nicotine derived from tobacco. The AHA agrees with the courts' rulings in defining e-cigarettes as tobacco products in legislation and regulation and has worked with public health partners to develop a consensus definition of tobacco products that includes e-cigarettes (Table 3). This definition includes e-cigarettes even if they do not contain nicotine, that is, any electronic device that delivers nicotine or other substances. The inclusion of all e-cigarettes in the definition facilitates implementation of laws and regulation. For example, when enforcing a clean indoor air policy, it would be impossible to determine whether someone who is "vaping" is using an e-cigarette that does or does not contain nicotine.

Future Research Agenda

Because e-cigarettes are relatively new products, little is known about their use, their characteristics, or their long-term health effects on individual users and public health. Extensive

research is required to address these questions. This will help in developing more robust policies to regulate e-cigarette use, marketing, and distribution. In view of the paucity of evidence, current guidelines must be regarded as provisional and should be revised in light of future research. However, e-cigarette research faces major challenges. E-cigarettes are not a well-defined entity but a collection of rapidly changing devices that deliver nicotine and contain a variety of additives that are also changing constantly. As a result, it is possible that research on specific e-cigarettes would become obsolete as product characteristics, design features, constituents, and additives change and new products appear on the market. Therefore, research will have to keep pace with the rapidly evolving market. Nonetheless, several invariant areas of future research could be identified, which are listed below.

Physicochemical Studies

Extensive work is required to develop a better understanding of the types of e-cigarettes currently in use and the ingredients they contain. To understand the nature of e-cigarette exposure, it is important to determine how heating time and duration of puffing alter exposure and the composition and characteristics of the vapor, as well as how each of these factors is affected by the design features of different devices. It will be important to evaluate how smoking e-cigarettes deposits nicotine and other chemicals in the environment and how these emissions and depositions affect secondhand and thirdhand exposures. Additional research is needed to evaluate the efficacy of vaping devices in delivering chemicals, drugs, and pharmaceuticals other than nicotine and to document manufacturing practices and quality control issues, so that the listed ingredients correspond to the actual composition of the device.

Perception

Profiles and perceptions of e-cigarette users have been documented in the literature; however, most of these data are derived from informal surveys from the Internet and other sources. New research is needed to determine the use and spread of e-cigarettes in different population subgroups and communities and to identify demographic factors that contribute to e-cigarette use in the general population. Additional research is also required to examine use trajectories, harm perception, and user expectations, as well as to determine how flavors affect perception and how future regulations might affect user profile and perception.

Use Pattern

Although extant data provide some indication of how e-cigarettes are currently being used, additional work is required to determine typical e-cigarette usage, with special emphasis on understanding brand/type preference and loyalty, frequency of use, brand switching, flavor preference, and the effects of puff duration. These issues also relate to questions about optimal dosing, such as the optimal dose (or use) for cessation by product type and the dose and use patterns that sustain nicotine addiction or satisfy nicotine craving over time. It would be important to know whether and how these devices are being used to deliver other drugs and medication and whether their

use is particularly widespread in vulnerable populations, such as youth, trendsetters, populations with low socioeconomic status, current smokers, ex-smokers, veterans, the mentally ill, those with substance use disorders, and the lesbian/gay/bisexual/transgender community.

Health Effects and Toxicity

Preclinical studies, preferably in animal models, are required to evaluate e-cigarette toxicity. Although animal models have obvious limitations, and their relevance to human exposures is often uncertain, these models could be useful in assessing the pharmacokinetic, pharmacodynamic, and toxicokinetic properties of e-cigarette exposures. Data from these studies will be useful in assessing acute and chronic toxicity, as well as the respiratory, carcinogenic, teratogenic, metabolic, immunological, and cardiovascular effects of e-cigarettes. The pathophysiological outcomes and biomarkers, identified in animal studies, should also be evaluated in controlled human exposure studies to develop validated concordance between animal and human data.

Data from in vitro and animal studies could inform the design of studies to evaluate the acute and chronic health effects of e-cigarettes. Acute effects could be evaluated in cross-sectional or cross-over studies examining the respiratory, metabolic, neurological, and cardiovascular effects, as well as the effects on insulin resistance, appetite, and weight loss. These data would be particularly informative and interesting if the health effects of e-cigarettes are compared directly with conventional cigarettes or other tobacco products. Such comparisons will help in identifying not only e-cigarette-specific health effects but also the effects common to e-cigarettes and other tobacco products. Because cross-sectional studies cannot establish directionality, progression, or causality, long-term longitudinal cohort studies are needed to assess how e-cigarette use affects the progression of subclinical disease. The results of well-powered, multicenter, prospective cohort studies with significant follow-up will provide important data for further refining policy recommendations.

Environmental Effects

Environmental research is needed to characterize e-cigarette emissions and to determine the chemical nature, size, and abundance of particulate matter generated in e-cigarette emission. In this research, it will be important to address the relative distribution of fine and ultrafine particles and to identify the chemical composition of these particles. Such studies are required to determine how changes in design features, additives, and constituents affect the direct toxicity of e-cigarette emissions. A particularly important issue that has direct bearing on regulation is the extent of secondhand and thirdhand exposure. Although e-cigarette emissions contain fewer chemicals and lower concentrations of toxicants than conventional cigarettes, the health effects of secondhand e-cigarette aerosol exposure are not known. Currently, most communities advocate the inclusion of e-cigarettes in smoking bans. This is justified because public use of e-cigarettes leads to involuntary exposure to a psychoactive drug (nicotine) in bystanders. However, additional work is required to identify constituents of e-cigarette emissions, how these emissions are dispersed in the environment, and how the

characteristics of the environment affect the dispersal and the health effects of such emissions.

Psychological Effects

Evaluation of the psychological effects of e-cigarettes is of utmost importance in understanding how the use of these devices supports or promotes nicotine addiction and whether they aid nicotine cessation or abstinence. Although the results of some studies suggest that as a cessation aid, e-cigarettes can be at least as effective as other NRTs, further work with larger cohorts is required to establish not only their efficacy as cessation aids but also how these devices affect nicotine addiction and withdrawal, as well as how they compare with other NRTs in user satisfaction and dependence. An important question is whether e-cigarette use merely facilitates abstinence from smoking conventional cigarettes or results in complete independence from nicotine addiction. In studying the use of these devices for cessation, it is important to determine whether counseling or behavioral support would enhance efficacy, and if so, what are the most effective instructions required for the proper use of these devices as a cessation aid? And should physicians and health providers counsel for or against e-cigarette use? Research findings addressing these questions are likely to have a major impact on our understanding of the nature of nicotine addiction and how it is supported by conventional cigarettes versus e-cigarettes. Again, prospective cohort studies with long-term follow-up will be most useful in assessing how e-cigarette use affects nicotine addiction.

Marketing and Communications

Marketing and communications research is needed to determine how e-cigarettes are being marketed and how information about them is being communicated to their target audience. Research is needed to identify how specific marketing techniques are used to target specific groups, which specific groups are being targeted, and what effects labeling, product placement, advertisements, free sample distribution, location in stores, and celebrity endorsement have on e-cigarette sales, preference, and use. Additional research is needed to identify effective communication techniques for conveying health information, potential hazard or benefit, and regulatory information. By establishing a partnership with consumers, it may be possible to identify consumer perceptions and expectations and to identify cultural, social, and economic factors that impact e-cigarette use.

Surveillance

Surveillance of e-cigarette use is just beginning at the national level in the United States and is generally lacking at the state and local level. At the national level, several surveys have been collecting information, including the National Youth Tobacco Survey in 2011 and 2012 (http://www.cdc.gov/tobacco/data_statistics/surveys/NYTS/), the National Health and Nutrition Examination Survey beginning in 2013 (http://www.cdc.gov/nchs/data/nhanes/nhanes_13_14/SMQ_ACASI_H.pdf), and the National Health Interview Survey beginning in 2014 (ftp://ftp.cdc.gov/pub/Health_Statistics/NCHS/Survey/Questionnaires/NHIS/2014/english/qadult.pdf). The Behavioral Risk Factor

Surveillance System, a major source of information regarding health behaviors at the state level, did not collect information about use of e-cigarettes as of 2013 (http://www.cdc.gov/brfss/questionnaires/pdf-ques/2013%20BRFSS_English.pdf).

The questions included in these surveys differ somewhat, primarily in the breadth of information collected. E-cigarette questions in the surveys above should use a similar format so the data can be pooled. Efforts to understand the public health impact of e-cigarettes require improved monitoring of awareness of the availability of e-cigarettes, beliefs about their health effects, and attitudes and behaviors regarding their use. Additional information is needed across the life span, especially in vulnerable groups, including children, and at the appropriate level to guide policy development, implementation, and evaluation; for these purposes, local and state-level data will be particularly important.

Postmarket surveillance is essential to understand and evaluate the public health impact of e-cigarettes. Such surveillance could include monitoring sales data, following the development and changes in the role of big tobacco companies and small entrepreneurs. Continuous pharmacovigilance is required to assess the safety and efficacy of these devices, changes in sales and marketing strategies, design features, and constituents. Such activities will be significantly facilitated by future regulation, which could define parameters for evaluating safety and regulatory compliance.

Economic Studies

Future research in economic issues relating to e-cigarettes is needed to evaluate the effect of taxation on e-cigarette sales and to assess the impact of e-cigarettes on healthcare costs and insurance premiums. Evaluation of the effect of taxation would be particularly important because this could have a significant impact on e-cigarette use across different populations. This type of research can be accomplished by both empirical research and observational studies, which will take longer and will require continuous analysis of sales data and purchasing behavior. Modeling work can be performed more quickly to predict what might happen with different approaches to taxation. Research in this area could be extended to include the cost of different devices and the contribution of e-cigarette sales to local and federal economies.

Legal and Regulatory Issues

Research is required to monitor and assess the effect of regulation on use, safety, and quality control and to determine the impact of legislation and regulation on industry and user responses.

Conclusions

E-cigarettes represent a major change in the tobacco control landscape. This policy guidance is developed from the current international evidence base and tobacco control environment in the United States. The AHA will continue to monitor the impact of these new technologies on population health, cardiovascular disease, and stroke and will give special attention to the effect on youth and adolescents. The association's policy position and clinical guidance will evolve over time with the rapidly emerging research and evidence base for this field.

Appendix: Definitions*

"Tobacco product" means:

- (a) Any product containing, made, or derived from tobacco or containing nicotine, whether synthetically produced or derived from other sources that is intended for human consumption (and not marketed for cessation), whether smoked, heated, chewed, absorbed, dissolved, inhaled, snorted, sniffed, or ingested by any other means, including but not limited to cigarettes, cigars, little cigars, chewing tobacco, pipe tobacco, snuff†; and
- (b) Any electronic device that delivers nicotine or other substances to the person inhaling from the device, including but not limited to an electronic cigarette (e-cigarette), cigar, pipe, or hookah.
- (c) Notwithstanding any provision of subsections (a) and (b) to the contrary, "tobacco product" includes any component, part, or accessory of a tobacco product, whether or not sold separately. "Tobacco product" does not include any product that has been approved by the US Food and Drug Administration for sale as a tobacco cessation product or for other therapeutic purposes where such product is marketed and sold solely for such an approved purpose.

It is important to note that this definition would include e-cigarettes, even if they do not contain nicotine. Thus, subsection (b) refers to "any electronic device that **delivers nicotine or other substances**" to cover devices (and components) regardless of whether they actually have nicotine or are being used to deliver nicotine. It was also recognized that there are alternative phrases that could be used to similarly expand coverage to non-nicotine products. For instance, the definition could refer to devices that "can be used to deliver nicotine."

"Simulate Smoking" Language

It is not desirable to include language describing e-cigarettes as devices that are, or can be, used to "simulate

*These definitions were developed by an expert advisory group convened by the Campaign for Tobacco-Free Kids in April 2014. Participants were Chris Sherwin of the American Heart Association, Thomas Carr of the American Lung Association, Cathy Calloway of the American Cancer Society Cancer Action Network, and Nichole Veatch, Denny Henigan, and Ann Boonn of the Campaign for Tobacco-Free Kids.

†This list of products is subject to adjustment to conform to terms used in specific state or local laws.

smoking." The vagueness of this phrase may give certain companies the opportunity to argue that their particular products are not covered because users are "vaping" instead of "smoking." Given the wide variety of e-cigarette designs emerging in the exploding marketplace for these products, there is some potential for companies to argue that their particular design looks nothing like a cigarette and that its use cannot be said to "simulate smoking." Because the phrase could have a limiting effect on the products covered and does not appear to be needed to effectively regulate e-cigarettes, it would be best to avoid including it.

Separate Definition of "E-Cigarette"

Generally speaking, use of this "tobacco product" definition or similar language would obviate the need to include a definition of "e-cigarette" that is separate and distinct from the definition of "tobacco product." However, in some states, it may not be possible to include the full description of e-cigarettes in the tobacco product definition. Also, if special circumstances arise in a state that suggests the desirability of both including e-cigarettes as "tobacco products" while also including a definition of e-cigarettes apart from the definition of "tobacco product," a separate definition of e-cigarette could be adapted from subparts (b) and (c) of the consensus "tobacco product" definition:

E-cigarette‡ means:

Any electronic device that delivers nicotine or other substances to the person inhaling from the device, including but not limited to an electronic cigarette, cigar, pipe, or hookah, including any component, part, or accessory of such a device, whether or not sold separately. E-cigarette shall not include any product that has been approved by the US States Food and Drug Administration for sale as a tobacco cessation product or for other therapeutic purposes where such product is marketed and sold solely for such an approved purpose.

Finally, if a definition of "e-cigarettes" separate from the definition of "tobacco product" is desirable, then the definition of "tobacco product" will need to list "e-cigarettes" as one of the products to be considered "tobacco products."

‡Terms such as "electronic smoking device" or "electronic nicotine delivery systems" could be used interchangeably with "e-cigarettes."

Disclosures

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Writing Group Member	Employment	Research Grant	Other Research Support	Speakers' Bureau/Honoraria	Expert Witness	Ownership Interest	Consultant/Advisory Board	Other
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Neal Benowitz	Professor of Medicine and Bioengineering & Therapeutic Sciences Chief, Division of Clinical Pharmacology University of California San Francisco	NIH grant: California Tobacco Related Disease Research Program†; Flight Attendant Medics Inst†	None	None	2014: Plaintiff, litigation against tobacco companies	None	Pfizer*	None
Chris Bullen	Director of the National Institute for Health Innovation and Associate Professor, School of Population Health, The University of Auckland, Auckland, New Zealand	In 2007, my group received funding from HealthNZ Ltd to conduct a small trial on Ruyan e-cigarettes; the product used in the trial was supplied by Ruyan Ltd.	Principal Investigator of the ASCEND e-cigarette efficacy trial, in which the e-cigarettes were provided by PGM International Ltd, a supplier of e-cigarettes (the trial was funded by the Health Research Council of NZ)*	None	None	None	Consultant on a USFDA/NIH cofunded TCORS grant on e-cigarettes	None
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Laurie P. Whitsel	Director of Policy Research, American Heart Association	None	None	None	None	None	None	None

This table represents the relationships of writing group members that may be perceived as actual or reasonably perceived conflicts of interest as reported on the Disclosure Questionnaire, which all members of the writing group are required to complete and submit. A relationship is considered to be "significant" if (a) the person receives \$10 000 or more during any 12-month period, or 5% or more of the person's gross income; or (b) the person owns 5% or more of the voting stock or share of the entity, or owns \$10 000 or more of the fair market value of the entity. A relationship is considered to be "modest" if it is less than "significant" under the preceding definition.

*Modest.

†Significant.

Reviewer Disclosures

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Maciej Goniewicz	Roswell Park Cancer Institute	Pfizer-Global Research Awards for Nicotine Dependence (GRAND) 2011*	None	None	None	None	None	None
Steve A. Schroeder	UCSF	Robert Wood Johnson Foundation†	American Legacy Foundation†	None	None	None	None	None
Kenneth Warner	University of Michigan	Robert Wood Johnson Foundation (finishing grant on the tobacco endgame)*; Robert Wood Johnson Foundation (finishing grant on Tobacco Regulation Economics that relates to FDA's economic analysis of its graphic warning proposal)*	None	None	None	None	None	None
Rachel Widome	University of Minnesota	None	None	None	None	None	Association for Non-Smokers Minnesota*	None

This table represents the relationships of reviewers that may be perceived as actual or reasonably perceived conflicts of interest as reported on the Disclosure Questionnaire, which all reviewers are required to complete and submit. A relationship is considered to be "significant" if (a) the person receives \$10 000 or more during any 12-month period, or 5% or more of the person's gross income; or (b) the person owns 5% or more of the voting stock or share of the entity, or owns \$10 000 or more of the fair market value of the entity. A relationship is considered to be "modest" if it is less than "significant" under the preceding definition.

*Modest.

†Significant.

