File I	No.	170441

Committee Item	No.	
Board Item No.	40	

COMMITTEE/BOARD OF SUPERVISORS

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	Referendum Certification Memo Receipt of Referendum Petition Affidavit of Receipt - July 31, 20 COB Memo - July 31, 2017 Petition Cover Letter - Received Small Business Commission Re Economic Impact Report - Rece Youth Commission Memo - May Referral - Youth Commission - May Referral - Small Business Comm	July 31 17 July 31 sponse ived Ju 7 18, 20 May 11,	, 2017 1, 2017 2 - Recense 14, 17 2017	eived June 14, 2017 2017
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[Health Code - Banning the Sale of Flavored Tobacco Products]

Ordinance amending the Health Code to prohibit tobacco retailers from selling flavored tobacco products, including menthol cigarettes.

Unchanged Code text and uncodified text are in plain Arial font.

Additions to Codes are in single-underline italics Times New Roman font.

Deletions to Codes are in strikethrough italics Times New Roman font.

Board amendment additions are in double-underlined Arial font.

Board amendment deletions are in strikethrough Arial font.

Asterisks (* * * *) indicate the omission of unchanged Code subsections or parts of tables.

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

Section 1. The Health Code is hereby amended by adding Article 19Q, entitled "Prohibiting the Sale of Flavored Tobacco Products," consisting of Sections 19Q.1 through 19Q.8, to read as follows:

ARTICLE 190: PROHIBITING THE SALE OF FLAVORED TOBACCO PRODUCTS

SEC. 19Q.1. FINDINGS.

(a) Tobacco use remains the leading cause of preventable death in the United States, killing more than 480,000 people each year. It causes or contributes to many forms of cancer, as well as heart disease and respiratory diseases, among other health disorders. Tobacco use remains a public health crisis of the first order, in terms of the human suffering and loss of life it causes, the financial costs it imposes on society, and the burdens it places on our health care system. The financial cost of tobacco use in San Francisco alone amounts to \$380 million per year in direct health care expenses and lost productivity.

(b) Flavored tobacco products are commonly sold by California tobacco retailers. For example: 97.4% of stores that sell cigarettes sell menthol cigarettes; 94.5% of stores that sell little cigars sell them in flavored varieties; 84.2% of stores that sell electronic smoking devices sell flavored varieties; and 83.8% of stores that sell chew or snus sell flavored varieties. 70% of tobacco retailers within 1,000 feet of San Francisco schools sell flavored tobacco products other than menthol cigarettes, and nearly all sell menthol cigarettes.

(c) Each day, about 2,500 children in the United States try their first cigarette; and another 400 children under 18 years of age become new regular, daily smokers. 81% of youth who have ever used a tobacco product report that the first tobacco product they used was flavored. Flavored tobacco products promote youth initiation of tobacco use and help young occasional smokers to become daily smokers by reducing or masking the natural harshness and taste of tobacco smoke and thereby increasing the appeal of tobacco products. As tobacco companies well know, menthol, in particular, cools and numbs the throat to reduce throat irritation and make the smoke feel smoother, making menthol cigarettes an appealing option for youth who are initiating tobacco use. Tobacco companies have used flavorings such as mint and wintergreen in smokeless tobacco products as part of a "graduation strategy" to encourage new users to start with tobacco products with lower levels of nicotine and progress to products with higher levels of nicotine. It is therefore unsurprising that young people are much more likely to use menthol-, candy- and fruit-flavored tobacco products, including not just cigarettes but also cigars, cigarillos, and hookah tobacco, than adults. Data from the National Youth Tobacco Survey indicate that more than two-fifths of U.S. middle school and high school smokers report using flavored little cigars or flavored cigarettes. Further, the Centers for Disease Control and Prevention has reported a more than 800% increase in electronic cigarette use among middle school and high school students between 2011 and 2015. Nicotine solutions, which are consumed via electronic smoking devices such as electronic cigarettes, are sold in thousands of flavors that appeal to youth, such as cotton candy and bubble gum.

- (d) Much as young people disproportionately use flavored tobacco products including menthol cigarettes, the same can be said of certain minority groups. In one survey, the percentage of people who smoke cigarettes that reported smoking menthol cigarettes in the prior month included, most dramatically, 82.6% of Blacks or African-Americans who smoke cigarettes. The statistics for other groups were: 53.2% of Native Hawaiians or Other Pacific Islanders who smoke cigarettes; 36.9% of individuals with multiracial backgrounds who smoke cigarettes; 32.3% of Hispanics or Latinos who smoke cigarettes; 31.2% of Asians who smoke cigarettes; 24.8% of American Indians or Alaska Natives who smoke cigarettes; and 23.8% of Whites or Caucasians who smoke cigarettes. People who identify as LGBT and young adults with mental health conditions also struggle with disproportionately high rates of menthol cigarette use. The disproportionate use of menthol cigarettes among targeted groups, especially the extremely high use among African-Americans, is troubling because of the long-term adverse health impacts on those groups.
- (e) Between 2004 and 2014, overall smoking prevalence decreased, but use of menthol cigarettes increased among both young adults (ages 18-25) and other adults (ages 26+). These statistics are consistent with the finding that smoking menthol cigarettes reduces the likelihood of successfully quitting smoking. Scientific modeling has projected that a national ban on menthol cigarettes could save between 300,000 and 600,000 lives by 2050.

SEC. 19Q.2. DEFINITIONS.

For purposes of this Article 19Q, the following definitions shall apply:

"Characterizing Flavor" means a Distinguishable taste or aroma or both, other than the taste or aroma of tobacco, imparted by a Tobacco Product or any byproduct produced by the Tobacco

Product. Characterizing Flavors include, but are not limited to, tastes or aromas relating to any fruit, chocolate, vanilla, honey, candy, cocoa, dessert, alcoholic beverage, menthol, mint, wintergreen, herb, or spice. A Tobacco Product shall not be determined to have a Characterizing Flavor solely because

1					
1	of the use of additives or flavorings or the provision of ingredient information. Rather, it is the				
2	presence of a Distinguishable taste or aroma or both, as described in the first sentence of this				
3	definition, that constitutes a Characterizing Flavor.				
4	"Cigarette" has the meaning set forth in 21 U.S.C. § 387(3), as may be amended from time to				
5	<u>time.</u>				
6	"Constituent" means any ingredient, substance, chemical, or compound, other than tobacco,				
7	water, or reconstituted tobacco sheet that is added by the manufacturer to a Tobacco Product during				
8	the processing, manufacture, or packing of the Tobacco Product.				
9	"Director" has the meaning set forth in Health Code Section 19H.2.				
10	"Distinguishable" means perceivable by either the sense of smell or taste.				
11	"Establishment" has the meaning set forth in Health Code Section 19H.2.				
12	"Flavored Cigarette" means a Cigarette that contains a Constituent that imparts a				
13	Characterizing Flavor.				
14	"Flavored Tobacco Product" means any Tobacco Product, other than a Cigarette, that				
15	contains a Constituent that imparts a Characterizing Flavor.				
16	"Labeling" means written, printed, pictorial, or graphic matter upon any Tobacco Product or				
17	any of its Packaging.				
18	"Packaging" means a pack, box, carton, or container of any kind or, if no other container, any				
19	wrapping (including cellophane) in which a Tobacco Product is sold or offered for sale to a consumer.				
20	"Tobacco Product" has the meaning set forth in Health Code Section 19H.2.				
21					
22	SEC 19Q.3. SALE OR DISTRIBUTION OF FLAVORED TOBACCO PRODUCTS				
23	PROHIBITED.				
24	(a) The sale or distribution by an Establishment of any Flavored Tobacco Product is				
25	prohibited.				
-					

SEC. 19Q.5. ADMINISTRATIVE REGULATIONS.

The Director may adopt rules, regulations, or guidelines for the implementation and enforcement of this Article 19Q.

SEC. 190.6. ENFORCEMENT.

The Director, or his or her designee, may enforce Sections 190.3 and 190.4 pursuant to Articles 19 et seq. of the Health Code, including but not limited to Article 19H.

SEC 190.7. NO CONFLICT WITH FEDERAL OR STATE LAW.

Nothing in this Article 19.Q shall be interpreted or applied so as to create any requirement, power, or duty that is preempted by federal or state law.

SEC. 19Q.8. SEVERABILITY.

If any section, subsection, sentence, clause, phrase, or word of this Article 19Q, or any application thereof to any person or circumstance, is held to be invalid or unconstitutional by a court of competent jurisdiction, such decision shall not affect the validity of the remaining portions or applications of the Article. The Board of Supervisors hereby declares that it would have passed this Article, and each section, subsection, sentence, clause, phrase, and word not declared invalid or unconstitutional without regard to whether any other portion of this Article or application thereof would be subsequently declared invalid or unconstitutional.

Section 2. The Health Code is hereby amended by adding Section 19H.14-2, to read as follows:

1	SEC. 19H.14-2. CONDUCT VIOLATING HEALTH CODE ARTICLE 19Q (PROHIBITING
2	THE SALE OF FLAVORED TOBACCO PRODUCTS).
3	(a) Upon a decision by the Director that the Permittee or the Permittee's agent or employee
4	has engaged in any conduct that violates Health Code Section 190.3 (Sale or Distribution of Flavored
5	Tobacco Products Prohibited), the Director may suspend a Tobacco Sales permit as set forth in Section
6	<u>19H.19.</u>
7	(b) Upon a decision by the Director that the Permittee or the Permittee's agent or employee
8	has engaged in any conduct that violates Health Code Section 19Q.4 (Sale or Distribution of Flavored
9	Cigarettes Prohibited), the Director may suspend a Tobacco Sales permit as set forth in Section
10	<u>19H.19.</u>
11	(c) The Director shall commence enforcement under this Section 19H.14-2 by serving either
12	a notice of correction under Section 19H.21 or a notice of initial determination under Section 19H.22
13	of this Article 19H.
14	
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Section 3. Effective and Operative Dates.

- (a) This ordinance shall become effective 30 days after enactment. Enactment occurs when the Mayor signs the ordinance, the Mayor returns the ordinance unsigned or does not sign the ordinance within ten days of receiving it, or the Board of Supervisors overrides the Mayor's veto of the ordinance.
 - (b) This ordinance shall become operative on January April 1, 2018.

APPROVED AS TO FORM:

DENNIS_J. HERRERA, City Attorney

By: My My My My Manne Pearson
Deputy City Attorney

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City and County of San Francisco Tails

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

Ordinance

File Number:

170441

Date Passed: June 27, 2017

Ordinance amending the Health Code to prohibit tobacco retailers from selling flavored tobacco products, including menthol cigarettes.

June 14, 2017 Public Safety and Neighborhood Services Committee - AMENDED, AN AMENDMENT OF THE WHOLE BEARING SAME TITLE

June 14, 2017 Public Safety and Neighborhood Services Committee - RECOMMENDED AS AMENDED

June 20, 2017 Board of Supervisors - AMENDED, AN AMENDMENT OF THE WHOLE BEARING SAME TITLE

Ayes: 9 - Breed, Cohen, Fewer, Peskin, Ronen, Safai, Sheehy, Tang and Yee Excused: 2 - Farrell and Kim

June 20, 2017 Board of Supervisors - PASSED ON FIRST READING AS AMENDED Ayes: 9 - Breed, Cohen, Fewer, Peskin, Ronen, Safai, Sheehy, Tang and Yee Excused: 2 - Farrell and Kim

June 27, 2017 Board of Supervisors - FINALLY PASSED Ayes: 11 - Breed, Cohen, Farrell, Fewer, Kim, Peskin, Ronen, Safai, Sheehy, Tang and Yee

File No. 170441

I hereby certify that the foregoing Ordinance was FINALLY PASSED on 6/27/2017 by the Board of Supervisors of the City and County of San Francisco.

> Angela Calvillo Clerk of the Board

REVISED LEGISLATIVE DIGEST

(6/20/2017, Amended in Board)

[Health Code - Banning the Sale of Flavored Tobacco Products]

Ordinance amending the Health Code to prohibit tobacco retailers from selling flavored tobacco products, including menthol cigarettes

Existing Law

Federal law bans the manufacture of cigarettes with characterizing flavors, other than the flavor of menthol and tobacco. Federal law does not ban the manufacture of menthol cigarettes or flavored tobacco products other than cigarettes.

Amendments to Current Law

The proposed ordinance amends the Health Code to prohibit local tobacco retailers from selling flavored tobacco products. The tobacco products that would be subject to the prohibition on sale would include, but not be limited to, flavored cigarettes, including menthol cigarettes, flavored cigars, flavored smokeless tobacco, flavored shisha, and flavored nicotine solutions that are used in electronic cigarettes.

The ordinance defines a flavored tobacco product as a tobacco product that contains a constituent that imparts a characterizing flavor. The ordinance would create a presumption that a tobacco product is flavored if the tobacco manufacturer makes a statement or claim that the product has a characterizing flavor. For example, if the packaging in which a tobacco product is sold is printed with the word "grape" or with an image of grapes, the tobacco product would be presumed to be flavored, and subject to the restriction on sale.

Violation of the ordinance would be punishable by a suspension of the retailer's tobacco license.

Background Information

Tobacco use remains the leading cause of preventable death in the United States, killing more than 480,000 people each year. It causes or contributes to many forms of cancer, as well as heart disease and respiratory diseases, among other health disorders. The financial cost of tobacco use in San Francisco alone amounts to \$380 million per year in direct health care expenses and lost productivity.

Although federal law prohibits the manufacture of flavored cigarettes, it does not ban menthol cigarettes or other types of flavored tobacco products, which are widely available in flavors

like bubble gum, cotton candy, banana, cherry and vanilla. Each day, about 2,500 children in the United States try their first cigarette, and another 400 children under 18 years of age become new regular, daily smokers. 81% of youth who have ever used a tobacco product report that the first tobacco product they used was flavored.

Flavored tobacco products promote youth initiation of tobacco use and help young occasional smokers to become daily smokers by reducing or masking the natural harshness and taste of tobacco smoke and thereby increasing the appeal of tobacco products. Menthol, in particular, cools and numbs the throat to reduce throat irritation and make the smoke feel smoother, making menthol cigarettes an appealing option for youth who are initiating tobacco use. Young people are much more likely to use menthol-, candy- and fruit-flavored tobacco products, including not just cigarettes but also cigars, cigarillos, and hookah tobacco, than adults.

Much as young people disproportionately use flavored tobacco products including menthol cigarettes, the same can be said of certain minority groups. In one survey, the percentage of people who smoke cigarettes that reported smoking menthol cigarettes in the prior month included, most dramatically, 82.6% of Blacks or African-Americans who smoke cigarettes. The statistics for other groups were: 53.2% of Native Hawaiians or Other Pacific Islanders who smoke cigarettes; 36.9% of individuals with multiracial backgrounds who smoke cigarettes; 32.3% of Hispanics or Latinos who smoke cigarettes; 31.2% of Asians who smoke cigarettes; 24.8% of American Indians or Alaska Natives who smoke cigarettes; and 23.8% of Whites or Caucasians who smoke cigarettes. People who identify as LGBT and young adults with mental health conditions also struggle with disproportionately high rates of menthol cigarette use. The disproportionate use of menthol cigarettes among targeted groups, especially the extremely high use among African-Americans, is troubling because of the long-term adverse health impacts on those groups.

Between 2004 and 2014, overall smoking prevalence decreased, but use of menthol cigarettes increased among both young adults (ages 18-25) and other adults (ages 26+). These statistics are consistent with the finding that smoking menthol cigarettes reduces the likelihood of successfully quitting smoking. Scientific modeling has projected that a national ban on menthol cigarettes could save between 300,000 and 600,000 lives by 2050.

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BOARD of SUPERVISORS



City Hall
1 Dr. Carlton B. Goodlett Place, Room 244
San Francisco 94102-4689
Tel. No. 554-5184
Fax No. 554-5163
TDD/TTY No. 544-5227

MEMORANDUM

Date:

August 4, 2017

To:

Honorable Members, Board of Supervisors

From:

Angela Calvillo, Clerk of the Board

Subject:

Referendum Decision by Department of Elections

The Clerk's Office is in receipt of the Certification for the Initiative Petition regarding the "Referendum Against the City and County of San Francisco's Ordinance Prohibiting the Sale of Flavored Tobacco Products, Including Menthol Cigarettes" (Ordinance No. 140-17; File No. 170441), dated August 4, 2017, from the Department of Elections.

The Department of Elections has completed a random sampling of 1,018 signatures of the total 33,941 submitted, and indicates that the petition contains the minimum of 19,040 valid signatures required to certify the petition; therefore, the petition has successfully passed its review.

Please be advised that this matter will be agendized for reconsideration at an upcoming Board meeting. If you rescind your decision of the Ordinance at this meeting, the matter would be rescinded and the Ordinance would be killed. If you do not rescind your decision, in whole or in part, your decision will be communicated to the Department of Elections where they would place the matter on the June 5, 2018 ballot.

Unless a majority of the Board directs me otherwise, this matter will be placed on the next Regular Meeting of September 5, 2017, pursuant to Charter, Section 14.102, and California Elections Code, Section 9115(f).

HAND DELIVERED

Aug 4, 2017

ANGELA CALVILLO, CLERK OF THE BOARD

1 Dr. Carlton B. Goodlett Place, Room 244 San Francisco, CA 94102

RE: CERTIFICATION FOR THE INITIATIVE PETITION: Referendum Against the City and County of San Francisco's Ordinance Prohibiting the Sale of Flavored Tobacco Products, Including Menthol Cigarettes

Enclosed is a copy of the letter sent to the proponent of the above named petition, certifying that the petition did contain sufficient valid signatures to qualify for the next general, municipal, or statewide election occurring in the City and County of San Francisco at any time after 90 days from the date of this certificate of sufficiency.

If you should have any questions or need additional information, please contact our Voter Services Manager Deborah Brown at (415) 554-5665.