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KEY WORDS: AHA Scientific Statements ■ cardiovascular disease ■ e-cigarettes ■ nicotine ■ public health ■ smoking ■ tobacco ■ tobacco smoke pollution



Circulation

JOURNAL OF THE AMERICAN HEART ASSOCIATION

EXHIBIT 7



Cite this: DOI: 10.1039/c4em00415a

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.

Received 27th July 2014
Accepted 21st August 2014

DOI: 10.1039/c4em00415a

rsc.li/process-impacts

Environmental impact

Since their commercialization, electronic cigarettes (e-cigarettes) have been marketed and used as “safer” surrogates of conventional tobacco-containing cigarettes. The increasing popularity of these devices during the past decade necessitates accurate identification of the environmental impacts of e-cigarette consumption and its potential health endpoints. While most of the few previous research efforts in this area have focused on characterization of gas-phase e-cigarette emissions, the much-needed data regarding e-cigarette's particulate emissions is scarce. This manuscript quantifies the level of exposure, as well as indoor emission rates of inorganic elements and organic compounds, providing insight regarding the toxico-chemical properties of e-cigarette's secondhand emissions and potential needs for regulatory supervision on the manufacturing of these devices.

1. Introduction

Use of electronic cigarettes (e-cigarettes) has rapidly increased worldwide during the past decade.¹ e-Cigarettes are battery-operated electronic nicotine delivery devices (ENDD) that

provide an aerosol from a liquid mixture of nicotine, propylene glycol, glycerol and flavorings (known as “e-liquid”).^{2,3} Considering that nicotine delivery by e-cigarettes is achieved by aerosolizing the “e-liquid” as opposed to the combustion of tobacco, e-cigarette consumption is presumed to carry with it lower health risks compared to normal cigarettes.^{1,4,5} e-Cigarettes, however, pose a significant regulatory challenge for the medical community and public health authorities. Although e-cigarettes are promoted as aids to reduce the use of tobacco-containing cigarettes,⁴ there are still uncertainties regarding the degree to which they promote a clinically relevant cessation rate in smokers.⁶ Moreover, unregulated production of e-cigarettes and e-liquids, in addition to the very limited scientific evidence regarding the chemical composition of the vapors and aerosols generated by e-cigarettes, have raised

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† Electronic supplementary information (ESI) available. See DOI: 10.1039/c4em00415a

concerns about the potential adverse health effects of e-cigarette consumption.^{7–9}

Based on recent studies, there is considerable inconsistencies in the levels of nicotine as well as organic compounds (such as propylene glycol and glycerol) in the vapors generated by different brands of e-cigarettes.^{10,11} Another recent study reported generally lower levels of organic species, including volatile organic compounds (VOCs), carbonyls, polycyclic aromatic hydrocarbons (PAHs) and glycols, in the vapors emitted from e-cigarettes compared to tobacco smoke.¹² Williams *et al.*¹³ analyzed 11 particulate elements in the aerosol generated by e-cigarettes and reported the presence of tin, silver, iron, nickel and aluminum in super-micron particles, and tin, chromium and nickel in sub-micron particles. Further analyses indicated that these potentially toxic elements originate from the e-cigarette's cartomizer, alerting us to the need for improved quality control in e-cigarette manufacture and further investigations on the potential adverse health impacts of e-cigarette consumption.¹³

The majority of the few previous studies on the chemical characterization of e-cigarette emissions focused on vapor-phase emissions, emphasizing the need for fundamental data pertaining to aerosols emissions from e-cigarettes. In this study, particles generated by the consumption of e-cigarettes as well as normal cigarettes were collected in a room under controlled conditions and comprehensive chemical analyses (including the quantification of 42 inorganic elements and various organic compounds) have been performed on the samples, in order to quantify the degree of secondhand exposure to particulate organic compounds and metals in a real-life setting. Moreover, emission rates of individual metals and organic compounds were determined using a single-compartment mass balance model and Monte-Carlo error estimation analysis.

2. Methodology

2.1. Sampling protocol

Samples of total suspended particles were collected indoors on quartz filters (Whatman International Ltd, Maidstone, England), using a high-volume PM sampler operating at a flow rate of 240 liters per minute (lpm), in a room having a volume of 48 m³ on the fifth floor of the Fondazione IRCCS Istituto Nazionale dei Tumori, an Italian cancer research center in Milan. The room was furnished with typical office furniture. In order to ensure a homogenous distribution of the aerosol, the air inside the room was well-mixed by means of three fans blowing into different directions during all experiments. The room's window faced a terrace, where outdoor particulate matter (PM) was simultaneously sampled and collected on similar quartz filters, using a similar high-volume PM sampler, operating at 240 lpm. The initial air exchange rate (AER) inside of the sampling room was estimated to range between 0.80 and 0.86 h⁻¹, by measuring the decay rate of carbon monoxide (CO) generated by combustion of incense sticks, and further increased to about 1.1 h⁻¹ during the sampling periods due to the additional AER caused by the sampler pump (operating at 240 lpm in a room of 48 m³).

One of the most popular European brands of e-cigarette (Elips Serie C, Tank System, Ovale Europe Srl) and a typical, widely used brand of normal (*i.e.* tobacco-containing) cigarette was used for all experiments. e-Cigarettes and normal cigarettes were smoked by three volunteer smoker subjects, including two males (aged 55 and 64 years old) and one female (aged 32 years old). Both the smoking procedure and indoor environment were designed in a way to simulate real-life conditions. Normal cigarettes were smoked '*ad libitum*' by the subjects, with an average rate of one puff every minute, leading to an average total time of seven minutes for completion of one tobacco-containing cigarette. A 3 minute pause was applied between two subsequent cigarettes. To enable a robust comparison between normal cigarette and e-cigarette emissions, the e-cigarette smoking procedure was designed to be similar to the smokers' conventional cigarette smoking habit. e-Cigarettes were therefore vaped at a rate of one puff per minute, lasting for seven minutes, followed by three minutes of pause and continuing again for another seven minutes. During the vaping/smoking, two people were present in the room, one smoker and one person for instrument operation. Smokers were positioned on one side of the room while all instruments and samplers were positioned on the other side in order to avoid direct blowing of vapors into the inlets of the instruments and to ensure the highest possible mixing in the room. The cartridge of the e-cigarette had a volume of 1.5 ml and was filled with the commercial e-liquid (consisting of propylene glycol, glycerol, aroma and water, based on the manufacturer). In order to investigate nicotine emission rate, e-cigarette samples were collected both without and with adding nicotine to the e-liquid (a concentration of 16 mg ml⁻¹ nicotine was used in the e-liquid for the latter). Using the above-mentioned smoking protocol, an approximate e-liquid volume of 1.3 ml was consumed per hour and the e-liquid cartridge was refilled frequently throughout the experiments. A total of 6 e-cigarette samples (3 with nicotine and 3 without nicotine) and 3 normal cigarette samples were collected, each with parallel outdoor samples. With the exception of the nicotine analysis, e-cigarette samples with and without nicotine were combined for all other analyses, in order to increase the statistical power of the results and comparisons.

2.2. Chemical analyses

The concentration of black carbon (BC) was measured inside the smoking room, using an Aethalometer (7-wavelength AE 31, Magee Scientific). Concentration of carbon monoxide (CO) was quantified by an indoor air quality analyzer (Graywolf Sensing Solutions, Shelton, CT, USA). Inorganic elements as well as organic compounds were measured by time-integrated PM samples collected on quartz filters. To measure the total concentration of elements in the PM, portions of the quartz filters were digested in an acid mixture (comprised of nitric acid, hydrochloric acid and hydrogen peroxide), inside of a microwave-assisted Teflon digestion bomb (Milestone ETHOS+), followed by analysis using a high-resolution magnetic sector inductively coupled plasma mass spectrometry (ICP-MS) (Thermo-Finnigan Element 2). Further details regarding this

method can be found in Herner *et al.*¹⁴ Concentration of individual organic species was measured by gas chromatography mass spectrometry (GC-MS) method (GC-6980, quadrupoleMS-5973, Agilent Technologies), as described in Stone *et al.*¹⁵ In brief, portions of quartz filters were extracted in a 1 : 1 solution of dichloromethane and acetone, using Soxhlets, followed by volume reduction using rotary evaporation, under high purity nitrogen and derivatization of carboxylic acids with diazomethane, and then analyzed by GC-MS. Concentration of elements and metals, as well as speciated organic compounds was also quantified in the e-liquid, using the same ICP-MS and GC-MS methods, respectively. For all of the analyses, detection limits of the measurements were calculated as 2 times the total analytical uncertainties, in the limit as the concentrations of the species approach zero (presented in Table S1†).

2.3. Determination of emission rates

In order to calculate the emission rate of particle-bound species, a single-compartment mass balance model was applied to the smoking room for each species. The overall mass balance equation in the room is given in eqn (1):

$$V \frac{dC_{in}}{dt} = S_i + C_{out}P(AER)V - C_{in}(AER)V - kC_{in}V \quad (1)$$

where C_{out} and C_{in} represent outdoor (*i.e.* ambient) concentration and indoor (*i.e.* inside of the smoking room) concentration, respectively (expressed in ng m^{-3}). P represents the penetration efficiency of particles and is dimensionless.¹⁶ AER and k are the air exchange rate and particle deposition loss, respectively, both measured in units of h^{-1} . V represents the volume of the smoking room (48 m^3) and S_i is the indoor emission rate of the species (ng h^{-1}). Assuming steady state conditions (*i.e.* $dC_{in}/dt = 0$, achieved by rather long sampling periods as well as relatively high air exchange rate) and homogeneous distribution of compounds in the room (achieved by continuously mixing the air using three fans during all experiments), the mass balance for each compound is simplified to eqn (2):

$$C_{in} = \frac{P(AER)C_{out}}{(AER + k)} + \frac{(S_i/V)}{(AER + k)} \quad (2)$$

Indoor and outdoor concentrations were determined following the chemical analyses on the filter samples and a total air exchange rate (AER) of $1.1 (\pm 0.06) \text{ h}^{-1}$ was determined for the experimental conditions (including 0.8 h^{-1} based on the decay rate of CO , in addition to 0.3 h^{-1} to account for the AER caused by the pump, operating at 240 lpm in a 48 m^3 room). Rate of deposition loss (k) and penetration efficiency (P) were estimated to vary between $0.1\text{--}0.2 \text{ h}^{-1}$ and $0.7\text{--}0.85$, respectively, based on the study by Long *et al.*¹⁶ Based on the variables' uncertainties, the uncertainties of indoor emission rates (S_i) were propagated using a Monte Carlo error estimation analysis,¹⁷ by calculating the standard deviation of the mean emission rate values after performing the Monte Carlo based on 1000 iterations using randomly selected variables.

3. Results and discussion

3.1. Mass concentration overview

Fig. 1 presents an overview of the total PM mass concentration indoors (*i.e.* inside of the smoking room) and outdoors, during e-cigarette and normal cigarette consumption. As seen in the figure, the overall increase in the indoor PM mass concentration level compared to the simultaneously-measured outdoor concentration is remarkable during normal cigarette smoking (from about $55 \mu\text{g m}^{-3}$ to more than $250 \mu\text{g m}^{-3}$), while for e-cigarette vaping, similar levels are observed for indoor and outdoor PM concentrations. As will be shown later in the emission rate calculation section, despite similar levels of total PM concentrations indoor compared to outdoor during e-cigarette vaping, indoor emission rates of specific metals and organic compounds are significant. We should also note that presence of nicotine in the e-liquid had a very small effect (less than 0.1%) on the e-cigarette's total PM emissions (as shown in Fig. S1, ESI†). Emission rate and indoor concentration of particle-phase nicotine during e-cigarette vaping are discussed separately, in Section 3.4.

Fig. 2 presents the mass fraction of aggregated elements, and groups of organic compounds (including PAHs, alkanes, organic acids, hopanes and levoglucosan). Concentration of these chemical groups in the air (*i.e.* normalized by the volume of air) is also presented in Fig. S2 (ESI†). Specific chemical species in each group and their corresponding concentrations are given in Table S1 (ESI†) for reference. As seen in Fig. 2, the mass fraction of alkanes and organic acids is 5–10-fold greater for normal cigarette samples compared to both e-cigarette and outdoor samples. Hopanes, tracers of gasoline and diesel engine combustion emissions,¹⁸ were only detected outdoors. PAHs were found in larger proportions in normal cigarette samples compared to outdoor ambient air (about 10 times), while they were undetected for indoor samples collected during e-cigarette vaping. Considering the potential carcinogenic effects of PAHs,^{19,20} reduced emission of PAHs is one of the most desirable outcomes of e-cigarette vaping compared to normal

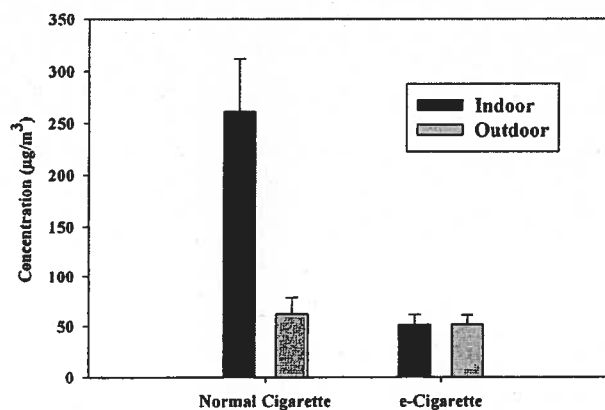


Fig. 1 Average outdoor and indoor (*i.e.* inside of the smoking room) mass concentration ($\mu\text{g m}^{-3}$) during smoking and vaping of normal cigarettes and e-cigarettes. Error bars represent one standard error.

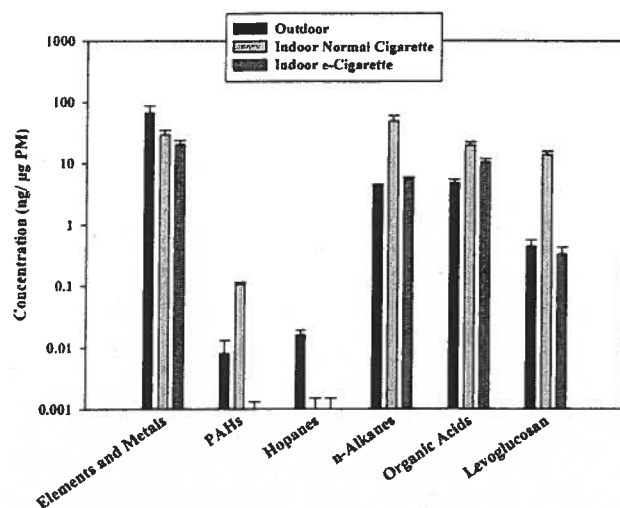


Fig. 2 Average total concentration of elements as well as organic groups (polycyclic aromatic hydrocarbons (PAHs), hopanes, *n*-alkanes, organic acids and levoglucosan), normalized by PM mass concentration ($\text{ng } \mu\text{g}^{-1} \text{ PM}$). Error bars represent analytical uncertainties.

cigarette consumption. The mass fraction of inorganic elements was highest for outdoor samples, driven by the considerably higher (10–60-fold) concentration of dust/soil dominated elements (such as Mg and Ca) in the ambient air (Table S1†). In the following sections, exposure concentrations as well as emission rates of specific chemical components are discussed.

3.2. Level of exposure to chemical species

3.2.1. Black carbon. Real-time Aethalometer-based black carbon (BC) measurements at 7 wavelengths (370, 470, 520, 590, 660, 880 and 950 nanometers) inside of the smoking room are presented in Fig. 3. BC concentrations in the aerosol are estimated from the absorption at the 880 nm wavelength (*i.e.* infrared).²¹ The light absorption associated with shorter wavelengths may provide insights on possible composition of the

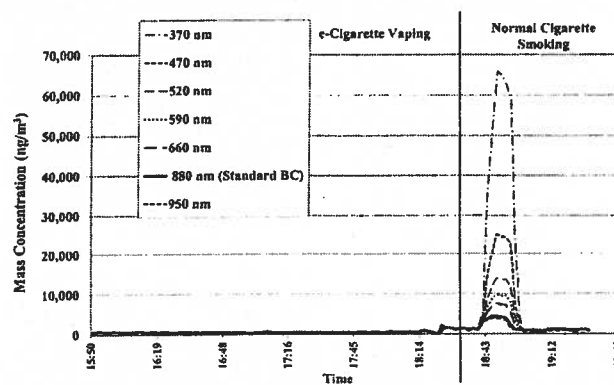


Fig. 3 Comparison of indoor black carbon (BC) mass concentration (ng m^{-3}) inside of the smoking room, between periods of normal cigarette and e-cigarette consumption.

aerosol in terms of organic species. Typically, aerosols with a high content of light-absorbing organic compounds would exhibit higher light absorbance at shorter wavelengths.²¹ Therefore, for an aerosol with low organic content, the reported BC concentration at 880 nm (*i.e.* actual or “standard” BC) would be close to that at shorter wavelengths, whereas for an aerosol with a high organic content (such as PAHs in tobacco smoke), the BC concentration reported for shorter wavelengths will be higher than that of standard BC concentration. As shown in Fig. 3, BC concentration during e-cigarette vaping is consistently close to zero, while during the period of normal cigarette consumption, a spectrum of distinct BC concentrations at different wavelengths is observed. The standard (*i.e.* actual) BC concentration during normal cigarette smoking (corresponding to 880 nm) peaks at $4.1 \mu\text{g m}^{-3}$, while the reported BC concentration at shorter wavelengths is much higher (*e.g.* $24.8 \mu\text{g m}^{-3}$ at 470 nm (“blue” light) and $65.4 \mu\text{g m}^{-3}$ at 370 nm (“ultraviolet” light)), likely due to the presence of ultraviolet-absorbing organic compounds in the tobacco smoke.²¹ As will be discussed in the following sections, results of our GC-MS analysis confirm the abundance of organic species (including, but not limited to, alkanes, organic acids and PAHs) in tobacco smoke.

3.2.2. Inorganic elements and metals. Indoor to outdoor concentration ratios (*I/O*) of the elements that were detected in e-cigarette samples are presented in Table 1, along with Pearson correlation coefficient (*R*) between indoor and outdoor concentrations. The actual air concentrations of 47 elements that were quantified by the ICP-MS analysis are also included in Table S1-a (ESI†). *I/O* ratio and correlation coefficient (*R*) together provide insights on the origin of the indoor aerosol. An *I/O* ratio greater than 1 and a low *R* indicate that indoor PM is originating predominantly from indoor sources, whereas an *I/O* ratio smaller than 1 with moderate to high (*i.e.* greater than 0.7) *R* is an indication of significant infiltration of outdoor PM. As shown in Table 1, the average *I/O* ratio for 6 elements (including B, K, Ni, Zn, Ag and La) is greater than unity with a low correlation coefficient ($-0.16 < R < 0.22$), indicating the presence of

Table 1 Average indoor (*i.e.* inside of the smoking room) to outdoor mass concentration ratio and Pearson correlation coefficient (*R*) of elemental constituents of e-cigarette samples. Values correspond to average $\pm$ standard error

Element	In/out ratio	<i>R</i>	Element	In/out ratio	<i>R</i>
B	13.13 (± 7.47)	0.17	Cu	0.43 (± 0.2)	−0.49
Mg	0.10 (± 0.06)	−0.35	Zn	1.26 (± 0.33)	0.13
Al	0.48 (± 0.11)	0.89	Rb	0.56 (± 0.07)	0.26
S	0.81 (± 0.27)	0.77	Sr	0.30 (± 0.09)	0.82
K	1.53 (± 0.56)	0.22	Mo	0.52 (± 0.17)	0.61
Ca	0.18 (± 0.16)	0.54	Ag	3.39 (± 1.15)	−0.10
Ti	0.80 (± 0.18)	0.45	Cd	0.91 (± 0.2)	0.66
V	0.48 (± 0.18)	0.37	Sn	0.37 (± 0.33)	−0.18
Cr	0.92 (± 0.44)	−0.12	Sb	0.30 (± 0.05)	0.95
Mn	0.33 (± 0.1)	−0.09	La	1.47 (± 0.68)	0.01
Fe	0.26 (± 0.1)	−0.27	W	0.85 (± 0.38)	0.08
Co	0.44 (± 0.23)	−0.07	Pb	0.89 (± 0.26)	0.00
Ni	1.75 (± 0.72)	−0.16			

indoor emission source(s) for these elements during e-cigarette vaping. In order to investigate the potential influence of the e-liquid's elemental content on the observed indoor levels of the aforementioned 6 elements, ICP-MS analysis was performed on the e-liquid samples and concentration of these elements in the e-liquid was quantified (results of the e-liquid analysis are presented in Table S3, ESI†). To segregate the contribution of e-liquid and other e-cigarette components to the emissions (which is of utmost importance from a regulatory standpoint), the single-compartment mass balance model (discussed in the Section 2.3) was employed to determine the portion of the indoor concentrations that originate from the e-liquid. The results are presented in Fig. 4. As seen in Fig. 4, for all of these elements (specifically Ni, Zn, Ag and La), the estimated contribution of the e-liquid to the indoor concentration is lower than the actual indoor levels during e-cigarette vaping, suggesting that these elements originate from another indoor source. In a recent study by Williams *et al.*,¹³ the cartomizer's elemental content was examined using electron microscopy and compared to the aerosol's elemental content. Their analysis confirmed the presence of metals such as Sn, Ag, Fe, Ni, Al and Cr in the cartomizer and their emission thereof in the aerosol generated by the e-cigarette, suggesting that the material used in the cartridge of the e-cigarette is a likely source contributing to the total emission of these metals in our study as well. Indoor concentration of B, K, Ni, Zn, Ag and La during e-cigarette vaping and normal cigarette smoking are compared in Fig. 5. The concentrations of B, K and La were statistically significantly ($p < 0.05$) higher in normal cigarettes. On the other hand, there was no statistically significant difference between e-cigarette and normal cigarette samples for Zn, Ni and Ag (potentially toxic and redox active species^{22,23}). Considering the potential adverse health effects associated with the inhalation of these metals (particularly Ni and Zn, and the emission observed both

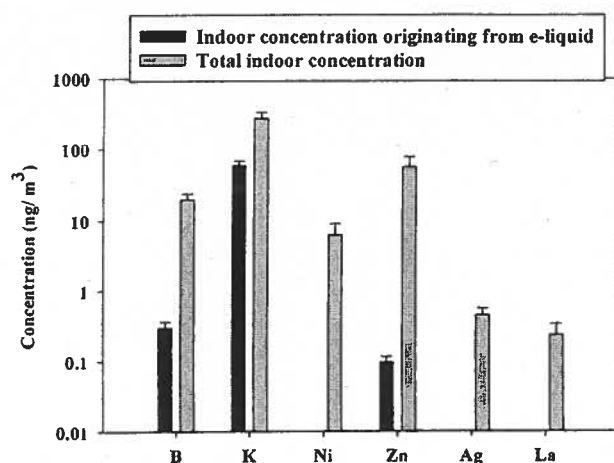


Fig. 4 Average indoor (i.e. inside of the smoking room) concentration (ng m^{-3}) of elements with average indoor to outdoor mass ratio greater than unity, compared to their estimated concentration caused by the e-liquid's elemental content. Error bars represent one standard error for the former and analytical uncertainties for the latter.

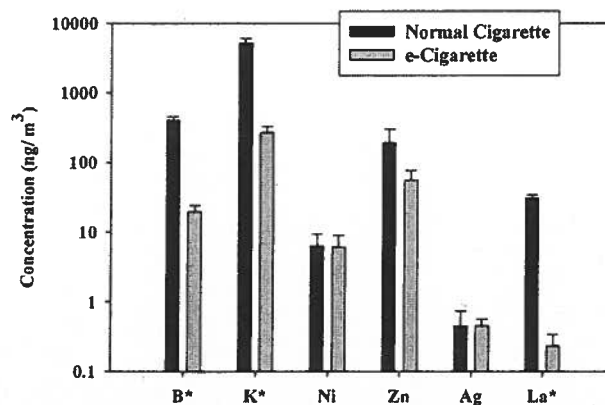


Fig. 5 Average indoor (i.e. inside of the smoking room) levels (ng m^{-3}) of e-cigarette versus normal cigarette emissions pertaining to the elements with average indoor to outdoor mass ratio greater than unity. Error bars represent one standard error. * indicates elements with statistically significant difference ($p < 0.05$) between regular cigarettes and e-cigarettes.

in our analysis as well as the study by Williams *et al.*¹³), attention should be directed toward eliminating the use of these metals in the cartridges during the manufacturing process of e-cigarettes.

3.2.3. Organic species. The concentration of individual organic species for both indoor and outdoor samples is shown in Table S1(b–e).† PAH concentrations, including benz(a)anthracene, chrysene, benzo(b)fluoranthene, benzo(k)fluoranthene, benzo(e)pyrene, benzo(a)pyrene, indeno(1,2,3-cd)pyrene and benzo(g,h,i)perylene, were found to be substantially higher indoors than outdoors during normal cigarette smoking (ranging between 1.4 to 5.1 ng m^{-3} for indoor and 0.19 ng m^{-3} or less for outdoor), while they were not detected in the indoor samples that were collected during e-cigarette vaping. Hopanes and steranes, tracers of lubricating/engine oil in diesel and gasoline vehicles,²⁴ were non-detected for all indoor samples associated with e-cigarettes. Levoglucosan, a tracer of biomass combustion,²⁵ was detected in all indoor and outdoor samples, with indoor concentration during e-cigarette vaping about 80-fold lower than that during normal cigarette smoking (which was expected due to the presence of biomass in normal tobacco-containing cigarettes) and about 3-fold lower than ambient levels. N-alkanes and organic acids were the only groups of organic species that were found at higher concentrations indoor than outdoor during e-cigarette use.

For all of the organic species with detectable indoor concentrations during e-cigarette vaping, the *I/O* concentration ratios as well as Pearson correlation coefficients between indoor and outdoor concentrations were determined (presented in Table 2). As seen in the table, levoglucosan is the only organic compound with an *I/O* ratio smaller than unity. Considering the strong association between outdoor and indoor levoglucosan levels during e-cigarette vaping ($R = 0.99$), the indoor levels of levoglucosan for e-cigarette samples are most likely associated with ambient levoglucosan that infiltrated indoors. Alkanes and organic acids presented in Table 2 had average *I/O* ratios greater

Table 2 Average indoor (*i.e.* inside of the smoking room) to outdoor mass concentration ratio and Pearson correlation coefficient (*R*) of organic species for e-cigarette samples. Polycyclic aromatic hydrocarbons (PAHs) were undetected for indoor e-cigarette samples and therefore not included in this table. Values correspond to average $\pm$ standard error

Species	I/O ratio	R	Species	I/O ratio	R
<i>n</i> -Eicosane	1.72 (± 0.33)	0.97	Tetradecanoic acid	8.25 (± 1.46)	-0.41
<i>n</i> -Docosane	1.83 (± 0.33)	0.93	Pentadecanoic acid	8.3 (± 1.34)	-0.4
<i>n</i> -Tetracosane	8.55 (± 3.06)	0.63	Hexadecanoic acid	13.57 (± 5.5)	-0.3
<i>n</i> -Pentacosane	8.35 (± 4.08)	0.55	Heptadecanoic acid	23.12 (± 5.55)	-0.62
<i>n</i> -Hexacosane	2.2 (± 0.3)	0.72	Nonadecanoic acid	3.91 (± 2.26)	0.1
<i>n</i> -Heptacosane	3.15 (± 2.08)	0.25	Palmitoleic acid	37.98 (± 8.05)	-0.86
Nonacosane	2.26 (± 1.14)	-0.26	Linoleic acid	4.53 (± 1.35)	0.73
Triacotane	7.39 (± 4.4)	-0.16	Eicosanoic acid	3.46 (± 2.26)	0.56
Hentriacontane	2.5 (± 1.25)	-0.07	Docosanoic acid	1.52 (± 0.36)	0.9
Dotriacontane	2.55 (± 1.18)	-0.2	Tricosanoic acid	1.65 (± 0.31)	0.16
Trtriacontane	1.52 (± 0.43)	-0.25	Tetracosanoic acid	2.72 (± 0.56)	0.15
Tetratriacontane	1.49 (± 0.43)	-0.29	Pentacosanoic acid	8.06 (± 2.64)	-0.65
Pentatriacontane	1.41 (± 0.34)	-0.25	Hexacosanoic acid	1.87 (± 0.27)	-0.07
Hexatriacontane	1.45 (± 0.34)	-0.34	Octacosanoic acid	1.31 (± 0.14)	-0.55
Heptatriacontane	1.3 (± 0.26)	-0.31	Triacotanoic acid	5.3 (± 4.15)	-0.65
Octatriacontane	1.5 (± 0.33)	-0.48	Suberic acid	1.66 (± 0.47)	-0.26
Decanoic acid	5.91 (± 1.81)	0.82	Azelaic acid	1.79 (± 0.47)	-0.07
Dodecanoic acid	2.5 (± 0.6)	0.68	Levogluconan	0.77 (± 0.31)	0.99

than one, indicating the presence of an indoor source for these species during e-cigarette consumption. This observation was further investigated by an analysis of the organics content of the e-liquid (presented in Table S3†). Excluding hexadecanoic acid and octadecanoic acid, which respectively displayed concentrations of 511 (± 148) and 247 (± 118) $\mu\text{g ml}^{-1}$ in the e-liquid, this analysis resulted in non-detectable levels for all measured compounds. Considering the non-detectable concentration of most *n*-alkanes and organic acids in the e-liquid, definitive conclusion regarding the sources of these organics in the indoor environment is not possible based on our data. The rather low concentration of these compounds during e-cigarette vaping (*i.e.* less than 100 ng m^{-3} for most of the species, as shown in Tables S1-d and S1-e†), is most likely indicative of a dominant background indoor level and is not representative of a specific source. It is important to note that additional quantification of the gas-phase organics in the indoor environment is needed to accurately determine the sources of indoor organic compounds, the emission of which may have disproportional partitioning in the gas-phase and particulate-phase. I/O ratio for alkanes and organic acids during normal cigarette smoking is also presented in Table S2 (ESI†), with all of the compounds exhibiting I/O ratios greater than unity (ranging from a minimum of 4.3 for hexatriacontane, up to more than 300 for species such as tritriacontane), demonstrating the presence of strong indoor emission source(s) for these species during normal cigarette smoking. Indoor emission rate of these organic species are calculated and discussed in the next section.

3.3. Emission rates of chemical species

A single-compartment mass balance model was employed to determine and compare the indoor emission rates of chemical species during e-cigarette vaping and normal cigarette smoking.

The results are presented in Tables 3 (inorganic elements) and 4 (organic species). A non-detectable (N.D.) emission rate indicates that there was no detectable indoor emission source for the species and the observed indoor concentrations were, therefore, mostly due to the penetration of outdoor aerosol to the indoor environment as a result of air exchange ($\text{AER} = 1.1 \text{ h}^{-1}$) between the indoor and outdoor environments. The indoor emission rates of several elements with adverse health effects upon inhalation are substantially decreased in e-cigarette's aerosol compared to that from normal cigarette. Cadmium and lead, for instance, are particularly toxic metals that have been consistently found in tobacco smoke in previous studies (*e.g.* ref. 26 and 27). Indoor emission rates associated with these metals during smoking of normal cigarettes were as high as 1012 ng h^{-1} and 657 ng h^{-1} for Pb and Cd, respectively, while for e-cigarette vaping these rates are lower by 2–3 orders of magnitude. Similarly, sulfur (another element commonly present in high concentrations in tobacco smoke²⁸) had an indoor emission rate of about 34 $\mu\text{g h}^{-1}$ during normal cigarette smoking, while it had no detectable indoor emission during e-cigarette consumption. With the exception of Ni, Ti, Cr and Ag (elements also found in the e-cigarette's aerosol in a previous study by Williams *et al.*¹³), the indoor emission rate of all elements was higher for normal cigarette smoking compared to e-cigarette vaping. This observation suggests that even though e-cigarette's aerosol contains fewer deleterious elements, and at lower concentrations, it does contain several metals such as Ag, Cr, and Ni (which are toxic metals^{22,23}) that are being emitted in higher rates from e-cigarettes. This is most likely due to the low quality and lack of supervision and control on the manufacturing process of e-cigarette's cartridges, as explained in the article by Williams *et al.*¹³ Moreover, although the emission of Pb was substantially decreased in e-cigarette compared

Table 3 Average emission rates (ng h^{-1}) of selected metals and elements during e-cigarette and normal cigarette consumption. Values correspond to average $\pm$ propagated uncertainty. "N.D." represents the emission rates that were not detectable based on the mass balance model (i.e. indicating zero emission rate from indoor sources)

Species	e-Cigarette (ng h^{-1})	Normal-cigarette (ng h^{-1})	Species	e-Cigarette (ng h^{-1})	Normal-cigarette (ng h^{-1})
B	963.8 (± 30.18)	23 680 (± 582.9)	Cu	N.D	1029 (± 113.8)
Mg	N.D	N.D	Zn	1142 (± 143.8)	8252 (± 332.3)
Al	N.D	N.D	Rb	N.D	200.1 (± 6.450)
S	N.D	34 540 (± 1580)	Sr	N.D	N.D
K	7765 (± 560.3)	297 500 (± 7044)	Mo	N.D	N.D
Ca	N.D	N.D	Ag	20.91 (± 0.730)	14.65 (± 0.900)
Ti	50.16 (± 26.29)	N.D	Cd	0.480 (± 0.300)	657.3 (± 15.10)
V	N.D	N.D	Sn	N.D	N.D
Cr	28.10 (± 13.64)	N.D	Sb	N.D	N.D
Mn	N.D	N.D	La	3.210 (± 0.690)	1846 (± 45.36)
Fe	N.D	N.D	W	N.D	N.D
Co	N.D	N.D	Pb	96.16 (± 29.93)	1012 (± 248.7)
Ni	130.5 (± 15.73)	36.39 (± 10.42)			

to normal cigarette, its presence in e-cigarette's aerosol can still be further reduced or eliminated by implementing better quality control procedures in the manufacturing process of e-cigarettes.