Sincerely,

John Arntz Director of Elections

Deborah Brown

Voter Services Manager

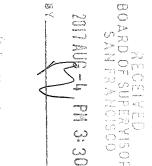
Encl. Copy of certified letter to proponent

Cc: Honorable Edwin Lee, Mayor Dennis Herrera, City Attorney John Arntz, Director of Elections BOARD OF SUPERVISOR
SAN FRANCISCO
2017 AUG -4 PM 3:30

Certified Mail: 7011 1940 0001 0678 3610

Aug 4, 2017

Joel S, Aurora 2350 Kerner Blvd., Ste 250 San Rafael, CA 94901



Re: Certification for the Initiative Petition "Referendum Against the City and County of San Francisco's Ordinance Prohibiting the Sale of Flavored Tobacco Products, Including Menthol Cigarettes"

The San Francisco Department of Elections has completed its review of a random sampling of 1,018 signatures of the total 33,941, as prescribed under California Elections Code section 9115 (a), that were submitted with the petition entitled Referendum Against the City and County of San Francisco's Ordinance Prohibiting the Sale of Flavored Tobacco Products, Including Menthol Cigarettes. The Department's review indicates that this petition contains at least the 19,040 valid signatures required to certify the petition. The total number of valid signatures required represents 10 percent of the voters cast for Mayor in the November 2015 Consolidated Municipal Election.

Thus, I hereby declare that the number of valid signatures on *Referendum Against the City and County of San* Francisco's Ordinance Prohibiting the Sale of Flavored Tobacco Products, Including Menthol Cigarettes is sufficient and I certify that the petition has successfully passed its review by this office.

If you should have any questions or need additional information, please contact our Voter Services Manager Deborah Brown at (415) 554-5665.

Respectfully,

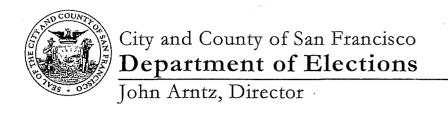
John Arntz Director of Elections

Deborah Brown

Voter Services Manager

Cc: Honorable Edwin Lee, Mayor Dennnis Herrera, City Attorney Angela Calvillo, Clerk of the Board of Supervisors John Arntz, Director of Elections





RECEIVED

BOARD OF SUPERVISORS
SAN FRANCISCO

2017 JUL 31 AM 10: 49
FOR OFFICE USE ONLY

A. V. J. L. A. A.

Receipt of Petition

I, John Arntz, Director of Elections, on the above date received from		Alisa Some ra (name of individual delivering petition)			
2, 651 (number	sections of Referendum Against Health Code	Banning the of Petition)	Sale of	Flavored	Tobacco
	signatures reported on this date is <u>33,894</u> .				
Requirem A blank co Letter of A	ents for Submission:, py of the petition: uthorization (If someone other than the proponent(s) is filing): formation for proponent(s): Joel Aurora 2350 Kerner Blyd, Suite 250 San Rafael, CA 94901			2017 JUL 31 - AP 10: 55	
Phone #	(415) 389 · 6800		•		
ву: <u> </u>	OF ELECTIONS				
Signatu	re of Elections Clerk				

FOR OFFICE USE ONLY				
CONTRACTOR OF THE PROPERTY OF				
Statewide	Date			
Countywide	# of Sections			
Other	# of Sig.			
Description (circle one):	Time Spent			
recall, initiative, referendum	_			

BOARD of SUPERVISORS



City Hall
1 Dr. Carlton B. Goodlett Place, Room 244
San Francisco 94102-4689
Tel. No. 554-5184
Fax No. 554-5163
TDD/TTY No. 554-5227

AFFIDAVIT OF RECEIPT OF REFERENDUM PETITIONS REGARDING THE ORDINANCE AMENDING THE HEALTH CODE BANNING THE SALE OF FLAVORED TOBACCO PRODUCTS

I, Angela Calvillo, Clerk of the Board of Supervisors, City and County of San Francisco, do hereby acknowledge that upon prima facie review, there are approximately 33,894 signatures filed in the Office of the Clerk of the Board regarding the Referendum Against an Ordinance Passed by the Board of Supervisors amending the Health Code to prohibit tobacco retailers from selling flavored tobacco products, including menthol cigarettes (Ordinance No. 140-17).

This 31st day of July, 2017

Angela Calvillo Clerk of the Board

BOARD of SUPERVISORS



City Hall
1 Dr. Carlton B. Goodlett Place, Room 244
San Francisco 94102-4689
Tel. No. 554-5184
Fax No. 554-5163
TDD/TTY No. 554-5227

MEMORANDUM

Date:

July 31, 2017

To:

John Arntz, Director, Department of Elections

From:

Angela Calvillo, Clerk of the Board

Subject:

Referendum Petitions - Ordinance No. 140-17

Please find attached Referendum Petition against Ordinance No. 140-17 which was received on Monday, July 31, 2017. In accordance with state and local laws, your office will have 30 days to validate and verify signatures on the petition.

We would like to communicate your findings at the September 5, 2017 Board Meeting and would appreciate if you could expedite this certification process.

Please contact me at (415) 554-5184 with any questions or concerns.

Thank you for your attention to this matter.



www.LetsBeRealSF.org

July 31, 2017

VIA Hand Delivery

John Arntz Director, Department of Elections City and County of San Francisco 1 Dr. Carlton B. Goodlett Place City Hall, Room 48 San Francisco, CA 94102

Re: Filing of the Referendum Petition Against Ordinance No. 140-17,

entitled, "Health Code - Banning the Sale of Flavored Tobacco"

Dear Mr. Arntz:

We hereby file this referendum petition against Ordinance Number 140-17, entitled, "Health Code – Banning the Sale of Flavored Tobacco." The referendum petition consists of 2,651 sections, bearing a total of 33,894 signatures, in eight (8) sealed boxes.

Let's Be Real San Francisco hereby respectfully requests written confirmation of the acceptance of the petition for filing as of today's date, July 31, 2017.

Please contact the undersigned at <u>jaurora@nmgovlaw.com</u> or 415.389.6800 should you have any questions concerning this filing. Please direct all mailed notices concerning this filing to: 2350 Kerner Blvd., Ste. 250, San Rafael, CA 94901.

Xul XT

Verv trulvvodurs.

Joel S. Aurora

Encl.

Let's Be Real San Francisco | 912 Cole St. #141, San Francisco, CA 94117 | letsberealsf.org

Paid for by Let's Be Real San Francisco, A Coalition of Concerned Citizens
Supporting Freedom of Choice, Adult Consumers, Community Leaders, and
Neighborhood Small Businesses with Major Funding by R.J. Reynolds Tobacco
Company. Financial disclosures available at sfethics.org.



Banning the Sale of Flavored Tobacco Products: Economic Impact Report

Office of Economic Analysis Item # 170441 June 13, 2017

Introduction

- The proposed legislation amends the San Francisco Health Code to prohibit local tobacco retailers from selling flavored tobacco products, including menthol cigarettes, flavored chewing tobacco, and flavored liquids containing nicotine designed to be used with electronic cigarettes.
- The law does not criminalize the possession or use of flavored tobacco, only its sale by retailers within the city.
- Unflavored tobacco product sales would not be affected. Tobacco products are considered to be flavored, if they are advertised as having a distinctive flavor.
- If passed, the law would go into effect on January 2018.
- Retailers in San Francisco are required to possess a permit to sell tobacco. The only penalty for violation of the ban is a potential of the suspension of tobacco sales permit, at the discretion of Director of Public Health.
- The Office of Economic Analysis has determined that if enacted, the proposed ban could have a material economic impact on the city's economy.

Controller's Office ● Office of Economic Analysis
City and County of San Francisco

History of Flavored Tobacco Bans at the Federal, State & Local Levels

- Flavored tobacco bans, including both traditional and electronic cigarettes, have become increasingly common across the United States in recent years.
- On September 22, 2009, the FDA banned "characterizing flavors" in cigarettes such as an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee.
- The ban was authorized by the FDA under the Family Smoking Prevention and Tobacco Control Act, which is a part of a national effort by the FDA to reduce smoking in America.
- However, the FDA stopped short of prohibiting menthol in cigarettes or flavoring in other tobacco products such as e-cigarettes, cigars, smokeless tobacco, etc. The FDA law, however, does not prohibit states and localities from banning flavored tobacco products.
- On October 28, 2009, New York City banned the sale of most flavored tobacco products, exempting only certain flavors.
- On July 1, 2009 Maine banned the sale of flavored cigarettes & cigars in the state.
- On October 1, 2008, New Jersey banned the sale of flavored cigarettes but exempted menthol and clove cigarettes.

Controller's Office ● Office of Economic Analysis City and County of San Francisco

Use of Electronic Smoking Devices and Flavored Tobacco Products

- According to a 2016 study* the use of electronic smoking devices (e-cigarettes, e-hookah, hookah pens, vape pens) has dramatically increased over the last few years. Nationally, only 3.7% of adults currently use e-cigarettes but in California the rate is 5.8%. The breakdown of the CA rate by age shows that the prevalence rate is 9.4% for young adults (aged 18-24) whereas the rate is 7.4% for smokers aged 25-44 and 2.6% for smokers aged 45-65. Currently, no data is available at the county level but similar trends are likely observed at the city level.
- The report also cited that nationally, e-cigarettes prevalence rate among high schoolers is 13.4% and is considered the most common tobacco product use; whereas the rate for Californian youth (aged 12-17) was reported to be 13.7%. The study also showed that the average (male & female) prevalence rate among 7th, 9th and 11th grader was 8.0%, 13.3% and 15.4%, respectively.

Controller's Office ● Office of Economic Analysis City and County of San Francisco

^{*} California Tobacco Facts and Figures: Over 25 Years of Tobacco Control in California, California Department of Public Health, California Tobacco Control Program, October 2016. https://archive.cdph.ca.gov/programs/tobacco/Documents/CDPH%20CTCP%20Refresh/Research%20and%20Evaluation/Facts%20and%20Figures/2016FactsFigures-Web.pdf

Use of Menthol Cigarettes and Other Flavored Tobacco Products

- Menthol and other flavoring additives can mask the harshness and taste of tobacco, and thus may particularly appeal to youths and potential new smokers.
- According to a 2016 study*, nationally, 70% to 80% of all current middle and high school tobacco users have used at least one flavored tobacco product in the past 30 days. Nationally, about 25% to 30% of cigarette smokers use menthol cigarettes. The study also cited that 34.9% of adult California smokers usually smoke menthol cigarettes.
- The overall adult cigarette smoking rate for California was reported to be 11.6%; whereas San Francisco rate was 10.1% which is about 15% lower than the state. No county level rates are currently available for either menthol or e-cigarettes but it is likely that city exhibits similarly 15% lower rate for menthol and e-cigarettes as well.
- The study also pointed out the menthol cigarettes are disproportionally smoked by adolescents, African Americans, and individuals who identify themselves as LGBT. Over 55% of African American adults in California usually smoke menthol cigarettes.

Controller's Office ● Office of Economic Analysis City and County of San Francisco

^{*} California Tobacco Facts and Figures: Over 25 Years of Tobacco Control in California, California Department of Public Health, California Tobacco Control Program, October 2016. https://archive.cdph.ca.gov/programs/tobacco/Documents/CDPH%20CTCP%20Refresh/Research%20and%20Evaluation/Facts%20and%20Figures/2016FactsFigures-Web.pdf

Population and Number of Potential Teen and Adult Smokers in the City

- Based on information from the California Health Information Survey, and the CDC's Behavioral Risk Factors Surveillance System, and population information from the Census, we estimate the following prevalence of cigarette and electronic cigarette use.
- Adults are more than twice as likely to smoke as to use electronic cigarettes, while teens are nearly twice as likely to use electronic cigarettes as to smoke.

	Teen (Ages 12-17)	Adult (Ages 18+)
Population	34,309	754,145
Cigarette Smokers (flavored and unflavored)	1,548	78,459
Percentage of population	4.5%	10.4%
Electronic Cigarette Smokers	2,892	37,244
Percentage of population	8.4%	4.9%

Controller's Office ● Office of Economic Analysis City and County of San Francisco

Estimated Sales of Flavored Cigarettes In San Francisco

- Based on the prevalence information on the previous page, the OEA has estimated the value of flavored tobacco cigarettes that would be affected by the legislation at approximately \$50 million per year, as detailed in the table below.
- Much less research has been done on the consumption of electronic cigarettes, and we do not have an estimate of those sales in the city.

	Teen (Ages 12-17)	Adult (Ages 18+)
Population	34,309	754,145
Cigarette Smokers (flavored and unflavored)	1,548	78,459
Average packs consumed per smoker, annually	212	. 212
Average price of a pack of cigarettes	\$8.50	\$8.50
Percentage of packs affected by the ban (Menthol)	35%	35%
Total spending on affected cigarettes (\$ M)	\$1.0	\$49.5

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Number and Composition of Affected Retailers in the City

- While we have estimates of the purchases made by San Francisco residents, we do not know how many of those purchases are made at San Francisco retailers who would be subject to the ban, as opposed to out-of-town or online retailers.
- Permitted tobacco retailers that sell cigarettes are required to pay the Cigarette Litter Abatement Fee to the City, to offset the City's cost of cleaning disposed cigarette butts.
- In the third quarter of 2016, the last quarter available, 726 local retailers paid the fee. Other permitted retailers, who sell flavored tobacco but do not sell cigarettes, do not pay the fee.
- Most of these retailers are small convenience stores or gasoline stations that sell fewer than 20 packs of cigarettes per day. We have no information on how many sell flavored cigarettes that would be subject to the ban, though in general, the California Department of Public Health reports that 35% of cigarettes sold are menthol-flavored, and thus would be covered by the ban.
- Because the City does not levy a fee on the sales of electronic cigarettes or nicotinebased liquids, we do not have any information on the sales of those products by San Francisco retailers.

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Economic Impact Factors and Assessment

- The proposed ban on flavored tobacco products can be expected to have three primary effects on the local economy:
 - Reduction in tobacco product use: By reducing access to flavored tobacco products that are
 particularly appealing to young people, it may reduce the future use of cigarettes and other
 affected tobacco products. The reduction of cigarette smoking, in particular, would lead to longterm health benefits. In this event, tobacco retailers would be harmed by reduced sales, but
 consumers, other retailers, and the public sector would benefit from replaced retail sales,
 improved health, and lower health care costs in the future.
 - 2. Switching from affected to unaffected tobacco products: Because some nicotine products are affected by the proposed ban, while others are not, existing users of flavored tobacco may replace the consumption of flavored tobacco products with unflavored. This switching behavior would likely occur most with cigarettes, since essentially all electronic cigarettes are affected. In this event, there will be essentially no impact on either consumers or retailers, since sales of one type of tobacco product would be replaced by another.
 - 3. Switching from affected retailers to online or out-of-town retailers: Electronic cigarettes, are widely available online, and our research suggests prices are roughly comparable to local retailers. If consumers choose to buy online, there would be a net loss to local retailers and the city's economy, without any countervailing benefit.
- Owing to an absence of detailed data on tobacco consumption in the city, we are unable to estimate the relative importance of these three responses to the legislation.

Controller's Office ● Office of Economic Analysis City and County of San Francisco

Staff Contact

Asim Khan, Ph.D., Principal Economist asim.khan@sfgov.org (415) 554-5369

Ted Egan, Ph.D., Chief Economist ted.egan@sfgov.org (415) 554-5268

Controller's Office ● Office of Economic Analysis City and County of San Francisco



CITY AND COUNTY OF SAN FRANCISCO EDWIN M. LEE, MAYOR

OFFICE OF SMALL BUSINESS REGINA DICK-ENDRIZZI, DIRECTOR

June 7, 2017

Ms. Angela Calvillo, Clerk of the Board City Hall Room 244 1 Dr. Carlton B. Goodlett Place San Francisco, CA 94102-4689

RE: BOS File No. 170441 [Health Code - Banning the Sale of Flavored Tobacco Products]

Small Business Commission Recommendation to the Board of Supervisors: Do not approve

Dear Ms. Calvillo,

On May 8, 2017, the Small Business Commission (SBC) voted (4-0, 2 absent, 1 recused) to recommend that the Board of Supervisors not approve BOS File No. 170441.

The Small Business Commission is supportive of the health-related intent behind the legislation, but questioned its implications and impact on San Francisco small businesses that sell tobacco products and impact the tax revenue that is collect that helps to offset the impacts of the tobacco. The SBC in general does not support outright bans as a means of achieving a policy objective, particularly when the ban is applying a year 2000 regulatory model that does not account for current day consumer behavior on where and how retail goods are purchased. The SBC noted that is best for San Francisco small businesses and health policy goals to implement such regulation at the state level.

One of the finding in this ordinance is to justify the need to ban flavored products is to reduce to youth access to smoking. San Francisco and the state of California changed the legal age to purchase tobacco from 18 to 21. The intent of these laws was to reduce youth access with a focus on teenagers between ages 15 and 17¹. The SBC sent a recommendation "To Approve" the age increase from 18 to 21.

San Francisco's law went into effective June 1, 2016 and California's law was effective June 9, 2016. It has been one year since these laws became effective. The SBC noted that before enacting this ordinance the Department of Public Health needs to report on whether the change in legal age from 18 to 21 has or has/not reduced youth access to tobacco products and becoming addicted. To continue to site national data to justify the need to ban any tobacco product at the local level now or in the future will not reflect the data and effectiveness of change in legal age in SF and California.

In the United States, California and Hawaii are the only 2 states where the legal age to purchase tobacco is 21; 4 states have the legal age at 19; and the remaining 44 states and two territories have

OFFICE OF SMALL BUSINESS ◆ SMALL BUSINESS COMMISSION

1 DR. CARLTON B. GOODLETT PLACE, ROOM 110, SAN FRANCISCO, CALIFORNIA 94102-4681

(415) 554-6408

¹ Institute of Medicine

the legal age at 18.