Tables 4 and 5 highlight the emission rates associated with organic species (*n*-alkanes and alkanic acids in Table 4 and PAHs in Table 5). As seen in Table 4, the emission rate of all particulate alkanes and organic acids decreased by 2–3 orders of magnitude for e-cigarette compared to normal cigarette. Seven PAHs were detected in normal cigarette samples (including chrysene, benzo(*b*)fluoranthene, benzo(*k*)fluoranthene, benzo(*e*)pyrene, benzo(*a*)pyrene, indeno(1,2,3-*cd*)pyrene and benzo(*g,h,i*)perylene) with indoor emission rates ranging from 105 ng h^{-1} benzo(*e*)pyrene to 307 ng h^{-1} benzo(*b*)fluoranthene, while none of these species were detected indoors during e-cigarette vaping. We note here that although our analysis indicates that the particle-phase organic content of e-cigarette's aerosol is considerably lower than that of normal cigarette smoke, another portion of e-cigarette's emissions are expected

to be in the vapor phase, the evaluation of which was not part of our analysis. Further analysis of vapor-phase e-cigarette emissions might be useful to uncover the vapor-phase levels of organic emissions from e-cigarettes.

3.4. Indoor concentration and emission rate of nicotine

In order to examine particle-phase nicotine levels and emission rates, e-cigarette samples without the addition of nicotine (i.e. loaded with e-liquid only) and with a nicotine concentration of 16 mg ml^{-1} (a typical dose of nicotine in commercially available nicotine-containing e-liquid) were collected and examined by GC-MS. The nicotine content of the e-liquid was also verified using our GC-MS methodology, which resulted in a nicotine concentration of 17.2 (± 0.5) mg ml^{-1} , indicating a very good agreement between the commercial nicotine label (i.e. 16 mg ml^{-1}) and the actual nicotine content of the e-liquid. Indoor concentrations and emission rates, as well as *I/O* ratio of nicotine for normal cigarette as well as e-cigarette samples with and without the addition of nicotine are presented in Table 6. The

Table 4 Average emission rates (ng h^{-1}) of selected alkanes and organic acids during e-cigarette and normal cigarette consumption. Values correspond to average $\pm$ propagated uncertainty

Species	e-Cigarette (ng h^{-1})	Normal-cigarette (ng h^{-1})	Species	e-Cigarette (ng h^{-1})	Normal-cigarette (ng h^{-1})
<i>n</i> -Eicosane	529.3 (± 40.54)	11 240 (± 287.3)	Tetradecanoic acid	8308 (± 240.3)	16 100 (± 397.6)
<i>n</i> -Docosane	477.3 (± 31.67)	9407 (± 240.1)	Pentadecanoic acid	2289 (± 65.12)	7685 (± 183.2)
<i>n</i> -Tetracosane	604.9 (± 20.12)	5131 (± 127.1)	Hexadecanoic acid	13 960 (± 395.4)	129 300 (± 3098)
<i>n</i> -Pentacosane	255.5 (± 9.143)	5765 (± 138.6)	Heptadecanoic acid	572.4 (± 20.12)	8113 (± 189.6)
<i>n</i> -Hexacosane	125.5 (± 6.123)	3593 (± 83.49)	Palmitoleic acid	1813 (± 46.77)	8308 (± 190.2)
Triacontane	241.4 (± 21.02)	23 490 (± 545.4)	Linoleic acid	444.1 (± 14.78)	65 100 (± 1477)
Hentriacontane	317.2 (± 34.21)	165 900 (± 3934)	Eicosanoic acid	136.4 (± 6.983)	13 900 (± 318.2)
Dotriacontane	312.6 (± 37.67)	35 900 (± 839.4)	Docosanoic acid	160.4 (± 10.36)	12 570 (± 287.4)
Trtriacontane	274.3 (± 38.72)	94 420 (± 2115)	Tricosanoic acid	112.6 (± 7.978)	6479 (± 157.2)
Tetratriacontane	284.1 (± 39.78)	4706 (± 114.3)	Tetracosanoic acid	449.3 (± 18.13)	10 260 (± 239.9)
Pentatriacontane	220.1 (± 28.34)	3887 (± 98.88)	Pentacosanoic acid	208.2 (± 8.873)	2842 (± 65.67)
Hexatriacontane	228.5 (± 26.35)	943.1 (± 29.34)	Hexacosanoic acid	218.6 (± 12.84)	3505 (± 84.23)
Heptatriacontane	153.7 (± 19.55)	1110 (± 30.33)	Octacosanoic acid	222.2 (± 18.93)	9880 (± 226.2)
Octatriacontane	208.8 (± 20.93)	776.6 (± 24.46)	Triacotanoic acid	228.6 (± 18.95)	6720 (± 163.8)
Decanoic acid	229.2 (± 8.981)	1368 (± 32.82)	Suberic acid	282.3 (± 20.13)	2264 (± 60.23)
Dodecanoic acid	2421 (± 102.2)	12 270 (± 278.8)	Azelaic acid	743.5 (± 48.80)	4979 (± 134.8)

Table 5 Average emission rate (ng h^{-1}) of polycyclic aromatic hydrocarbons (PAHs) during e-cigarette and normal cigarette consumption. Values correspond to average $\pm$ propagated uncertainty. "N.D." represents the emission rates that were not detectable based on the mass balance model (i.e. indicating zero emission rate from indoor sources)

Species	e-Cigarette (ng h^{-1})	Normal-cigarette (ng h^{-1})
Chrysene	N.D	213.3 (± 5.983)
Benzo(b)fluoranthene	N.D	307.2 (± 7.237)
Benzo(k)fluoranthene	N.D	130.4 (± 3.235)
Benzo(e)pyrene	N.D	105.6 (± 3.982)
Benzo(a)pyrene	N.D	281.7 (± 6.873)
Indeno(1,2,3-cd)pyrene	N.D	270.2 (± 6.532)
Benzo(g,h,i)Perylene	N.D	187.0 (± 4.231)

Table 6 Indoor to outdoor mass concentration ratio and emission rates (ng h^{-1}) of nicotine for e-cigarette samples with and without nicotine as well as normal cigarette. Values correspond to average $\pm$ standard error for indoor to outdoor ratios and mass concentrations, and average $\pm$ propagated uncertainty for emission rates

Parameter	Sample	Nicotine
Concentration (ng m^{-3})	Normal cigarette	1524 (± 80.4)
	e-Cigarette	60.68 (± 20.91)
	e-Cigarette + nicotine	123.0 (± 34.5)
Indoor/outdoor mass ratio	Normal cigarette	254.3 (± 13.4)
	e-Cigarette	6.7 (± 3.5)
	e-Cigarette + nicotine	18.6 (± 7)
Emission strength (ng h^{-1})	Normal cigarette	91 161 (± 2170)
	e-Cigarette	2759 (± 93)
	e-Cigarette + nicotine	7103 (± 172)

indoor concentration and emission rate of particle-phase nicotine were both about 13 times higher during smoking of normal cigarette compared to the consumption of e-cigarette containing 16 mg ml^{-1} of nicotine in the e-liquid (1524 ng m^{-3} versus 123 ng m^{-3} and $91\,161 \text{ ng h}^{-1}$ versus 7103 ng h^{-1} , respectively). Detectable levels of nicotine were found in particles collected during the experimental trials of e-cigarette without nicotine in the e-liquid. Nicotine is a semi-volatile compound, with strong affinity and persistence on indoor surfaces.^{29,30} The observed (small) nicotine levels in e-cigarette samples without nicotine could, therefore, be due to particle-bound nicotine re-suspension in the room during sampling and can be considered as a "background" or "blank" emission level. Re-suspension of residual nicotine in indoor environments has been previously considered as one of the pathways of passive exposure to nicotine in houses with active smoker residents.³⁰ It should be mentioned that the concentration of residual and side-stream nicotine in an indoor environment can be significantly affected by gas-to-particle partitioning of nicotine, which is strongly dependent on the environmental conditions such as temperature, pressure and acidity of the aerosol.^{31,32} In our study, the average consumption rate of the e-liquid was about 1.3 ml h^{-1} , which, considering a nicotine concentration of 17.2 mg ml^{-1} in the e-liquid (measured by the GC-MS method),

would result in a total emission rate of about 22.36 mg h^{-1} nicotine from e-cigarettes (including both gas-phase and particle-phase nicotine). Based on our data, the indoor emission rate of particle-phase nicotine (after subtraction of nicotine level from e-cigarette without nicotine; which was considered as a "background" level) was about 4344 ng h^{-1} , accounting for about 0.02% of the total nicotine emission, implying that a trivial fraction of the total nicotine emissions from e-cigarettes is found in secondhand particulate emissions. Further investigation is required for accurate determination of nicotine's gas-to-particle partitioning ratio in e-cigarette's aerosol, which can provide useful insight about secondhand exposure to nicotine during e-cigarette vaping under different conditions.

4. Summary and conclusions

Analysis of secondhand emissions from a popular and widely-used e-cigarette brand indicated a very large reduction of particle-phase emissions compared to normal tobacco-containing cigarettes in a real-life setting. BC and particle-phase PAHs, deleterious chemical species present in high concentrations in tobacco smoke, were not detected in e-cigarette's aerosol. Emission rates of organic compounds (including alkanes and organic acids) as well as total emission of inorganic elements and metals were also significantly reduced (more than 100 times for organics and 10 times for elements) in e-cigarettes compared to normal cigarettes. Analysis of elemental emissions indicated the presence of toxic metals (such as Ni, Zn and Ag) in e-cigarette's aerosol, with Ni and Ag having higher indoor emission rates compared to normal cigarettes. Moreover, analysis of nicotine indicated that secondhand particle-phase nicotine accounted for about 0.02% of the total nicotine generation and emission during e-cigarette vaping. Based on our results, use of e-cigarettes from a public health perspective appears to be an improvement compared to normal tobacco-containing cigarettes, as exposure to most of the toxic and/or undesirable chemical species was found to be much lower than that for normal cigarettes. However, considering the lack of regulation on the manufacturing process of e-cigarettes, there appears to be a potential for utilization of toxic material (such as metals) in e-cigarettes, which could lead to their emission in e-cigarette's vapor and aerosol.^{4,13} Implementing quality control regulations on the design and manufacturing process of e-cigarettes is therefore necessary to prevent potential utilization of non-desirable material in e-cigarettes and e-liquids.

Acknowledgements

This study was supported by the grant (number: 5345070013) from Fondazione IRCCS Istituto Nazionale dei Tumori (Milan, Italy) to the University of Southern California. This grant was provided in part by funds obtained through an Italian law allowing taxpayers to allocate 0.5 percent share of their income tax contribution to a research institution of their choice. The authors thank the staff at the Wisconsin state Laboratory of Hygiene (WSLH) for their assistance in the chemical analyses. We also acknowledge the support of USC's Viterbi PhD

fellowship. We wish to dedicate the work *in memoriam* of Giovanni Invernizzi.

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EXHIBIT 8

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TOBACCO EDUCATION AND RESEARCH OVERSIGHT COMMITTEE**

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Professor
Department of Family and Preventive Medicine
University of California, San Diego

TO: California Department of Public Health (CDPH), University of California (UC), and the California Department of Education (CDE)

FROM: Tobacco Education and Research Oversight Committee (TEROC)

DATE: June 13, 2013

SUBJECT: Position on Electronic-Cigarettes (e-cigarettes)

The Tobacco Education and Research Oversight Committee (TEROC) is a legislatively mandated oversight committee (California Health and Safety Code Sections 104365-104370) that monitors the use of Proposition (Prop) 99 tobacco tax revenues for tobacco control, prevention education and tobacco-related research in California. TEROC advises the CDPH, the UC, and the CDE with respect to: policy development, tobacco control and prevention integration, evaluation of tobacco education programs (funded by Prop 99), and is responsible for the development of a master plan for the future implementation of tobacco control.

TEROC conducted a meeting on May 22, 2013 where the Committee deliberated, voted upon, and adopted an official position regarding e-cigarettes:

***The Tobacco Education and Research Oversight Committee (TEROC)
opposes the use of e-cigarettes in all areas where other tobacco
products are banned.***

If you have questions regarding this subject, please contact Michael Ong, M.D., Ph.D., Chairperson at MOng@Mednet.ucla.edu.



STAFFED BY CALIFORNIA DEPARTMENT OF PUBLIC HEALTH, CALIFORNIA TOBACCO CONTROL PROGRAM
1616 CAPITOL AVENUE, P.O. BOX 997377 MS#7206, SACRAMENTO, CALIFORNIA 95899-7377, (916) 449-5500

EXHIBIT 9

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**Corey, C., Johnson, S., Apelberg, B., et al.
(2013). "Notes from the Field: Electronic
Cigarette Use Among Middle and High School
Students - United States, 2011- 2012."
Morbidity and Mortality Weekly Report
(*MMWR*), 62(35):729-730**

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Morbidity and Mortality Weekly Report (MMWR)

Notes from the Field: Electronic Cigarette Use Among Middle and High School Students — United States, 2011– 2012

Weekly

September 6, 2013 / 62(35):729–730

Electronic cigarettes, or e-cigarettes, are battery-powered devices that provide doses of nicotine and other additives to the user in an aerosol. Depending on the brand, e-cigarette cartridges typically contain nicotine, a component to produce the aerosol (e.g., propylene glycol or glycerol), and flavorings (e.g., fruit, mint, or chocolate) (1). Potentially harmful constituents also have been documented in some e-cigarette cartridges, including irritants, genotoxins, and animal carcinogens (1). E-cigarettes that are not marketed for therapeutic purposes are currently unregulated by the Food and Drug Administration, and in most states there are no restrictions on the sale of e-cigarettes to minors. Use of e-cigarettes has increased among U.S. adult current and former smokers in recent years (2); however, the extent of use among youths is uncertain.

Data from the 2011 and 2012 National Youth Tobacco Survey (NYTS), a school-based, pencil-and-paper questionnaire given to U.S. middle school (grades 6–8) and high school (grades 9–12) students, were used to estimate the prevalence of ever and current (≥ 1 day in the past 30 days) use of e-cigarettes, ever and current (≥ 1 day in the past 30 days) use of conventional cigarettes, and use of both. NYTS consists of a cross-sectional, nationally representative sample of students in grades 6–12 from all 50 states and the District of Columbia (3).

During 2011–2012, among all students in grades 6–12, ever e-cigarette use increased from 3.3% to 6.8% ($p < 0.05$) (Figure); current e-cigarette use increased from 1.1% to 2.1% ($p < 0.05$), and current use of both e-cigarettes and conventional cigarettes increased from 0.8% to 1.6% ($p < 0.05$). In 2012, among ever e-cigarette users, 9.3% reported never smoking conventional cigarettes; among current e-cigarette users, 76.3% reported current conventional cigarette smoking.

Among middle school students, ever e-cigarette use increased from 1.4% to 2.7% during 2011–2012 ($p < 0.05$) (Figure); current e-cigarette use increased from 0.6% to 1.1% ($p < 0.05$), and current use of both e-cigarettes and conventional cigarettes increased from 0.3% to 0.7% ($p < 0.05$). In 2012, among middle school ever e-cigarette users, 20.3% reported never smoking conventional cigarettes; among middle school current e-cigarette users, 61.1% reported current conventional cigarette smoking.

Among high school students, ever e-cigarette use increased from 4.7% to 10.0% during 2011–2012 ($p < 0.05$) (Figure); current e-cigarette use increased from 1.5% to 2.8% ($p < 0.05$), and current use of both e-cigarettes and conventional cigarettes increased from 1.2% to 2.2% ($p < 0.05$). In 2012, among high school ever e-cigarette users, 7.2% reported never smoking conventional cigarettes; among high school current e-cigarette users, 80.5% reported current conventional cigarette smoking.

E-cigarette experimentation and recent use doubled among U.S. middle and high school students during 2011–2012, resulting in an estimated 1.78 million students having ever used e-cigarettes as of 2012. Moreover, in 2012, an estimated 160,000 students who reported ever using e-cigarettes had never used conventional cigarettes. This is a serious concern because the overall impact of e-cigarette use on public health remains uncertain. In youths, concerns include the potential negative impact of nicotine on adolescent brain development (4), as well as the risk for nicotine addiction and initiation of the use of conventional cigarettes or other tobacco products.