Figure 1: U.S. Map of Tobacco Minimum Purchase Age



The SBC noted that to achieve the health policy goal of this ordinance the definition of "Establishment" needs to include online retailers and delivery apps based outside of SF. The law does not prohibit individuals from online purchases or utilizing delivery apps of businesses outside San Francisco; it does prohibit the sale and delivery of those products by San Francisco businesses (whether in physical stores or on local business websites). It is not logical that an individual located in San Francisco is not be able to purchase from an online retailer in SF, but can purchase the same product from an online retailer that is located outside of SF.

Flavored tobacco products can be easily purchased in Daly City and any other city easily accessible to San Francisco boarders.

The SBC did note that while other cities are passing laws reducing access to flavored tobacco, these cities do not have a full ban on all flavored tobacco products for all tobacco license holders and this proposed ordinance does.

- New York City: There is a ban on flavored tobacco products, excluding menthol flavored products.
- Chicago: Based retailers located within a 500 foot radius of an elementary, middle or secondary school. Exception for a "Retail Tobacco Store" that derives more than 80% of its gross revenue from the sale of loose tobacco, cigarettes, cigarillos, cigars, pipes, other smoking devices and accessories.
- Berkeley (600 foot buffer zone around K-12 schools). Effective Jan. 1, 2017
- Santa Clara County: Retailers only accessible to 21+ are exempted and can still sell flavored tobacco products. The existing ordinance does not include flavored electronic cigarettes, and the enforcement policy will not be applied to adult-only tobacco retailers.
- Hayward: Banned new hookah lounges and vapor stores that sell e-cigarettes. Existing vapor stores, hookah lounges, and businesses that sell tobacco would not be affected.
- Pending: Oakland the ordinance would prohibit all flavored tobacco products from being sold in Oakland, except for stores that primarily sell tobacco and are off limits to people younger than 18.
- Pending: San Leandro bans opening new hookah lounges and vapor stores that sell ecigarettes. The proposal to ban menthol cigarettes was put on hold.

OFFICE OF SMALL BUSINESS . SMALL BUSINESS COMMISSION

Director's Note:

Much of the flavored tobacco products can be purchased online without having to present ID at purchase or delivery of the product. Cigarettes are not as easily purchased through an online retailer. Attached are two receipts of products that I purchased online. I did not have to pay the 27.3% tobacco tax that is required by the State of California for non-cigarette tobacco products. Because I wanted to test the ease of purchasing and delivery of these flavored tobacco products I paid a fairly high shipping charge due to the small amount of items purchased. For this company purchasing approximately \$64.00 in product the base shipping cost is the equivalent to the 27.3% that and individual would pay in tax for similar goods purchased in SF.

San Francisco is ground zero for app creation. People are becoming more accustom of being able to purchase anything they want to through the fingertips of their phone and if it does not exist then it will be created. It naïve to think that reducing access via brick and mortar will not spur the creation of apps to fill the gap. Any additional legislation being considered to further restrict the access to tobacco and cigarettes will definitely drive the creation of this market.

In summary the SBC recommends the Board of Supervisors consider:

- Do an analysis on the effect of raising the legal purchase age from 18 to 21 do determine if it does meet its object of reducing youth access and addition.
- Amend the law so that is also restricts any online sales and delivery of flavored tobacco products into San Francisco.

Thank you for considering the Commission's comments. Please feel free to contact me should you have any questions.

Sincerely,

Regina Dick-Endrizzi

Director, Office of Small Business

ZM)ick Lidenzi

cc: Malia Cohen, Board of Supervisors
Ahsha Safai, Board of Supervisors
London Breed, Board of Supervisors
Mark Farrell, Board of Supervisors
Jeff Sheehy, Board of Supervisors
Katy Tang, Board of Supervisors
Nicole Elliott, Mayor's Office
Mawuli Tugbenyoh, Mayor's Office
Lisa Pagan, Office of Economic and Workforce Development
Erica Major, Public Safety & Neighborhood Services Committee
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1617-RBM-07

Youth Commission

City Hall ~ Room 345 1 Dr. Carlton B. Goodlett Place San Francisco, CA 94102~4532



(415) 554-6446 (415) 554-6140 FAX www.sfgov.org/youth_commission

YOUTH COMMISSION MEMORANDUM

TO:

Erica Major, Clerk, Public Safety & Neighborhood Services

FROM:

Youth Commission

DATE:

Wednesday, May 17, 2018

RE:

Referral response to BOS File No. 170441 [[Health Code - Banning the Sale of

Flavored Tobacco Products

At our **Monday**, **May 8**, **2017 meeting**, the Youth Commission voted to support the following motion:

To support BOS File No. 170441 – Ordinance amending the Health Code to prohibit tobacco retailers from selling flavored tobacco products, including menthol cigarettes.

Youth Commissioners thank the Board of Supervisors for their attention to this issue. If you have any questions, please contact our office at (415) 554-6446, or your Youth Commissioner.

Chair, Madeleine Matz

Adopted on May 15, 2017

2016-2017 San Francisco Youth Commission

Somera, Alisa (BOS)

From:

Ken Richard <nplnsolo1@gmail.com>

Sent:

Friday, June 30, 2017 11:37 AM

To:

Somera, Alisa (BOS)

Subject:

attn Ms. Angela Cavillo

I was wondering if there is any information available in the history of the menthol cigarette measure which would lend support towards indicating that a net health benefit and expense reduction would accrue as a result of measures passage?

I believe that there are rising health care costs as a result of reduced national tobacco consumption owing to the principle of substitution in that for each percentage decline in adult tobacco consumption there has been a near identical rise in the rate of obesity within the same population and time frame, 1997 - 2017. As one scale has gone down, the other has gone up. Obesity, ironically, is purportedly medically more costly than are those health care costs associated with smoking. There are similarities and disparities between the two activities in that they are both oral, social, pleasurable, potentially compulsive, and may lend themselves to abuse. Smoking, however, may act as an appetite suppressant. And, parents are less likely to share their cigarettes with their offspring than they are to commonly share food with them, which would suggest modeling of unhealthy consumption patterns at an earlier age and stage of development. Once someone reducing tobacco consumption or quits smoking entirely, they may begin to receive health benefits near immediately. However, in the case of obesity, even in the face of reduced calories a body may attempt to maintain an unhealthy composition owing to the principle of physiological memory.

Owing to that, and the recent popularity of legislation opposing flavored tobacco sales, I was attempting to lead up to the suggestion that the Board work its way towards reviewing current processed food labeling, with the idea in mind that total calories should follow total ounces on the front of all such packages. But, it is a measure which would actually require being taken up by the State. I appreciate the opportunity to speak before the Board, earlier in this week, however, the atmosphere in the chamber is soured, either intentionally or unwittingly by a few habitual characters. At any rate, if you have any study in your records that indicates global net cost benefit analysis on the national level, owing to lessened tobacco consumption, and other than common sense assumption, I hope you will pass it along.

Kenneth Richard

knnth_richard@yahoo.com

Carroll, John (BOS)

From:

Board of Supervisors, (BOS)

Sent:

Thursday, June 22, 2017 8:09 AM BOS-Supervisors; Carroll, John (BOS)

Cc:

Major, Erica (BOS)

Subject:

FW: The Board: Are you aware of the difference between tobacco products and tobacco

products

Categories:

170441

From: Bengt-Olof Wiberg [mailto:bengt-olof.wiberg@bowsolutions.se]

Sent: Wednesday, June 21, 2017 11:54 PM

To: Board of Supervisors, (BOS) <board.of.supervisors@sfgov.org>

Subject: Att: The Board: Are you aware of the difference between tobacco products and tobacco products

Dear Board members. It saddens me and and millions of people around the world to hear that you have forbidden flavors in non combustion, smokeless tobacco products in what was once a liberal and intelligent city.

I trust you have heard about #tobaccoharmreduction. At least most of the rest of the world has. In January 2017 the word health organization publish a frightening report stating the facts that tobacco cigarette smoking causes 6 million dead at a cost for the world society of astronomical 1,1 trillion US dollars annually.

Vaping, snus, snuff and dip has never caused anyone's death and has not caused any cost for the health either.

By forbidding flavors, not only for cigarettes, but also for the above mentioned significantly less harmful products you have therefore given smokers of traditional cigarettes an excuse to continue smoking these and besides human tragedy by causing lung cancer and cardio vascular disease's it will also continue to be a huge burdon of your health are budget.

I propose therefore that you make a clear distinction between the deadly tobacco smoking and #harmreduction products.

I also suggest that you examine the works of Dr Brad Rodu, professor at Louisville University.

Best regards

Bengt Wiberg

CEO & patent holder

B-O Wiberg Solutions AB Lidingö Org.nr. 556922-7902 Tel. +46-760151082 www.bowsolutions.se www.facebook.com/Stingfreesnus www.Stingfreesnus.com info@bowsolutions.se info@stingfreesnus.com

Tel: +46-760151082

Carroll, John (BOS)

From:

Board of Supervisors, (BOS)

Sent:

Thursday, June 22, 2017 11:46 AM

To:

ahall31@baker.edu; Carroll, John (BOS)

Cc:

Major, Erica (BOS)

Subject:

FW: Regarding Eliquid Ban File No. 170441

Categories:

170441

Hello,

Thank you for your email. It has been forwarded to the Board Members and will be added to the Petitions and Communications section of our July 11, 2017 agenda. Looping in the Public Safety and Neighborhood Services Clerk to add it to the official file.

Regards,

Board of Supervisors

1 Dr. Carlton B. Goodlett Place, City Hall, Room 244

San Francisco, CA 94102-4689

Phone: (415) 554-7703 | Fax: (415) 554-5163 Board.of.supervisors@sfgov.org | 415-554-5184

From: Ashley Hall [mailto:ahall31@baker.edu] Sent: Thursday, June 22, 2017 11:26 AM

To: Board of Supervisors, (BOS) <board.of.supervisors@sfgov.org>

Subject: Regarding Eliquid Ban

To whom it may concern,

As a smoker who was able to quit smoking due to vaping, it is a lifesaver. I was smoking since I was 18 and I am almost 28. The delicious flavors that is in Eliquid is what helped me to quit smoking. Menthol, tobacco, and similar flavors did not help me quit. It was my flavor Cinnamilk, which is a Creamy Cinnamon flavor. Since quitting smoking, I can now climb stairs and play with my child with much better ease. The eliquid keeps me from smoking. I honestly would end up going back to cigarettes if I didn't have any. I don't want those harsh chemicals back in my lungs, but the patch and other techniques similar do not work. I will just end up going back every time.

With Eliquid, I am able to use it for my oral and touch stimulation that I received during smoking. Also, I am no longer exposed to first, second, or third hand smoke. My child is no longer under exposure of second or third hand smoke. We do not get as sick as often, and our seasonal allergies do not impact us as much as they used to.

Please take time to consider that vaping is an appropriate method to quit smoking. If anything, it is helping keep this kids off of smoking cigarettes. Preventing the sale of Eliquid will only increase smoking cigarettes, including for teenagers.

Sincerely, a concerned mother,

Ashley Hall Waterford, MI (248) 979 -3948

Carroll, John (BOS)

From: Sent: Board of Supervisors, (BOS)

Sen

Thursday, June 22, 2017 1:42 PM

To: Cc: cyclicscooby@googlemail.com

Subject:

BOS-Supervisors; Carroll, John (BOS) FW: Recent ban on eliquids File No. 170441

Categories:

170441

Hello.

Thank you for your email. It has been forwarded to the Board Members and added to the Petitions and Communications section of our July 11, 2017 agenda. Looping in the Public Safety and Neighborhood Services Clerk to add it to the official file

Regards,

Board of Supervisors 1 Dr. Carlton B. Goodlett Place, City Hall, Room 244 San Francisco, CA 94102-4689 Phone: (415) 554-7703 | Fax: (415) 554-5163 Board.of.supervisors@sfgov.org | 415-554-5184

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From: Chrisie Webb [mailto:cyclicscooby@googlemail.com]

Sent: Thursday, June 22, 2017 12:50 PM

To: Board of Supervisors, (BOS) <board.of.supervisors@sfgov.org>

Subject: Recent ban on eliquids

To whom it may concern..

I live in the UK. I smoked cigarettes and cannabis for 20 year's, then last November I bought a vape. I tried a Strawberry flavoured eliquid, at full 18mg/ml strength, and stopped smoking THAT DAY.. I haven't had a single cigarettes or joint since then... It worked OVERNIGHT...!!!!

7 months later, I'm vaping 2mg/ml homemade eliquid, in various fruity flavours, and haven't looked back.. I started reducing the nicotine strength within a month from 18mg, then 6mg to just 3mg..

Now I don't cough up 'gunk' every morning, I feel more awake, energetic, and also sleep better.. I also haven't had a headache, something which has plagued my adult life..

The UK medical society has proven vaping to be 95% LESS HARMFUL than tobacco..

I only smoked cigarettes, as a means to an end, to get my nicotine 'fix'. I now realise the taste was horrible, even disgusting, but the addiction made me carry on regardless..

If it wasn't for the flavoured eliquid, which are the same flavours used in food, and all approved by the FSA, I probably wouldn't have quit smoking.

I think what you have done, banning flavoured eliquids is a crime against your own people, and a short sighted approach to an I'll informed government..

Surely your only reason for this insane decision, is that you are bowing to the requests of the huge tobacco industry at the cost of human lives and suffering of thousands of people from smoking related illnesses..

Vaping eliquid has just FOUR ingredients, only one of which is addictive, the nicotine. Again it's proven by the highest medical professionals that on its own, nicotine is no more harmful than caffeine..

Cigarettes on the other hand have over a thousand very nasty poisons, which harm both the smoker and those around them, unlike vaping...

I hope you read this in full and think about your decision. I am disgusted that you are prepared to directly kill so many people for money, power, and friends at the golf club

Kind regards
A truly disappointed vaper and EX smoker

Carroll, John (BOS)

From:

Somera, Alisa (BOS)

Ordinance 170441.pdf

Sent:

Tuesday, June 20, 2017 9:53 AM

To:

Carroll, John (BOS); Major, Erica (BOS)

Subject: Attachments:

FW: File No. 170441 - Public/Written Comment for Regular Meeting 6/20/17 Agenda Item #15 AAGA Public Comment File No 170441.pdf; Arab Cultural and Community Center Letter Re

Categories:

170441

Please place in file and for next Board packet

Alisa Somera

Legislative Deputy Director San Francisco Board of Supervisors 1 Dr. Carlton B. Goodlett Place, Room 244 San Francisco, CA 94102 415.554.7711 direct | 415.554.5163 fax alisa.somera@sfgov.org

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From: Calvillo, Angela (BOS)

Sent: Tuesday, June 20, 2017 7:56 AM

To: Somera, Alisa (BOS) <alisa.somera@sfgov.org>

Subject: FW: File No. 170441 - Public/Written Comment for Regular Meeting 6/20/17 Agenda Item #15

For the file please.

Angela

From: Miriam Zouzounis [mailto:miriam.zouzounis@gmail.com]

Sent: Monday, June 19, 2017 12:15 PM

To: BOS-Legislative Aides

sides@sfgov.org>

Subject: File No. 170441 - Public/Written Comment for Regular Meeting 6/20/17 Agenda Item #15

File No. 170441 - Public/Written Comment for Regular Meeting 6/20/17 Agenda Item #15

Thank you.



6/19/2017

Re: File No. 170441

Honorable Supervisors,

Many of the locally founded San Francisco enterprises that you often praise; C.R.E.A.M, Bi-Rite, Gus's, Philz Coffee, etc. were once Corner Markets. The opportunities and hard work that lead to the transformations you see today were no easy feat, yet newer immigrant store owners will not be allowed the same prospects with the current and developing restrictions and prohibitions levied on this sector. The Arab American Grocers Association, whom represents over 400 businesses, in particular, has been a consistent civic partner since its inception and through generations while at the same time upholding establishments that are vital parts of neighborhoods and treasures of a rapidly changing City. We have members who have gone out of business due to loss of lease (Rose's Market, across from SF General) and those who have tried to transition their model to a full grocer with no alcohol or tobacco, and were swiftly run out of business by formula retail and larger grocery stores (Healthy Haven, Divisadero). The factors facing this sector are many; workforce depletion via the gig economy, including online retail, automation and TNC drivers, supply chain disruptions due to Formula Retail pressuring distributors to raise minimums and street and sidewalk changes, increased State taxes, onerous fees, permits, and regulations on the City level and an environment of fear and confusion as a result of policies on the Federal level targeting a large demographic of those working in this sector.

Many store owners and workers, including more than half our membership who was able to attend the Public Safety and Neighborhood Services Committee Hearing, were not able to sit in the main Committee room due to overcrowding, and were relegated to the overflow room. We are not the Tobacco Industry, we are not being paid to do this, we are working for a living, and we should not have to continually defend the fact that we are worthy people let alone worthy U.S. Citizens, and throughout this process both have been put into question.

We feel there is still much more the Supervisors owe us in terms of an explanation of their logic. Why are we not banning labeling? There are precedents in existing law that refer to the signage and advertising discussed in Committee--we are already legally restricted from these types of advertisements and accessible table top displays of products. Why not expand this particular precedent to address the concerns of seductive packaging and access? Why are the sponsors not entertaining substantive amendments that merely give consideration to the amount of time these stores will need to default on a lease or sell off inventory they have already paid taxes on, or possibly recreate a completely different business model? Will this follow with an already drafted Ban on Filtered Cigarettes? Where is the local data in this Ordinance? There have been at least 5 laws in the past year that have sought to address the same health policy goals, including contradicting policy processes, i.e. long term phase outs like Article 19H which counteracts with immediate prohibition. Why are you disregarding the mechanisms already in place? We experience non-stop sting operations from Federal, State and local entities, and SFPD is tasked to enforce things 3-4 times over. And how do you respond to the fact that the taxes and fees we pay on our licenses goes directly to these very Departmental bodies, non-profits, and lobby organizations that are vilifying us and demanding our submission? How do you pledge to protect and retain *all* the people of San Francisco? The world is in a delicate place in which the severity of public safety and health issues are often recited as hashtags, however, to proclaim solidarity and good will, means nothing when the economic dimension is being ignored.