CDC and the Food and Drug Administration will continue to explore ways to increase surveillance and research on e-cigarettes. Given the rapid increase in use and youths' susceptibility to social and environmental influences to use tobacco, developing strategies to prevent marketing, sales, and use of e-cigarettes among youths is critical.

Reported by

Catherine Corey, MSPH, Baoguang Wang, MD, Sarah E. Johnson, PhD, Benjamin Apelberg, PhD, Corinne Husten, MD, Center for Tobacco Products, Food and Drug Administration. Brian A. King, PhD, Tim A. McAfee, MD, Rebecca Bunnell, PhD, René A. Arrazola, MPH, Shanta R. Dube, PhD, Office on Smoking and Health, National Center for Chronic Disease Prevention and Health Promotion, CDC. Corresponding contributor: Brian A. King, baking@cdc.gov, 770-488-5107.

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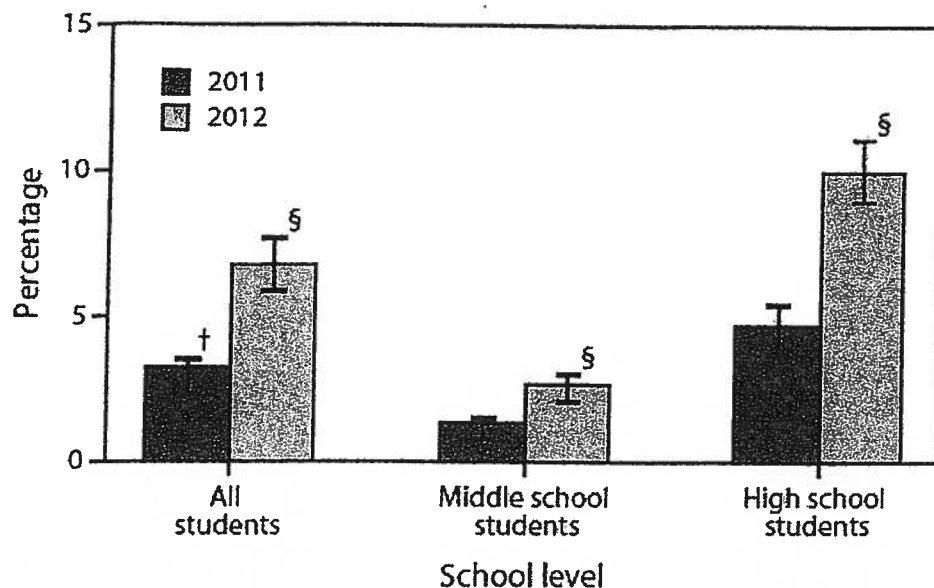
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* Ever electronic cigarette use defined as having ever used electronic cigarettes, even just one time.

† 95% confidence interval.

§ Statistically significant difference between 2011 and 2012 (chi-square, $p < 0.05$).

FIGURE. Ever electronic cigarette use* among middle and high school students, by year — National Youth Tobacco Survey, United States, 2011–2012



Alternate Text: The figure above shows ever electronic cigarette (e-cigarette) use among middle and high school students, by year, in the United States during 2011-2012. During 2011-2012, among all students in grades 6-12, ever e-cigarette use increased from 3.3% to 6.8% ($p < 0.05$); current e-cigarette use increased from 1.1% to 2.1% ($p < 0.05$), and current use of both e-cigarettes and conventional cigarettes increased from 0.8% to 1.6% ($p < 0.05$).

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****Questions or messages regarding errors in formatting should be addressed to mmwrq@cdc.gov.**

Page last reviewed: September 06, 2013

Page last updated: September 06, 2013

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King, B.A., Alam, S., and Promoff, G., et al. (2013). "Awareness and Ever Use of Electronic Cigarettes Among U.S. Adults, 2010-2011." *Nicotine and Tobacco Research*

BRIEF REPORT

Awareness and Ever Use of Electronic Cigarettes Among U.S. Adults, 2010–2011

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Received August 10, 2012; accepted January 18, 2013

ABSTRACT

Introduction: Electronic cigarettes, or e-cigarettes, were introduced into the U.S. market in recent years. However, little is known about the health impact of the product or the extent of its use. This study assessed the prevalence and correlates of awareness and ever use of e-cigarettes among U.S. adults during 2010–2011.

Methods: Data were obtained from the *HealthStyles* survey, a national consumer-based survey of U.S. adults aged ≥18 years old. In 2010, data collection for the *HealthStyles* survey was both mail-based ($n = 4,184$) and web-based ($n = 2,505$), and in 2011, web-based ($n = 4,050$) only. Estimates of awareness and ever use of e-cigarettes were calculated overall and by sex, age, race/ethnicity, educational attainment, household income, region, and smoking status.

Results: In 2010, overall awareness of e-cigarettes was 38.5% (mail survey) and 40.9% (web survey); in 2011, awareness was 57.9% (web survey). Ever use of e-cigarettes among all respondents was 2.1% in the 2010 mail survey, 3.3% in the 2010 web survey, and 6.2% in the 2011 web survey. Ever use of e-cigarettes was significantly higher among current smokers compared with both former and never-smokers, irrespective of survey method or year. During 2010–2011, ever use increased among both sexes, those aged 45–54 years, non-Hispanic Whites, those living in the South, and current and former smokers.

Conclusions: Awareness and ever use of e-cigarettes increased among U.S. adults from 2010 to 2011. In 2011, approximately 1 in 5 current smokers reported having ever used e-cigarettes. Continued surveillance of e-cigarettes is needed for public health planning.

INTRODUCTION

Electronic cigarettes, or e-cigarettes, are battery powered devices that provide inhaled doses of nicotine and other additives to the user (Food and Drug Administration [FDA], 2009). Depending on the brand, e-cigarette cartridges typically contain nicotine, humectants to produce the vapor (e.g., propylene glycol or glycerol), and flavorings (e.g., tobacco, mint, fruit, chocolate) (Etter, Bullen, Flouris, Laugesen, & Eissenberg, 2011). Since becoming available in the United States, e-cigarettes have been promoted as being more cost-effective, amenable to use in smoking-restricted environments, and socially acceptable than traditional cigarettes (Cobb, Byron, Abrams, & Shields, 2010; Henningfield & Zaatari, 2010). E-cigarettes have also been marketed as smoking cessation aids (FDA, 2010a, 2010b, 2010c, 2010d, 2010e). However, there is currently no conclusive scientific evidence that e-cigarettes promote long-term

cessation (Etter et al., 2011), and e-cigarettes are not included as a recommended smoking cessation method by the U.S. Public Health Service (PHS, 2008).

The Family Smoking Prevention and Tobacco Control Act of 2009 gave the U.S. FDA the authority to regulate tobacco products, including the ability to propose certain requirements and restrictions on manufacturing, marketing, and distribution (Government Printing Office [GPO], 2009). The Act defines a tobacco product, in part, as any product made or derived from tobacco that is not a drug, device, or combination product under the Act. In 2010, the U.S. Court of Appeals held that e-cigarettes and other products made or derived from tobacco can be regulated as tobacco products under the Act unless they are marketed for therapeutic purposes, in which case they are regulated as drugs and/or devices (D.C. Circuit, U.S. Court of Appeals, 2010). Currently, e-cigarettes that are marketed for therapeutic purposes are regulated by the FDA Center for

doi:10.1093/ntr/ntt013

Published by Oxford University Press on behalf of the Society for Research on Nicotine and Tobacco 2013.

Awareness and ever use of e-cigarettes among U.S. adults

Drug Evaluation and Research (FDA, 2012). The FDA Center for Tobacco Products currently regulates cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco (FDA, 2012), and in 2011, announced its intent to expand jurisdiction to all tobacco products, including e-cigarettes (GPO, 2011).

Many public health professionals are concerned that e-cigarettes may have an adverse impact on users' health, encourage smoking initiation, perpetuate the use of nicotine and tobacco products among smokers who might otherwise quit, and counter the effectiveness of smoke-free policies (Etter et al., 2011; Henningfield & Zaatari, 2010). Potentially harmful constituents also have been identified in some e-cigarette cartridges (Cobb et al., 2010; FDA, 2009). Conversely, proponents of e-cigarettes contend that the product is markedly less harmful to health than traditional cigarettes and may help some smokers quit (Cahn & Siegel, 2011). Although e-cigarettes are becoming increasingly popular (Ayers, Ribisl, & Brownstein, 2011), data on awareness and use of the product are limited (McMillen, Maduka, & Winickoff, 2012; Pearson, Richardson, Niaura, Vallone, & Abrams, 2012). A recent study found that awareness of e-cigarettes doubled from 16.4% in 2009 to 32.2% in 2010, whereas ever use among those aware of the product quadrupled from 0.6% to 2.7% (Regan, Promoff, Dube, & Arrazola, 2011). However, no known study has assessed more recent changes in e-cigarette awareness and use. To address this need, we analyzed data from the 2010 and 2011 *HealthStyles* surveys to determine estimates of the prevalence and sociodemographic correlates of awareness and ever use of e-cigarettes among U.S. adults.

METHODS

Data Source

Data were obtained from *Styles*, a series of national consumer panel surveys administered in seasonal waves. The *HealthStyles* survey assesses exposure to health-related information and self-reported symptoms, risk factors, and diseases among U.S. adults aged ≥18 years old. In preparation for transitioning to online-only methodology, both mail (August–September) and web (July–August) versions of *HealthStyles* were fielded in 2010. Only a web (July–August) version was fielded in 2011.

Sample

For the 2010 mail-based *Styles*, sampling and data collection were conducted by Synovate, Inc., which recruited consumers to join a mail panel. Stratified random sampling (by region, household income, population density, age, and household size) of the panel was used to select a nationally representative sample, which received the *ConsumerStyles* survey. The 2010 mail-based *HealthStyles* was sent to households that completed *ConsumerStyles* ($n = 6,255$).

For the 2010 and 2011 web-based *Styles*, sampling and data collection were conducted by Knowledge Networks, which recruited a nationally representative online panel. Panel members are randomly recruited by probability-based sampling (random-digit dial and address based) to reach respondents regardless of whether they have a landline phone or Internet access. Households are provided with a computer and Internet access as needed. The panel is continuously replenished and

maintains approximately 50,000 panelists. A random sample of 3,922 and 5,865 panelists were asked to participate in the 2010 and 2011 web-based *HealthStyles*, respectively.

Final sample sizes were 4,184 for the 2010 mail survey, 2,505 for the 2010 web survey, and 4,050 for the 2011 web survey. Response rates were 66.9%, 64.0%, and 69.0%, respectively.

Measures

Awareness

Awareness of e-cigarettes was assessed using the question, "Which, if any, of the following products have you heard of?" Respondents who selected "electronic cigarettes or e-cigarettes" were considered aware of e-cigarettes.

Ever Use

Ever use of e-cigarettes was assessed using the question, "Have you ever tried any of the following products, even just one time?" Respondents who selected "electronic cigarettes or e-cigarettes" were considered ever e-cigarette users.

Respondent Characteristics

Respondent characteristics included sex, age, race/ethnicity, education, annual household income, U.S. Census region, and smoking status. Current smokers were defined as respondents who smoked ≥100 cigarettes in their lifetime and now smoked everyday or somedays.

Analysis

Data were analyzed using SAS v. 9.2 and weighted according to 2010 and 2011 Current Population Survey population distributions. National prevalence estimates and 95% CIs were calculated. Differences were considered statistically significant if CIs did not overlap. Estimates with a relative SE of ≥40% were not reported.

RESULTS

Awareness

Awareness of e-cigarettes was 38.5% in the 2010 mail survey, 40.9% in the 2010 web survey, and 57.9% in the 2011 web survey (Table 1). No significant difference in awareness of e-cigarettes was observed between males and females, irrespective of survey method or year. In all three surveys, awareness of e-cigarettes was significantly lower among individuals ≥65 years old compared with younger age groups, and significantly lower among non-Hispanic Blacks compared with non-Hispanic Whites. Awareness of e-cigarettes was significantly lower among those with less than a high school education in the 2010 mail and 2011 web surveys, but no significant difference was observed by education level in the 2011 mail survey. No consistent differences in awareness of e-cigarettes were observed by income level or U.S. region across surveys. By smoking status, awareness of e-cigarettes was significantly higher among current smokers compared with former and never-smokers, regardless of survey method or year. When compared with the 2010 web survey, awareness of e-cigarettes in the 2011 web survey increased among all subpopulations except for those aged 18–34 years,

Table 1. Awareness and Ever Use of Electronic Cigarettes Among U.S. Adults—*HealthStyles*, 2010–2011

	Characteristic	Awareness of electronic cigarettes ^a (% [95% CI])			Ever use of electronic cigarettes ^b (% [95% CI])			
		2010 Mail <i>n</i> = 4,184	2010 Web <i>n</i> = 2,505	2011 Web <i>n</i> = 4,050	2010 Mail <i>n</i> = 4,184	2010 Web <i>n</i> = 2,505	2011 Web <i>n</i> = 4,050	
3.5	Sex							
	Male	40.8 [37.4–44.2]	44.1 [40.7–47.5]	60.9 [57.9–63.8]	2.3 [1.3–3.4]	3.0 [1.9–4.2]	5.8 [4.4–7.2]	3.70
	Female	36.4 [32.7–40.1]	37.9 [34.7–41.1]	55.1 [52.2–58.0]	1.9 [1.3–2.6]	3.7 [2.4–4.9]	6.6 [5.1–8.2]	
3.10	Age (years)							
	18–24	47.4 [32.6–62.2]	45.0 [37.4–52.6]	56.8 [49.7–63.9]	^c	7.0 [3.0–10.9]	8.1 [4.0–12.2]	
	25–34	48.6 [43.0–54.1]	48.4 [42.6–54.3]	58.3 [52.6–63.8]	2.9 [1.1–4.7]	3.1 [1.4–4.8]	6.6 [3.9–9.3]	
	35–44	39.9 [35.8–43.9]	43.7 [38.3–49.1]	60.0 [55.4–64.6]	3.4 [2.0–4.8]	3.2 [1.4–5.0]	5.7 [3.6–7.7]	3.75
	45–54	42.8 [39.7–45.8]	47.9 [42.6–53.2]	65.4 [61.1–69.6]	1.9 [1.0–2.8]	3.2 [1.3–5.2]	8.0 [5.5–10.5]	
3.15	55–64	33.8 [30.1–37.4]	37.7 [32.6–42.8]	61.2 [56.8–65.6]	2.2 [0.9–3.4]	2.9 [1.1–4.8]	5.5 [3.4–7.5]	
	≥65	19.0 [16.2–21.7]	21.4 [16.9–25.9]	44.6 [40.0–49.2]	0.8 [0.2–1.4]	^c	3.7 [1.9–5.4]	
	Race/ethnicity							
	White, non-Hispanic	42.5 [39.6–45.4]	44.3 [41.5–47.2]	62.6 [60.3–64.9]	2.4 [1.6–3.2]	3.8 [2.7–4.9]	6.8 [5.6–8.1]	3.80
	Black, non-Hispanic	26.6 [20.8–32.3]	25.6 [19.7–31.4]	50.0 [43.0–57.0]	^c	^c	4.5 [1.6–7.3]	
3.20	Other, non-Hispanic	31.3 [23.6–39.0]	41.8 [32.6–51.1]	48.5 [39.4–57.6]	1.8 [0.4–3.2]	^c	6.1 [1.8–10.4]	
	Hispanic	31.9 [23.3–40.6]	36.2 [30.1–42.3]	44.4 [37.8–51.1]	2.3 [0.9–3.7]	3.0 [1.0–5.1]	3.9 [1.1–6.7]	
	Education							
	Less than high school	19.1 [12.8–25.3]	40.3 [33.9–46.7]	42.6 [35.0–50.2]	^c	4.3 [1.7–6.9]	7.4 [3.4–11.4]	3.85
	High school graduate	37.2 [32.3–42.0]	41.0 [36.8–45.2]	56.4 [52.6–60.3]	3.1 [1.3–5.0]	4.0 [2.2–5.7]	7.5 [5.4–9.7]	
3.25	Some college	41.3 [36.6–46.0]	40.6 [36.3–44.9]	62.5 [59.0–66.0]	2.3 [1.4–3.2]	3.6 [2.0–5.1]	6.1 [4.6–7.7]	
	College graduate	39.3 [36.1–42.5]	41.4 [36.8–45.9]	61.7 [58.4–64.9]	1.5 [0.7–2.2]	2.0 [0.8–3.2]	4.4 [2.9–5.9]	
	Annual household income							
	<\$15,000	26.1 [21.1–31.1]	42.6 [36.2–49.0]	52.1 [45.2–58.9]	1.1 [0.3–1.9]	3.5 [1.5–5.6]	7.5 [4.3–10.7]	3.90
	\$15,000–\$24,999	31.8 [24.7–39.0]	43.5 [36.0–50.9]	54.6 [47.2–62.0]	1.6 [0.4–2.9]	^c	5.7 [1.9–9.4]	
3.30	\$25,000–\$39,999	39.5 [32.8–46.3]	36.4 [31.1–41.6]	55.9 [50.4–61.3]	2.9 [0.6–5.2]	3.5 [1.3–5.8]	9.4 [5.7–13.0]	
	\$40,000–\$59,999	41.2 [35.3–47.1]	41.7 [36.5–46.8]	53.4 [48.4–58.4]	1.9 [0.7–3.1]	2.5 [1.1–3.8]	4.9 [2.9–6.9]	
	≥\$60,000	42.7 [38.8–46.6]	41.1 [37.3–44.8]	61.8 [59.0–64.6]	2.4 [1.5–3.3]	3.5 [2.1–4.9]	5.6 [4.3–7.0]	
	U.S. Census region ^d							
	Northeast	35.3 [29.1–41.5]	38.5 [32.7–44.3]	57.3 [52.6–62.0]	1.1 [0.3–1.9]	^c	5.6 [3.5–7.7]	3.95
	Midwest	46.3 [41.3–51.3]	46.6 [42.0–51.2]	61.1 [57.0–65.1]	3.3 [1.5–5.1]	5.4 [3.1–7.6]	7.7 [5.3–10.1]	
3.35	South	35.3 [31.5–39.1]	38.4 [34.4–42.4]	57.9 [54.3–61.5]	1.4 [0.8–2.0]	2.5 [1.4–3.6]	6.2 [4.4–8.0]	
	West	37.4 [31.4–43.4]	41.3 [36.7–46.0]	55.4 [51.0–59.7]	3.0 [1.7–4.2]	3.7 [2.0–5.5]	5.3 [3.3–7.3]	
	Smoking status							
	Current smokers	58.5 [52.5–64.4]	59.3 [54.2–64.3]	76.9 [72.2–81.5]	6.8 [4.6–8.9]	9.8 [6.9–12.6]	21.2 [17.0–25.4]	3.100
	Former smoker	36.2 [31.8–40.5]	41.5 [37.0–46.0]	65.4 [61.7–69.1]	0.6 [0.2–1.1]	2.5 [0.8–4.2]	7.4 [5.0–9.7]	
3.40	Never-smoker	33.8 [30.4–37.3]	34.6 [31.3–37.8]	50.1 [47.3–52.9]	1.2 [0.5–2.0]	1.3 [0.5–2.0]	1.3 [0.7–1.8]	
	Total	38.5 [36.0–41.0]	40.9 [38.6–43.2]	57.9 [55.8–60.0]	2.1 [1.5–2.7]	3.3 [2.5–4.2]	6.2 [5.2–7.3]	