We urge you to consider the consequences of this type of legislation.

Sincerely.

AAGA Board and Members



Arab Cultural and Community Center

2 Plaza Street, San Francisco, CA 94116

June 12, 2017

Honorable Supervisors,

BOARD MEMBERS

Altayeb Abdulrahim (President)
Samer Elbandak (Vice President)
Linda Khonry-Umili (Secretary)
Shadi Elkarra
Ahmed Saleh
Souhil Zaim (Ex: Officio)

The Arab Cultural and Community Center (ACCC) was established in 1973 in San Francisco. We serve 6,000 people a year with direct social service, youth and cultural programming. The Arab community is diverse in income, ethnicity and religion, but our programming has inevitably had to direct attention to those fleeing war since the 1990's. We are a diaspora that have found a home for generations in San Francisco and where many have become established, we still have considerable demographics of low-income residents and vulnerable populations. We have worked with the City and County over the years and collaborated with the Girls and Boys Club, SFUSD, etc. to establish programming and direct services. The Middle Eastern, Arab, Muslim, and South Asian communities have been living in a real state of fear, especially in the current climate and with laws coming down from the Federal level. One of our member trade organizations is the Arab American Grocer Association (AAGA). This industry in particular has been suffering as workers and operators fear increased criminalization of the corner market industry with increased sting operations, difficulty in understanding new laws, misunderstanding the purpose of enforcement or regulatory bodies that may be visiting their workplace, and are constantly battling restrictions in sending money to family still in their country of origin. We are writing as a Community Organization in San Francisco to express our concern and opposition to Ordinance 170441, Banning the Sale of Flavored Tobacco Products', as it will only increase this criminalization of legally operating businesses including hookah lounges, ethnic/import stores, corner markets and smoke shops, and will disproportionately affect our communities. The introduction of increased taxes and fees and ongoing difficulties to doing business including increased rents, have already adversely affected this sector and thwarted a clear path for the future for many families that are supported by this vital demographic of small businesses. This law not only shows a lack of regard for the sensitive federal climate but also the direct impact that this will have on the Arab, Muslim and Sikh communities in San Francisco.

We encourage your deep consideration before a vote on this Legislation. Additionally, we ask that the final Board vote be postponed until after the Holy Month of Ramadan, which is observed by a large majority of these store owners. A final Board vote following Committee would fall not only during a crucial breaking of fast time, but potentially also the ending Eid-al Fitr Holiday.

Altayeb Abdulrahim
President of the Board of Directors 2017

Arab Cultural & Community Center
2 Plaza Street ◆ San Francisco, CA 94116 ◆ (415) 664-2200
www.arabculturecenter.org



MISSION DISTRICT, SF 2301 Mission St #201, San Francisco, CA 94110 | tel 415.487.9203 f 415.487.9022

MISSION DISTRICT, SF 2301 Mission St #201, San Francisco, CA 94124 | tel 415.864.8372 f 415.864.8373

BAYVIEW DISTRICT, SF 2145 Keith Street, San Francisco, CA 94124 | tel 415.864.8372 f 510.763.5824

WEST OAKLAND 3268 San Pablo Avenue, Oakland, CA 94608 | tel 510.763.5877 f 510.763.5824

WEST OAKLAND 3268 San Pablo Avenue, Oakland, CA 94603 9124 International Blvd., Oakland, CA 94603

MAILING PO Box 3596, Oakland, CA 94609

File No 170441

Honorable Supervisors,

Causa Justa:: Just Cause is writing to join in support with the Arab American Grocers Association and to express our concern and opposition to Ordinance 170441, 'Banning the Sale of Flavored Tobacco Products'. The introduction of increased taxes and fees and ongoing regulations to doing business, have already adversely affected this sector and thwarted a clear path for the future for many families that are supported by this vital demographic of small businesses. This law not only shows a lack of regard for the climate of increased vacancies and gentrification which is disproportionally impacting communities of color and Immigrant communities in San Francisco but also the value this mom and pop industry has as community serving businesses.

Furthermore we are deeply worried about the impacts this will have on already marginalized communities that depend on retail as their sources of income and sustenance in an already gentrifying city and who might completely be priced out and displaced out of the city. We hope to support efforts to improve health quality for all San Franciscan's but do not believe that this banning effort effectively does that and the impacts to the livelihood of many middle class business long term-contributing business owners and their employers outweigh the benefits of the legislation. Lastly, banning flavor Tabaco sales in SF but not in neighboring cities will mean that many community members will be selling and acquiring these products through the underground economy of our city, we worry greatly about the criminalizing impact this can have on already highly criminalized Black, Immigrant community members.

Thank you for your consideration.

Kitzia Esteva-Martinez Community Rights Co-director,

Causa Justa: Just Cause

20 P# 2: 09

SANTRAHCISCO



Electronic Vaping Coalition of America

DC Address: 1629 K Street, NW, Suite 300, Washington, DC 20006 Wisconsin Address; P.O. Box 510564, New Berlin, WI 53151 www.evapingcoalition.org



To: The San Francisco Board of Supervisors

From: Mark Block, Director,
Electronic Vaping Coalition of America

Re: An Outline of the lawsuit that will be filed upon passage of the anti-vaping ordinance by this board

June 20, 2017

June 20, 2017

TO: The San Francisco Board of Supervisors

FROM: Mark Block, Executive Director, Electronic Vaping Coalition of America (EVCA) mark.block@evapingcoalition.org

RE: An outline of the lawsuit that will be filed upon passage of the anti-vaping ordinance by this board.

Members of the Board, you have launched a campaign based on flawed facts, science and theory. Under the guise of protecting youth from the evils of cigarettes, you have set about to prohibit the one effective, safe way for tobacco addicts to get relief from the life of illness and death they eventually face.

You know as well as anyone, indeed, better than most, that vaping is at a *minimum*, **95 percent safer than combustible cigarettes**, and in the words of Dr. Dunn, it is completely safe. You know better than most that nearly half a billion people die every year from illness and death resulting from smoking combustible cigarettes.

And you know better than most what will happen to your cigarette/tobacco settlement money as vaping sales grow - sales of tobacco will go down, down, and down. As a result, your available cash for the budget will be there at the first of the cycle, but not for the end and beginning of the next.

Your justification for regulating flavors is that in this way you can control youth behavior. Think again. Outlawing e-liquids will simply entice minors who might be wavering to do that which is forbidden. It will not deter those who smoke, it will not induce those who have no intention of smoking, but it will hurry along the experiment of those that would experiment. Nothing motivates a teenager seeking mischief so much as unlawfulness in securing something he or she is not supposed to have.

So, in order to achieve economic value for your government budget you will sacrifice public health, safety and welfare.

But we will try to stop you, and expect to file a lawsuit that will incorporate at least the causes of action set forth herein:

I. EQUAL PROTECTION OF LAWS.

If passed, the ordinance will violate the equal protection clause of the constitutions of *both* the state of California and the United States of America; California's as complement to the U.S. except that it may go even further, and if so, a separate California case would be filed for at least one to three users of vaping, store owners and users of cigarettes.

In analyzing the facts, please consider:

Henry can, on one side of a store buy and drink a flavored alcoholic beverage; while Jason, on the other side of the *same* store, cannot buy, nor can the store sell, a flavored vaping liquid. The distinction is made even more absurd by the fact that alcohol is specially treated under the California Constitution where the people established through initiative, control of alcohol, acknowledging that alcohol is a dangerous substance deserving of restrictions by the people. Vaping and tobacco are not, particularly vaping - Congress has said that cigarettes cannot be prohibited and has not declared vaping to be dangerous.

The case that most clearly makes this out to be an equal protection violation is **Brown v. Merlo**, 506 P.2d 212 (Supreme Court of California en banc, Tobriner, J. writing the opinion) referring to, and making a part of the argument in every leading U. S. Supreme Court decision.

The Court said that when an equal protection argument is raised, the Court must determine whether "persons similarly situated with respect to the legitimate purpose of the law receive like treatment."

The Court also cited the *federal* rule: "The Equal Protection Clause...denies to the States the power to legislate that different treatment be accorded to persons placed by a statute into different classes on the basis of criteria wholly unrelated to the objective of that statute. A classification must be reasonable, not arbitrary, and must rest on some ground of difference having a fair and substantial relation to the object of the legislation, so that all persons similarly circumstanced shall be treated alike." 38 P. 500 citing Purdy & Fitzpatrick v. state of California, 456 P.2d 645, 38 ALR 3d 1194, Darcy v. Mayor etc., of San Jose, 38 P. 500, 1894), Reed v. Reed, 404 U.S. 71, 75-6; Royster Guana Co. v. Virginia, 253 U.S. 412; Eisenstadt v. Baird, 405 U.S. 438, 446-447; Weber v. Aetna Casualty & Surety Co, 406 U.S. 164. Thus, the rule is that when a statute subjects one person to a different treatment, there is a requirement of "some rationality in the nature of the class"

signaled out." Rinaldi v. Yeager, 384 U.S. 305, 308-9; H ayes v. Superior Court, 490 P.2d 1171

In a portion of the opinion particularly telling to this case is that which holds that in determining the scope of the class of citizens singled out for action by the state, "a court cannot confine its view to the terms of the specific statute under attack, but must judge the enactment's operation against the background of other legislative, administrative and judicial directives which govern the legal rights of similarly situated persons. As the United States Supreme Court recognized long ago: 'The question of constitutional validity is not to be determined by artificial standards [continuing review 'within the four corners of a statute). What is required is that state action, whether through one agency or another, or through one enactment or more than one, shall be consistent with the restrictions of the Federal Constitution." Gregg Dying Co. v. Query, 286 U.S. 472; James v. strange, 408 U.S. 128.