Note. ^aDefined as a response of “electronic cigarettes or e-cigarettes” to the question, “Which, if any, of the following products have you heard of?”

^bDefined as a response of “electronic cigarettes or e-cigarettes” to the question, “Have you tried any of the following products, even just one time?”

^cRelative SE ≥ 40%.

^dNortheast = Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont;

Midwest = Indiana, Illinois, Iowa, Kansas, Michigan, Minnesota, Missouri, Nebraska, North Dakota, Ohio, South Dakota, Wisconsin;

South = Alabama, Arkansas, Delaware, District of Columbia, Florida, Georgia, Kentucky, Louisiana, Maryland, Mississippi, North

Carolina, Oklahoma, South Carolina, Tennessee, Texas, Virginia, West Virginia; West = Alaska, Arizona, California, Colorado, Hawaii,

Idaho, New Mexico, Montana, Oregon, Nevada, Utah, Washington, Wyoming.

Hispanics, those of non-Hispanic “Other” race, those with less than a high school education, and those with annual household income <\$25,000.

Ever Use

Ever use of e-cigarettes was 2.1% in the 2010 mail survey, 3.3% in the 2010 web survey, and 6.2% in the 2011 web survey

(Table 1). Irrespective of survey method or year, no significant difference in ever use of e-cigarettes was observed by sex, age, race/ethnicity, education, income, or U.S. region. In all three surveys, ever use of e-cigarettes was significantly higher among current smokers compared with both former and never-smokers. Among current smokers, ever use of e-cigarettes was 21.2% in the 2011 web survey compared with 6.8% in the 2010 mail survey and 9.8% in the 2010 web survey. When

Awareness and ever use of e-cigarettes among U.S. adults

compared with the 2010 web survey, ever use of e-cigarettes in the 2011 web survey increased among both sexes, those aged 45–54 years, non-Hispanic Whites, those who live in the South, and both current and former smokers.

DISCUSSION

This study is the first to report changes in the national prevalence of e-cigarette awareness and use among U.S. adults between 2010 and 2011. The findings reveal that the awareness and use of e-cigarettes are increasing. Approximately 6 in 10 adults were aware of e-cigarettes in 2011 compared with 4 in 10 adults in 2010. Moreover, in 2011, 6.2% of all adults and 21.2% of current smokers had ever used e-cigarettes, representing an approximate doubling of 2010 estimates. These findings underscore the need for rigorous surveillance of e-cigarettes and their impact on smoking initiation, smoking cessation, concurrent use with combustible products, users' health, and smoke-free policy compliance.

Differences in awareness and use of e-cigarettes were observed across subpopulations. Specifically, adults <65 years of age, non-Hispanic Whites, and current/former smokers were most aware of e-cigarettes. Higher awareness among younger adults may be related to the fact that e-cigarettes are traditionally marketed through electronic and social media (Noel, Rees, & Connolly, 2011; Yamin, Bitton, & Bates, 2010). In contrast, the only consistent statistically significant difference in e-cigarette use was between current smokers and nonsmokers. The higher prevalence of use among current smokers could be related to the marketing of e-cigarettes as smoking cessation aids (FDA, 2010a, 2010b, 2010c, 2010d, 2010e). Because e-cigarettes resemble traditional cigarettes and their use could potentially result in increased nicotine addiction and the initiation of tobacco smoking, further surveillance of e-cigarette use is warranted, particularly among youth and young adults, who are particularly susceptible to social and environmental influences to use tobacco (U.S. Department of Health and Human Services, 2012).

The impact of e-cigarette use on public health remains uncertain (Etter et al., 2011). Some research has shown that e-cigarettes are most frequently used as a smoking cessation aid (Etter, 2010), might alleviate the desire to smoke after abstinence (Bullen et al., 2010), and may reduce cigarette consumption and encourage short periods of smoking abstinence (Caponnetto, Polosa, Russo, Leotta, & Campagna, 2011; Polosa et al., 2011; Siegel, Tanwar, & Wood, 2011). However, e-cigarettes are presently unregulated and produced by numerous small manufacturers (Etter et al., 2011). Potentially harmful constituents have also been documented in some e-cigarette cartridges, including diethylene glycol, irritants, genotoxins, and animal carcinogens (Cobb et al., 2010; FDA, 2009). In addition, the tobacco industry is evolving rapidly. The e-cigarette manufacturer, blu Cigs, was recently acquired by Lorillard, Inc. (PR Newswire, 2012), and the product has been advertised as an alternative to cigarettes in a nationally televised commercial (Internet Movie Database, 2012). Other noncombustible nicotine products have been promoted by the tobacco industry as an alternative that allows smokers to access nicotine in situations where it is legally or socially unacceptable to smoke (Curry, Pederson, & Stryker, 2011). Accordingly,

further research is needed on the long-term impact of e-cigarette use on tobacco cessation and initiation, concurrent product use, and users' health.

The impact of e-cigarettes on smoke-free policy compliance should also be evaluated. The use of e-cigarettes in public areas in which cigarette smoking is prohibited could counter the effectiveness of these policies by complicating enforcement and giving the appearance that smoking is acceptable (Etter et al., 2011). Research suggests that smoke-free policies increase the social unacceptability of smoking and enhance quit intentions and behaviors (Brown, Moodie, & Hastings, 2009). To date, some states and localities have enacted policies that restrict e-cigarette use in public places, whereas others have exempted e-cigarettes from smoke-free legislation (Global Advisors Smoke-Free Policy, 2011).

This study is subject to at least four limitations. First, *HealthStyles* is not a population-based probability survey. Research suggests that random-digit-dial and Internet panel probability samples may be more representative than nonprobability Internet samples (Yeager et al., 2011). Nonetheless, data were weighted to be nationally representative and tobacco use estimates from *Styles* are consistent with other national household surveys (Regan et al., 2011). Second, data collection methods varied across surveys; however, estimates from the 2010 mail and web surveys were comparable. Third, small sample sizes for some subpopulations resulted in less precise estimates that could not be presented. Limited sample size also prevented the presentation of estimates of current e-cigarette use. Finally, survey responses were self-reported, which could lead to reporting bias; although studies have confirmed the validity of self-reported smoking (Caraballo, Giovino, & Pechacek, 2004), the accuracy of self-reported e-cigarette use is uncertain.

In conclusion, findings from the *HealthStyles* survey suggest that awareness and use of e-cigarettes increased among U.S. adults during 2010–2011, particularly among current smokers. Since e-cigarette use may continue to increase with time and could have either deleterious or beneficial effects on public health depending on its impact on smoking initiation and cessation, appropriate public health surveillance of the product is warranted.

FUNDING

This project was supported in part by an appointment to the Research Participation Program at the Centers for Disease Control and Prevention (CDC) administered by the Oak Ridge Institute for Science and Education through an interagency agreement between the U.S. Department of Energy and the CDC (DE-AC05-06OR23100).

DECLARATION OF INTEREST

None declared.

ACKNOWLEDGMENTS

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

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World Medical Association. *Statement on Electronic Cigarettes and Other Electronic Nicotine Delivery Systems.* October 2012

1021745.1



WMA Statement on Electronic Cigarettes and Other Electronic Nicotine Delivery Systems

Adopted by the 63rd WMA General Assembly, Bangkok, Thailand, October 2012

INTRODUCTION

Electronic cigarettes (e-cigarettes) are products designed to deliver nicotine to a user in the form of a vapor. They are usually composed of a rechargeable battery-operated heating element, a replaceable cartridge that contains nicotine and/or other chemicals, and an atomizer that, when heated, turns the contents of the cartridge into a vapor (not smoke). This vapor is then inhaled by the user. These products are often made to look like other tobacco-derived products like cigarettes, cigars, and pipes. They can also be made to look like everyday items such as pens and USB memory sticks.

No standard definition of e-cigarettes exists and different manufacturers use different designs and different ingredients. Quality control processes used to manufacture these products are substandard or non-existent. Few studies have been done to analyze the level of nicotine delivered to the user and the composition of the vapor produced.

Manufacturers and marketers of e-cigarettes often claim that use of their products is a safe alternative to smoking, particularly since they do not produce carcinogenic smoke. However, no studies have been conducted to determine that the vapor is not carcinogenic, and there are other potential risks associated with these devices: Appeal to children, especially when flavors like strawberry or chocolate are added to the cartridges. E-cigarettes can increase nicotine addiction among young people and their use may lead to experimenting with other tobacco products.

Manufacturers and distributors mislead people into believing these devices are acceptable alternatives to scientifically proven cessation techniques, thus delaying actual smoking cessation. E-cigarettes are not comparable to scientifically-proven methods of smoking cessation. Their dosage, manufacture, and ingredients are not

consistent or clearly labelled. Brand stretching by using known cigarette logos is to be deplored.

Unknown amounts of nicotine are delivered to the user, and the level of absorption is unclear, leading to potentially toxic levels of nicotine in the system. These products may also contain other ingredients toxic to humans.

High potential of toxic exposure to nicotine by children, either by ingestion or dermal absorption, because the nicotine cartridges and refill liquid are readily available over the Internet and are not sold in child resistant packaging.

Due to the lack of rigorous chemical and animal studies, as well as clinical trials on commercially available e-cigarettes, neither their value as therapeutic aids for smoking cessation nor their safety as cigarette replacements is established. Lack of product testing does not permit the conclusion that e-cigarettes do not produce any harmful products even if they produce fewer dangerous substances than conventional cigarettes.

Clinical testing, large population studies and full analyses of e-cigarette ingredients and manufacturing processes need to be conducted before their safety, viability and impacts can be determined as either clinical tools or as widely available effective alternatives to tobacco use.

RECOMMENDATIONS

That the manufacture and sale of e-cigarettes and other electronic nicotine delivery systems be subject to national regulatory bodies prior approval based on testing and research as either a new form of tobacco product or as a drug delivery device.

That the marketing of e-cigarettes and other electronic nicotine delivery systems as a valid method for smoking cessation must be based on evidence and must be approved by appropriate regulatory bodies based on safety and efficacy data.

That e-cigarettes and other electronic nicotine delivery systems be included in smoke free laws.

Physicians should inform their patients of the risks of using e-cigarettes even if regulatory authorities have not taken a position on the efficacy and safety of these products.

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**Cobb, N.K., Byron, J., and Abrams, D.B., et al.
"Novel Nicotine Delivery Systems and Public
Health: The Rise of the 'E-Cigarette.'"
American Journal of Public Health, 100 (12):
2340-2342, 2010**

1021745.1

Novel Nicotine Delivery Systems and Public Health: The Rise of the “E-Cigarette”

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All authors contributed substantially to the authorship of the editorial. N. K. Cobb is the guarantor and accepts full responsibility for the work.

Accepted July 26, 2010.

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Inhalation of smoke from burning tobacco remains the most deadly risky behavior in the United States. For years, corporations have sought alternative methods to administer nicotine to the brain without the harms of combustion while retaining the immediate rewarding aspects of cigarettes that make them so profitable, pleasurable, and addictive. The latest attempt at reduced harm products is a heterogeneous collection of battery-driven inhalers termed by the World Health Organization (WHO) as electronic nicotine delivery systems (ENDS)¹ or more popularly as electronic cigarettes or e-cigarettes. These devices pose significant challenges to the public health community because their distribution and use has become widespread in the United States while simultaneously evading most regulatory structures. Ultimately, these devices force a close consideration of how the health and regulatory system evaluates claims of safety and harm reduction in a dynamic, consumer driven environment to ensure the broad protection of public health.

No standard definition of ENDS exists; different manufacturers use differing designs and incorporate a range of ingredients. Thus, a challenge to consumers, researchers, regulators, and policymakers is that specific attributes identified for any given ENDS brand may not apply to other brands. Three characteristics, however, appear common: (1) a cartridge containing a humectant carrier, such as propylene glycol, and often with nicotine in solution in different concentrations but no tobacco per se; (2) a tube into which the cartridge is inserted and through which the user inhales; and (3) a battery powered heating element across which the solution is drawn, causing the humectant to vaporize, forming a mist. Distributors also sell bottles of “juice” to refill cartridges with solutions that can contain high concentrations of nicotine and other substances.

Currently, the regulatory status of these devices remains in limbo in the United States. The Family Smoking and Tobacco Control Act of 2009 (HR 1256), provides for a new regulatory pathway for reduced harm products through the Food and Drug Administration (FDA) Center for Tobacco Products (CTP), but medicinal nicotine products remain regulated through the FDA Center for Drug Evaluation and Research (CDER). The CTP has a mandate to evaluate health claims provided by manufacturers, but inherent in the concept of harm reduction is a process of premarket evaluation and the demonstrable absence of unintended consequences on both health and behavior at individual and population levels.² Historically, tobacco companies have marketed oral and other noncombustible tobacco products purporting to reduce

harm without actually providing evidence of such. In March 2010, RJ Reynolds was found liable for falsely claiming harm reduction for the Eclipse cigarette—a predecessor of ENDS that delivered nicotine in a heated glycol solution drawn through a tobacco plug.³

Until recently, attempts to market nicotine products outside of medicinal nicotine replacement therapy (NRT) were subject to regulatory hurdles. Products were either regulated (i.e., FDA approved) cessation aids, such as the nicotine patch, or clearly tobacco industry-based and unregulated, such as Eclipse. Nonpharmaceutical products containing nicotine (such as lollipops and water) have been rapidly removed from the market with little controversy. In general, addiction liability and physiological harm are greatest with inhaled tobacco smoke, and least with medicinal NRT products.² In cigarettes and other tobacco products, the maximum dose of nicotine is limited by concentrations available in a fixed amount of tobacco. Although a cigarette may contain a highly toxic dose of 10–15mg of nicotine, serious poisoning is rare because presystemic metabolism and spontaneous vomiting limits the systemic absorption of nicotine in swallowed tobacco.⁴ These upper limits may not apply to nicotine in high concentrations in ENDS or refill “juice” bottles if inhaled, swallowed, or spilled on the skin. Thus ENDS may introduce a new set of risks similar to those in nicotine-based pesticides and not normally present in leaf tobacco products.

WHAT REALLY MATTERS TO THE PUBLIC HEALTH COMMUNITY?

Go to:

Cigarettes remain a major source of preventable mortality; an alternative to smoking that reduces exposure to toxins from tobacco combustion may be an acceptable strategy for harm reduction, provided it is evaluated on a premarket basis and introduces no new deleterious effects on either health or unintended changes in patterns of tobacco use behavior in the broader context of public health.^{2,5} In adopting a harm-reduction language, manufacturers have promoted ENDS as an alternative to cigarettes rather than as a cessation aid, although ENDS are presumably used for cessation despite the absence of efficacy data. One manufacturer's lawyer stated: “we don't want people weaned off the e-cigarette, we want them smoking it as long as they smoked regular cigarettes.”⁶ Proponents have claimed that ENDS are logically safer than cigarettes since they avoid or reduce most of the carcinogens from tobacco, particularly its combustion.^{5,7} Despite claims, the novel construction of ENDS has raised new challenging concerns of other potential risks, including appeal to and addiction of children (especially when flavors like strawberry or chocolate are added), displacement of effective cessation, long-term inhalation of propylene glycol, chemical contamination, uncontrolled levels of nicotine, misleading advertising of contents, variable nicotine delivery leading to unclear absorption mechanics or even potentially lethal systemic delivery, and accidental ingestion by young children because ENDS and “juice” are generally not sold in child resistant containers, are readily obtained via the Internet, and, for some refill kits, even come with a syringe.

WHAT DO WE CURRENTLY KNOW?

Go to:

Based on FDA testing⁸ and independent testing of 2 ENDS brands by our group (full report available on request), we know that despite claims, nicotine varies across manufacturers, devices, cartridges, and, even, puff to puff. Such variations make generalizations of any testing results difficult; nonetheless we found the nicotine in the tested ENDS cartridges was 3- to 5-fold less than claimed (Table 1). Ultimately, the nicotine in the delivered vapor in the products tested is a fraction of that in the cartridge, and plasma testing suggests that current designs produce little systemic delivery of nicotine.^{8–10} This may stem from any number of reasons; our testing of one device demonstrated an abrupt fall-off in delivery after the first 10 puffs, possibly from a rectifiable manufacturing defect, such as inconsistent current delivery. Triggering lag time from the pressure sensor or heating element may produce a nonlinear delivery curve per puff, causing shorter test puffs to have low nicotine delivery and deeper inhalations to have much more. The pH of the delivered solution may result in an ionized form of nicotine that is slowly absorbed through the tissue membranes, delaying uptake. At minimum, the variability in tested ENDS indicates poor quality control, so their addiction liability remains unclear.

TABLE 1

Summary of ENDS (E-Cigarette) Nicotine Testing

Based on products tested, our results and the FDA's⁸ confirm a manufacturer-sponsored study¹¹ demonstrating tobacco specific impurities and nitrosamines in cartridges at much lower levels than those found in cigarette smoke. Potentially concerning, and consistent with poor quality control, was the presence of humectants other than propylene glycol—in our case, glycerin, and for the FDA⁸ diethylene glycol. The latter has a history of mass poisonings and deaths when inadvertently substituted for propylene glycol in consumer products.¹² The additional presence of irritants, solvents, genotoxins, and animal carcinogens (e.g., butyl acetate, diethyl carbonate, benzoic acid, quinoline, dioctyl phthalate 2,6-dimethyl phenol) is of unclear significance but needs further consideration.

RESEARCH, REGULATION, AND POLICY IMPLICATIONS

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Although the tested ENDS delivered lower nicotine levels than advertised, without regulatory oversight there are no limits on increasing the dose or probability of accidental ingestion. Aftermarket selling of concentrated "juice" is worrisome—one supplier touts a solution containing 54mg of nicotine per mL (over 1.5 g per 30 mL bottle).¹³ Propylene glycol is common in some oral and topical products but has not been studied rigorously for long-term inhalational safety in humans. Poor quality control raises additional concerns about other possibly lethal ingredients. Despite these concerns, the regulatory status of ENDS in the United States remains unclear. After asserting that ENDS are drug delivery systems, the FDA was met with a lawsuit.¹⁴ The court ruling that ENDS are not drug delivery devices is under appeal, but the ruling is unclear about whether ENDS should be regulated by the FDA's traditional CEDR or the new CTP. Critically, despite the FDA action, ENDS remain widely available in the United States,¹⁴ although through regulation they have been effectively banned in many other countries such as Australia, Canada, Singapore and Brazil owing to lack of safety or efficacy data.⁵

The ENDS tested so far have demonstrated poor quality control; toxic contaminants, albeit at low levels; misrepresentation of the nicotine delivered; and insufficient evidence of overall public health benefit. Ongoing, rigorous safety testing is needed, including determining real-world use patterns and further laboratory testing across device constructions to determine actual systemic nicotine delivery and exposure to harmful constituents. We recognize a manufacturer's desire to market their product and advocates who say ENDS are logically safer than cigarettes. However, to allow their unregulated sale on presumption is not protecting public health. ENDS should be removed from the market and permitted back only if and when it has been demonstrated that they are safe, that their benefits outweigh their harms to overall public health, and that a comprehensive regulatory structure has been established under an appropriate FDA division. It is possible that ENDS-like devices will eventually provide safer alternatives to smoking that do not increase uptake among youths, that foster cessation, and that are less harmful or addictive than cigarettes. Until then, health and safety claims based on assumptions are unacceptable.

Acknowledgments

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The study was funded in part by a grant from the National Cancer Institute (5R01CA114377; Laboratory-Based Evaluation of Tobacco Harm Reduction) and the American Legacy Foundation.

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**McMillen, R., Maduka, J., and Winickoff, .J.
"Use of Emerging Tobacco Products in the
United States." *Journal of Environmental and
Public Health***

Research Article

Use of Emerging Tobacco Products in the United States

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Received 2 December 2011; Accepted 1 March 2012

Academic Editor: Joanna Cohen

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This paper provides the first nationally representative estimates for use of four emerging products. Addressing the issue of land-line substitution with cell phones, we used a mixed-mode survey to obtain two representative samples of US adults. Of 3,240 eligible respondents contacted, 74% completed surveys. In the weighted analysis, 13.6% have tried at least one emerging tobacco product; 5.1% snus; 8.8% waterpipe; 0.6% dissolvable tobacco products; 1.8% electronic nicotine delivery systems (ENDS) products. Daily smokers (25.1%) and nondaily smokers (34.9%) were the most likely to have tried at least one of these products, compared to former smokers (17.2%) and never smokers (7.7%), $P < .001$. 18.2% of young adults 18–24 and 12.8% of those >24 have tried one of these products, $P < .01$. In multivariable analysis, current daily (5.5, 4.3–7.6), nondaily (6.1, 4.0–9.3), and former smoking status (2.7, 2.1–3.6) remained significant, as did young adults (2.2, 1.6–3.0); males (3.5, 2.8–4.5); higher educational attainment; some college (2.7, 1.7–4.2); college degree (2.0, 1.3–3.3). Use of these products raises concerns about nonsmokers being at risk for nicotine dependence and current smokers maintaining their dependence. Greater awareness of emerging tobacco product prevalence and the high risk demographic user groups might inform efforts to determine appropriate public health policy and regulatory action.

1. Introduction

Recently, snus, dissolvable tobacco products, and electronic nicotine delivery systems (sometimes called “e-cigarettes” or ENDS) have been introduced to the US market, while waterpipes (hookah), especially in group social settings, have gained popularity [1]. Snus, dissolvables, ENDS, and waterpipes are often promoted as safer alternatives to traditional cigarettes and a potential way to decrease the harm caused by tobacco [2–4]. However, people who may never have smoked a cigarette or who had been addicted to nicotine in the past may be enticed to use tobacco by these alternative products, posing an individual and public health risk. Once in a tobacco using culture and exposed to nicotine, individuals may be at higher risk of regular cigarette use [5]. There is also the potential that current smokers may use these products as an alternative to cessation [6]. Polytobacco use among

current smokers may increase levels of nicotine exposure and risk of persistent tobacco dependence relative to the exclusive use of cigarettes [7]. Despite these concerns, little is known about the use of these products among US adults. Although substantial research has examined other alternative tobacco products [8, 9], this is the first nationally representative study to examine the prevalence rates for these new emerging products. Data on the use of these emerging products is urgently needed as the FDA considers regulation of these products.

Snus is a smokeless tobacco product that does not require the user to spit. The tobacco in some snus has low concentrations of nitrosamines [2] and is marketed to smokers as a reduced harm product. Snus is also marketed in airports as a tobacco product that can be used in places where smoking is not allowed. If snus was to replace cigarette smoking entirely for an individual, it would be less harmful than cigarettes [3], but its most significant health risks may be in maintaining

dependence to cigarettes and as a starter product for other forms of tobacco [10]. Proponents of the promotion of snus as a harm reduction policy look to the Swedish experience where studies have found that while snus use is increasing, smoking prevalence is declining [7]. However, promoting snus in the United States for harm reduction may reduce smoking cessation [11], perhaps because the USA already has ongoing tobacco control programs. Additionally, US tobacco companies market dual usage of both snus and cigarettes with slogans like: "When you cannot smoke, snus" [12].

Dissolvable tobacco products are also smokeless spitless tobacco products. These products are typically flavored forms of finely milled tobacco and dissolve in the mouth. Like snus, these products are frequently marketed as forms of tobacco that can be used in places where smoking is prohibited or that are tobacco-free. To illustrate, one producer claims, "dissolvable tobacco has no boundaries, there are no locations or situations where you cannot use it, and nobody can tell you're using it" [13]. These products may also appeal to adolescents, due to the attractive packaging, flavoring, and dissolvable delivery system.

ENDS are a category of products that deliver a vapor of nicotine and flavoring on inhalation [14]. These products are very new and are marketed as both cessation devices and an alternative to cessation [6]. ENDS come in a variety of tobacco, fruit, and food flavors, and, although they do not actually burn tobacco, some ENDS contain a light-emitting diode at the tip that resembles the burning end of a cigarette [6]. Because of their recent emergence, little research exists on their attractiveness.

Developed in India during the 1700s [15], a waterpipe is an instrument for inhaling charcoal tobacco smoke that has been cooled by passing through water. Although users may think that smoke inhaled from a waterpipe is safer than smoke from a cigarette, studies show that waterpipe use produces concentrations of carbon monoxide, nicotine, tar, and heavy metals at levels similar to, or higher than, cigarettes [1]. There is also the risk of infectious disease transmission, including herpes, from waterpipe mouthpieces [1]. Due to misperceptions that waterpipes are safe, and the use of these waterpipes in social settings, there is also the risk that nonsmokers might be attracted to waterpipe smoking. Most waterpipe users are intermittent cigarette smokers [16], which facilitates an opportunity in a tobacco-friendly environment for nonsmokers to become initiated to the cigarette smoking social culture as well [17].

The purpose of this study is to assess the prevalence of use of snus, waterpipe, dissolvable tobacco products, and ENDS. The prevalence of lifetime use and current use of these products by cigarette smoking status are examined, as well as other correlates of lifetime use. Results from this study can inform regulatory decisions about these products, while the identification of potential high risk demographic groups can guide clinical counseling efforts regarding the risks of any tobacco use. Finally, the use of these products among former smokers is examined to determine whether former smokers used these products as an acute form of nicotine replacement therapy to aid in cessation or used these products years after successfully quitting cigarettes.

2. Methods

2.1. Respondents. The Social Climate Survey of Tobacco Control (SCS-TC) is a nationally representative annual cross-sectional survey that contains items pertaining to normative beliefs, practices/policies, and knowledge regarding tobacco control. Previously, this survey has utilized a random-digit-dialing (RDD) frame of households with landline telephones [18, 19]. However, substitution of cell phones for landlines continues to increase and 27.8% of US households are currently wireless only [20]. Moreover, wireless substitution is particularly problematic for surveys of tobacco use, as smoking status, as well as age, region, and several other demographic factors vary by telephone status [20]. In order to reduce noncoverage issues arising from wireless substitution, mixed-mode, mixed-frame surveys representing national probability samples of adults were administered in 2010. The design included an RDD (mode 1) frame and an internet panel (mode 2) frame developed from a probability sample. The Institutional Review Board at Mississippi State University approved this study on July 30, 2010.

The mode 1 frame included households with listed and unlisted landline telephones. Telephone interviews with respondents were conducted in October and November 2010. Household telephone numbers were selected using RDD sampling procedures. Once a household was contacted, the adult to be interviewed was selected by asking to speak with the person in the household who is 18 years of age or older and who will have the next birthday. Five attempts were made to contact those selected adults who were not home.

The mode 2 frame included an online survey, administered in September and October of 2010 to a randomly selected sample from a nationally representative pre-established 50,000 member research panel [21, 22].

The 50,000 panel members were randomly recruited by probability-based sampling, and households were provided with access to the Internet and hardware if needed in order to develop a panel that is representative of the entire US population [21]. This panel is based on a sampling frame which includes both listed and unlisted numbers, those without a landline telephone, and does not accept self-selected volunteers [21, 22]. Probability-based recruitment for the panel includes two frames. The RDD frame uses list-assisted RDD sampling techniques and the Address-Based Sampling (ABS) frame from the US Postal Service's Delivery Sequence File, which includes all households serviced by the US Postal Service [21]. The use of RDD and ABS frames for recruiting panel members provides sample coverage for 99% of US households [23]. A recent study examining this probability panel revealed that the panel's primary demographics are representative of the US Census [24]. Moreover, more than a hundred peer-reviewed papers have applied this survey methodology [25], including articles published in health journals [26–29].

Overall weights were computed in two steps. First, the two modes were weighted based upon 2009 US Census estimates to be representative of the US population. Second, three adjustments to these initial weights were computed to account for the overlap in the two samples. Weights from

the mode 1 frame were multiplied by .818 to adjust for the overlap (81.8% of households in the mode 2 frame had a landline). Composite adjustments were then computed to combine the two sampling frames. According to AAPOR [30], observations from two sampling frames with overlap may be combined using composite weights. Two compositing factors that sum to one are typically selected. Given that the effective sample sizes of the mode 1 frame and mode 2 frame are similar, the two compositing factors were set to 0.5. The weights of respondents who were represented in both sampling frames (i.e., landline owners) were multiplied by the compositing factor. In the final adjustment, a restandardized weight was computed so that the weighted sample size matched the sum for effective sample size for both independent frames.

2.2. Measures. Results are from data on a subset of the measures included in the SCS-TC. To assess current cigarette smoking status of respondents, respondents were asked, "Have you smoked at least 100 cigarettes in your entire life?". Respondents who reported that they had were then asked, "Do you now smoke cigarettes every day, some days, or not at all?". Respondents who reported that they have smoked at least 100 cigarettes and now smoke every day or some days were categorized as daily and nondaily smokers; respondents who had not smoked at least 100 cigarettes were categorized as never smokers; and respondents who reported that they have smoked at least 100 cigarettes, but no longer smokers were categorized as former smokers.

One set of items assessed lifetime use of emerging tobacco products. Which of the following products have you tried, even just one time? (1) Smokeless tobacco, (2) snus, such as Camel or Marlboro snus, (3) roll-your-own cigarettes, (4) smoking tobacco from a hookah or a waterpipe, (5) dissolvable tobacco products like Ariva/Stonewall/Camel/Camel Orbs/Camel sticks, (6) electronic cigarettes or E-cigarettes, such as Ruyan or NJOY. Respondents who had tried a product were asked if they had used that product in the past 30 days. Those who had were considered to be current users (analyses in this paper were limited to products that are new to the US market or that have recently gained popularity).

Sociodemographic variables included four categories for region (determined by the US Census regions), three categories for self-reported race (white, single race; black, single race; and all other responses), two categories for age (18–24 and 25+), and sex. The two age categories were selected in order to determine if younger adults were the most susceptible to using these emerging products.

2.3. Analyses. Chi-square tests were used to examine smoking status and sociodemographic characteristics among lifetime and current users of these nicotine-containing products. For the analyses by smoking status, post hoc multiple comparisons of never smokers versus former smokers and nondaily smokers versus daily smokers were conducted with an adjusted alpha level set at 0.05/6 or 0.008.

Multivariable analysis was applied to assess the relationship of smoking status, age, and other sociodemographic

characteristics with lifetime use. To explore the possibility that adults were using these products as a form of nicotine replacement therapy, chi-square analyses were used to compare use of at least one of these products among former smokers by the length of time since cessation.

In order to address the possibility that former smokers used one of these emerging products prior to cessation, chi-square tests were used to examine use of these products among former smokers who quit less than a year ago, one to five years ago, five to 10 years, and more than 10 years. Although our data do not allow us to directly determine whether use of these emerging products occurred before or after smoking cessation, these analyses will provide insight into whether smoking cessation or use of an emerging product occurred first. It is doubtful that someone who quit smoking more than five years ago used one of these emerging products prior to cessation.

3. Results

In mode 1, of 2,128 eligible respondents contacted, 1,504 (70.7%) completed surveys [30]. For the mode 2 frame, 2,272 panelists were randomly drawn from the probability panel [31]; 1,736 responded to the invitation, yielding a final stage completion rate [26] of 67.5% percent. Length of time on the panel for the mode 2 frame ranged from 0.09 to 11.08 years, with a median length of time on the panel of 2.29 years. Table 1 shows the demographic characteristics of the overall sample.

3.1. Lifetime Users of Emerging Tobacco Products. Although most adults have not tried any of these tobacco products (86.4%), some adults have tried a waterpipe (8.8%) or snus (5.1%). Fewer adults have tried an ENDS product (1.8%) or dissolvable tobacco products (0.6%). Nondaily (34.9%) and daily smokers (25.1%) were the most likely to have tried each of these tobacco products ($P < .001$); however, some nonsmokers had tried at least one of these products (see Table 2). Among the nonsmokers, former smokers (17.2%) were more likely than never smokers (7.7%) to have used at least one of these tobacco products ($P < .001$). Use of these products also varied across nondaily and daily smokers. Although daily smokers (12.9%) were more likely to have tried snus than nondaily smokers (4.1%), $P = .003$, ever use of waterpipe was higher among nondaily smokers 26.0% than daily smokers (12.9%), $P < .001$.

Age, sex, region, race, and education were also significantly associated with lifetime use for at least one of these products (see Table 2). Younger adults were more likely than older adults to have tried snus and water pipe (8.0% versus 4.6%, 12.3% versus 8.2%, resp., $P < .01$); males were more likely than females to have tried each of these products (see Table 2), with the exception of electronic cigarettes.

Table 3 presents the odds ratios from a logistic regression of lifetime use of at least one of these emerging products on smoking status, region, race, age, education, and sex (the pattern of results did not change when this logistic regression model was replicated with sample frame included

TABLE 1: Demographic characteristics of respondents (unweighted $N = 3,240$).

Demographic variable	Overall N	Overall weighted percent	Mode 1 frame unweighted percent	Mode 2 frame unweighted percent
Smoking status				
Never smoker	1,802	56.9%	56.9%	52.3%
Former smoker	787	24.8%	28.3%	28.3%
Nondaily smoker	146	4.6%	1.6%	4.0%
Daily smoker	434	13.7%	13.2%	15.4%
Region				
Northeast	404	12.6%	18.7%	18.9%
Midwest	589	18.4%	25.5%	22.4%
South	1,203	37.6%	39.5%	37.0%
West	1,007	31.4%	16.4%	21.7%
Race				
White	2,346	74.2%	87.2%	73.8%
African American	364	11.5%	10.0%	8.5%
Other	454	14.3%	2.7%	17.7%
Age				
18–24	440	13.7%	8.3%	8.1%
25+	2,763	86.3%	91.7%	91.9%
Education				
Not a high school graduate	291	9.2%	5.6%	11.2%
High school graduate	903	28.5%	28.6%	29.0%
Some college	929	29.3%	25.9%	28.0%
College graduate	1,044	33.0%	40.0%	31.7%
Sex				
Female	1,523	52.3%	36.2%	46.7%
Male	1,675	47.6%	63.8%	53.3%

as a predictor). Most notable was the strong association between use of emerging tobacco products with young age, male gender, and higher education when controlling for smoking status.

3.2. Current Users of Emerging Tobacco Products. Current use of these tobacco products was rare (current use did not exceed 1% for any of these products). However, current use among adults who had ever used these products was nontrivial, snus (14.4%), waterpipe (11.4%), and ENDS (19.7%). Conversely, current use of dissolvable tobacco products among ever users was less than one percent.

3.3. Cessation and Use of Emerging Tobacco Products. Of significant concern is the use of these products by former smokers after they had successfully quit smoking cigarettes. However, it is possible that some former smokers used these emerging tobacco products as a form of nicotine replacement therapy to help them quit, or simply tried one of these products before they quit smoking cigarettes. To address this possibility, we compared the use of these products among former smokers who quit smoking less than 1 year ago (7.2%), one to five years ago (17.1%), five to 10 years (14.6%), and more than 10 years (61.0%). People who had

quit smoking more recently (<1 year ago) were the most likely to report having tried one of these products 32.1%; 27.1%; 14.9%; 13.5%, respectively ($P < .001$ for trend). However, the distant former smokers, defined as >5 years quit, accounted for 59.7% of those who had every tried one of these products.

4. Discussion

There are many concerns regarding emerging tobacco products; this is the first study to examine use of these products in a nationally representative sample. Our findings demonstrate that more than one in 10 US adults have tried at least one emerging tobacco product. Although overall current use of these products was low, a nontrivial percentage of people who had tried snus, waterpipe, or ENDS were current users. More people have tried a waterpipe than snus or ENDS, however ENDS and snus are newer to the US market. Daily and nondaily smokers were the most likely to have tried each of these products. Furthermore, nondaily smokers are the most likely to have tried a waterpipe.

Our study also demonstrates that lifetime use of these products is more common among males than females and younger adults than older adults, whereas lifetime use is

TABLE 2: Ever use of nicotine products by respondent characteristics.

	Snus	Waterpipe	Dissolvable tobacco products	ENDS	At least one of these products
Overall	5.1% (n = 162)	8.8% (n = 281)	0.6% (n = 20)	1.8% (n = 56)	13.6% (n = 435)
Smoking status	P < .001	P < .001	P = .001	P < .001	P < .001
Never smokers	2.7% (n = 48)	5.4% (n = 97)	0.2% (n = 3)	0.3% (n = 6)	7.7% (n = 139)
Former smokers	6.5% (n = 51)	11.4% (n = 90)	1.1% (n = 9)	1.5% (n = 12)	17.2% (n = 135)
Nondaily smokers	4.1% (n = 6)	26.0% (n = 38)	2.7% (n = 4)	8.2% (n = 12)	34.9% (n = 51)
Daily smokers	12.9% (n = 56)	12.9% (n = 56)	0.9% (n = 4)	6.2% (n = 27)	25.1% (n = 109)
Region	P = .076	P < .001	P = .520	P = .396	P < .001
Northeast	3.2% (n = 13)	12.6% (n = 51)	0.2% (n = 1)	2.7% (n = 11)	15.6% (n = 63)
Midwest	6.5% (n = 38)	10.0% (n = 59)	0.5% (n = 3)	1.4% (n = 8)	15.1% (n = 89)
South	4.5% (n = 54)	4.8% (n = 58)	0.6% (n = 7)	1.6% (n = 19)	9.5% (n = 114)
West	5.7% (n = 57)	11.2% (n = 113)	0.9% (n = 9)	1.9% (n = 19)	16.9% (n = 170)
Race	P = .372	P = .006	P = .786	P = .971	P = .002
White	5.3% (n = 124)	9.5% (n = 222)	0.6% (n = 15)	1.7% (n = 41)	14.6% (n = 343)
Black	3.6% (n = 13)	4.4% (n = 16)	0.8% (n = 3)	1.9% (n = 7)	7.7% (n = 28)
Other	4.8% (n = 22)	9.5% (n = 43)	0.4% (n = 2)	1.8% (n = 8)	13.2% (n = 60)
Age	P = .003	P = .005	P = .626	P = .195	P = .002
18–24	8.0% (n = 35)	12.3% (n = 54)	0.5% (n = 2)	2.5% (n = 11)	18.2% (n = 80)
25+	4.6% (n = 128)	8.2% (n = 227)	0.7% (n = 18)	1.6% (n = 45)	12.8% (n = 355)
Sex	P < .001	P < .001	P < .001	P = .087	P < .001
Males	8.5% (n = 130)	13.6% (n = 208)	1.2% (n = 18)	2.2% (n = 33)	20.8% (n = 317)
Females	2.0% (n = 33)	4.4% (n = 74)	0.1% (n = 2)	1.4% (n = 23)	7.0% (n = 118)
Education	P < .001	P < .001	P = .107	P < .001	P < .001
Less than HS	3.8% (n = 11)	8.2% (n = 24)	0.0% (n = 0)	0.7% (n = 2)	10.3% (n = 30)
High school	7.8% (n = 70)	4.9% (n = 44)	0.3% (n = 3)	1.7% (n = 15)	12.7% (n = 115)
Some college	4.8% (n = 45)	12.8% (n = 119)	1.1% (n = 10)	3.7% (n = 34)	18.2% (n = 169)
College degree	3.2% (n = 33)	8.9% (n = 93)	0.7% (n = 7)	0.5% (n = 5)	11.3% (n = 118)

lowest among adults living in the southern region of the US. Contrary to cigarette use patterns, higher levels of education are associated with higher use of at least one of these emerging products. This relationship is the inverse of the trend toward decreased cigarette use in the higher educated demographic groups, suggesting that emerging products may have the capacity to “re-normalize” tobacco use in a demographic that has had significant denormalization of tobacco use previously.

All forms of tobacco are potentially harmful but the use of these emerging products is concerning for at least four additional reasons. First, the use of these products by people who have never smoked cigarettes may lead to desensitization to the concept of using tobacco products in general. Tolerance to tobacco and less normative resistance to tobacco could lead to future use of cigarettes. In addition, these products contain nicotine and will therefore start the upregulation of nicotine receptors in the reward centers of the brain, setting up the potential for nicotine addiction and a facilitated leap to the cigarette [5]. Second, people who have quit smoking may relapse to nicotine addiction after using these products. Recent former smokers are particularly susceptible to relapse early on, whereas distant former smokers may still relapse back to smoking cigarettes especially when using other tobacco products [32]. Third,

current smokers may use these products as an alternative to cessation [33]. Although replacing cigarettes with these other tobacco delivery devices might be beneficial, the risk of relapse to cigarette smoking may be elevated compared to people who overcome their addiction without continuing the behavioral act of cigarette use itself. And fourth, the lifetime prevalence of using waterpipe among nondaily smokers is more than 25% and substantially higher than among daily smokers and nonsmokers. Poly tobacco use among these nondaily smokers may also increase levels of nicotine exposure and risk of persistent tobacco dependence relative to the exclusive use of cigarettes [7].

The higher lifetime prevalence rate for use of these products among young adults, males, more educated adults, and residents outside of the southern region suggest that public health strategies should prioritize preventing additional or further use of these products in these populations, while maintaining lower lifetime prevalence rates in other groups. Almost 20% of young adults have tried at least one of these emerging tobacco products.

There are at least two unique strengths of this study. These are the first nationally representative data on the prevalence of use of these emerging products. This information can help to inform efforts to determine the need for regulatory protections. Furthermore, these findings are based

TABLE 3: Final logistic regression model showing odds of having tried a waterpipe, snus, or ENDS ($N = 3,158$).

Predictors	Have tried one of these products adjusted OR (95% confidence interval)
Smoking status	
Former smoker	2.71 (2.06, 3.56)
Nondaily smoker	6.13 (4.02, 9.33)
Daily smoker	5.53 (4.03, 7.58)
Region	
Northeast	1.68 (1.16, 2.42)
Midwest	1.65 (1.20, 2.28)
West	1.80 (1.36, 2.39)
Age	
18–24	2.18 (1.60, 2.97)
Sex	
Males	3.51 (2.77, 4.45)
Education	
High school	1.58 (.99, 2.51)
Some college	2.67 (1.69, 4.22)
College degree	2.04 (1.26, 3.30)

Model also included race, not significant. Reference groups were as follows: never smokers, south region, 25 years of age and older, females, and no high school degree.

on a nationally-representative sample of US adults obtained from a mixed-mode frame that substantially reduces concerns of the increasing bias in RDD surveys arising from noncoverage due to wireless substitution. However, this study is subject to at least five limitations.

First, although the mixed-mode design substantially reduced noncoverage bias compared to an RDD design by including respondents who did not have a landline telephone in their home, it is possible that the dual sampling frame did not entirely eliminate noncoverage issues. The use of the internet panel raises some concern about the representativeness of the sample. However, several comparison studies have demonstrated that this approach yields results comparable to well-designed RDD surveys, in terms of demographics and outcome variables [24, 34]. Chang and Krosnick compared findings from this internet panel, an RDD survey, and a nonprobability internet survey (Harris Interactive Internet Panel). The RDD and internet panel probability samples were found to be more representative than the nonprobability internet sample. Compared to the RDD sample, this internet probability panel demonstrated less evidence of survey satisficing and social desirability than the RDD survey, frequent concerns with tobacco use survey research [34]. More recently, Yeager and colleagues conducted a similar comparison study that also included benchmarks from the National Health Interview Survey and the Current Population Survey [24]. Again, this internet panel probability sample was comparable to these large government surveys in terms of demographic, behavioral, and attitudinal benchmarks and were found to be more

representative than seven different nonprobability internet surveys [24].

Second, ongoing engagement might lead to panel conditioning, and thereby reduce data reliability if respondents develop a “time-in-sample bias” due to increased experience with completing surveys. However, results from the primary analyses did not change with the inclusion of a variable that measured time on the panel. (For the mode 2 frame, analyses presented in Tables 2 and 3 were replicated with the inclusion of a variable that measured length of time on the panel. The pattern of results did not change, and no evidence of a “time-on-panel bias” was detected.)

Third, the cumulative response rate for the mode 2 frame is significantly lower than the response rate from mode 1. However, it is important to note the differences between an RDD telephone sample and a probability-based internet panel. An online panel is composed of people recruited at different times and, more importantly, committed to answer many surveys for a period of time and not just that single survey. Further, panelists must also complete profiling surveys in order to become members of the panel. These differences are reflected in the recruitment and profile rates reported above. These differences make directly comparing response rates between one-time surveys and panel surveys difficult and perhaps not illuminating.

When considering the first three limitations, it is worth comparing estimates from the 2010 SCS-TC to those from a large-scale national survey. Both the SCS-TC and the National Health Interview Survey (NHIS) [35] assess current smoking status using the same survey items, and produced very similar estimates (SCS-TC, 18.3%, NHIS, 19.4%). Thus this prevalence estimate from the SCS-TC is comparable to that from one of the principal sources of information about the health of the US population.

The fourth limitation relates to whether any of the recent former smokers had quit cigarettes because of these emerging tobacco products, or, rather, had used these products after successfully quitting. Obviously those former smokers who quit before these products emerged in the US market did not use these products as a cessation strategy, but this is an area for future study among people who have recently quit smoking.

The fifth limitation concerns the cross-sectional nature and scope of these data. As noted above, it is not possible from this survey to determine when adults, particularly former smokers, tried these products. Moreover, an expanded pool of survey items that assessed when and under what scenarios people used these products would provide more conclusive insight into the risks that these products pose. Further studies should include more detailed items to examine perceptions and use of these emerging products among adolescents and young adults who are closer to the median age of cigarette smoking initiation.

An expanding pool of tobacco products with little or no regulation may increase the overall number of individuals who become nicotine dependent and later use cigarettes. This study demonstrates that some young adults, distant former, and never cigarette smokers have used these emerging nicotine-containing tobacco products, suggesting a need to

restrict how and to whom these products are marketed, sold, and used. Furthermore, clinicians need to be aware of emerging tobacco products, both to better screen high risk demographic groups, and to offer counseling about the risks of these products as another form of tobacco use.

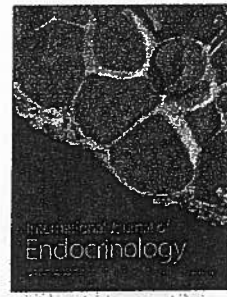
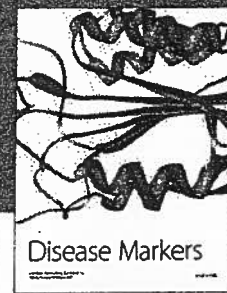
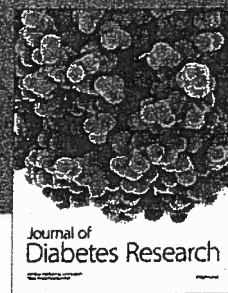
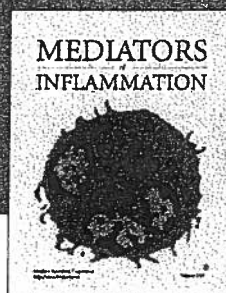
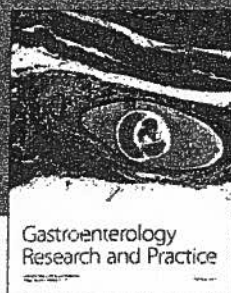
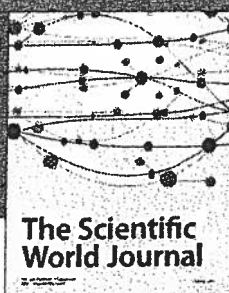
Acknowledgments

The authors are supported by the American Academy of Pediatrics Julius B. Richmond Center of Excellence, funded by grants from the Flight Attendant Medical Research Institute and Legacy. The findings and conclusions are those of the authors and do not necessarily represent the official position of any of these institutions. No financial disclosures were reported by the authors of this paper.

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