When a classification is based upon a policy that has changed, or on facts no longer existent, the classification ends.

If a law overreaches and is overbroad, and "reaches out beyond the individuals 'tainted with the mischief' at which a statute is directed, it imposes its burden on innocent individuals who do not share he condemning characteristics.

Putting these rules into place on the facts of the proposed ordinance, one can see the argument as follows:

California has a general policy toward substance abuse or disabilities that requires treatment and assistance. That is set forth in both the California Constitution and laws (the Alcohol Control Act that implements XXII of the Constitution and the Unruh Civil rights Act)

You will remember from the language in Merlo, above, that one cannot judge the situation on one statute alone when there are many which make up the matrix of the base statutes at issue. Here there are several, because involved are people entitled to protection and care and treatment under state pre-emptive law, and San Francisco has not the power to change state policy and pre-emptions.

Alcohol and tobacco are both in the classification, yet they are treated differently: flavored alcohol can be purchased by adults, flavored eliquid and e-cigarettes cannot now (Under the ordinance). There is no rational relationship between the two differing positions. In fact, the

result is completely irrational: the more dangerous of the substances, alcohol, triggers no action of prohibition, while the less dangerous, vaping, is placed in the prohibition. That is not rational thought.

With all of the evidence that vaping is a safer alternative to tobacco use, the city is attempting to end that practice, thus flying in the face of article XXII of the state Constitution.

The announced purpose of the ordinance is to prevent kids under 21 from taking up smoking - the prevailing idea is that these youth will be more inclined to try vaping because of the flavor, then will switch to cigarettes.

But the ordinance overreaches because by outlawing sales to keep youth from vaping, sales are outlawed for adults, and adults with a nicotine addiction have a protected state. Thus being overbroad, the ordinance should be set aside.

In other words, in the language of **Brown v. Merlo**, the persons who would be doing mischief and need protection are youngsters under 21, but the Council is not satisfied with that so they would prohibit all such use even by adults. This scenario shows an ordinance drastically overreaching and punishing adults who would be prevented from vaping with perfectly legal e-liquid and devices in order to be free of disease and death.

Under **Brown**, and the myriad cases cited therein, we feel comfortable in seeking relief from the ordinance on the equal protection of laws on this theory.

II. TORTIOUS INTENTIONAL INTERFERENCE WITH PROSPECTIVE ECONOMIC ADVANTAGE.

The stores that sell, and the manufacturers who produce, and the dealers and retailers who deliver and share vaping and e-related products, will have cause of action of intentional interference to their business.

Nature of the Tort of Intentional Interference with Prospective Economic Advantage

The elements of that tort of are: '(1) an economic relationship between [the plaintiff and some third person] containing the probability of future economic benefit to the [plaintiff], (2) knowledge by the defendant of the existence of the relationship, (3) intentional acts on the part of the defendant designed to

disrupt the relationship, (4) actual disruption of the relationship, [and] (5) damages to the plaintiff proximately caused by the acts of the defendant.' (Buckaloo v. Johnson (1975) 14 Cal.3d 815, 827.)

It seems clear that this tort is the broader of the two so-called interference torts. The other is interference with contract. The tort of 'interference with contractual relations has its roots in the tort of 'inducing breach of contract." (Seaman's Direct Buying Service Inc. v. Standard Oil Co. (1984) 36 Cal.3d 752, 765.) The latter is merely a species of the former. The principal difference between them is that 'the existence of a legally binding agreement is not a sine qua non to the maintenance of a suit based on the more inclusive wrong.' (Buckaloo, supra, at 823.) 'Both the tort of interference with contract relations and the tort of interference with prospective contract or business relations involve basically the same conduct on the part of the tortfeasor.

In one case, the interference takes place when a contract is already in existence, in the other, when a contract would, with certainty, have been consummated but for the conduct of the tortfeasor.

Rather than characterizing the two as separate torts, the more rational approach seems to be that the basic tort of interference with economic relations can be established by showing, inter alia, an interference with an existing contract or a contract which is certain to be consummated, with broader grounds for justification of the interference where the latter situation is presented.' (Builders Corporation of America v. U.S. (N.D.Cal.'57) 148 F.Supp. 482, 484, fn. 1, revd. on other grounds (9th Cir.'58) 259 F.2d 766, see also Pacific Gas & Electric Co. v. Bear Stearns & Co.(1990) 50 Cal.3d 1118, 1126.)

In either case, '[A]s Justice Tobriner said in the context of voidable contracts: 'The actionable wrong lies in the inducement to break the contract or to sever the relationship, not in the kind of contract or relationship so disrupted, whether it is written or oral, enforceable or not enforceable.' (Pacific Gas & Electric Co. v. Bear Stearns & Co., supra, 50 Cal.3d at 1127.)

However, it must be remembered that these torts are intentional torts.

In discussing the related tort of inducing breach of contract, the Supreme Court has stated: 'The act of inducing the breach must be an intentional one. If the actor had no knowledge of the existence of the contract or his actions were not intended to induce a breach, he cannot be held liable though an actual breach results from his lawful and proper acts. 'Imperial Ice Co. v. Rossier (1941) 18 Cal.2d 33, 37.)

The Restatement of Torts explained it this way, 'The essential thing is the purpose to cause the result. If the actor does not have this purpose, his conduct does not subject him to liability under this rule even if it has the unintended effect of deterring the third person from dealing with the other.' (Rest., Torts, section 766, com. d, emphasis added.)

And here, we have the ultimate in intentional tort. The chairwoman has made it perfectly clear in public statements that her intent is to cause the result of interference. And, since she has made that clear, and the others ae going along with the flow without negating or even questioning, they are acting intentionally also. [T]o prevail on a cause of action for intentional interference with prospective economic advantage, plaintiff must plead and prove 'intentional acts on the part of the defendant designed to disrupt the relationship.' (Ibid., quoting from Buckaloo v. Johnson, supra, 14 Cal.3d at 827.)

III. ENVIRONMENTAL CAUSES OF ACTION

The flavored ban runs contrary to both public health and environmental law.

- Vaping is a new technology that significantly reduces the impact on the environment. (Not unlike solar energy: Solar is sustainable and vaping is sustainable.)
- Vaping does not contain thousands of toxic chemicals into the air and soil. (As compared to tobacco cigarettes.)
- 3. Vaping is reusable and positively impacts oceans and forests. (Akin to bringing your own re-usable grocery bag to the store.)
- 4. Vaping has a simple manufacturing process, and in many instances, does not require any nicotine at all in the products.
- 5. There is no actual tobacco included in vaping products.

Issue: First cause of action: Deforestation

<u>Smoking</u>: Deforestation is caused due to planting of tobacco fields. It is also caused by "wrapping" cigarettes with paper.

Vaping: No Deforestation

Conclusion: Vaping is better because it does not cause Deforestation and does not require wrapping.

<u>Issue: Second cause of action: Species Extinction in Forests and Wooded Areas</u>

<u>Smoking</u>: Tobacco fields and destruction of wooded areas destroys ecosystems and kills endangered species.

Vaping: No impact on species.

Conclusion: Vaping does not contribute to endangered species.

Issue: Third cause of action: Global Warming

<u>Smoking</u>: Deforestation and "Air-curing" cause pollution, lung cancer, and climate change

<u>Vaping</u>: Does not use burning and "Air-curing" as part of the manufacturing process.

Conclusion: Vaping does not cause Global warming

Issue: Forth cause of action: Soil Erosion

<u>Smoking:</u> Tobacco farming releases thousands of chemicals into the soil and destroys land.

<u>Vaping:</u> This is not required as part of the vaping manufacturing process.

Conclusion: Vaping does not erode soil.

Issue: Fifth cause of action: Pesticides

<u>Smoking</u>: Pesticides are sprayed on plants. Often workers are exposed to these pesticides. This may apply to children/minors* working in the fields

<u>Vaping</u>: Vaping does not use pesticides in the manufacturing process.

Conclusion: Vaping does not involve pesticides

Issue: Sixth cause of action: Littering

Smoking: Cigarette butts are the most littered item in the world.

Vaping: Vaping mods are reusable and can last years.

Conclusion: Vaping is sustainable.

Issue: Seventh cause of action: Oceans and Marine life

Smoking: Cigarettes pollute the oceans and end up in drains.

Vaping: Vaping has no impact on the oceans.

Conclusion: Vaping will lead to sustainable oceans.

Issue: Eighth cause of action: Air pollution and second-hand smoke

<u>Smoking:</u> There are a large number of deaths every year to second hand smoke due to air pollution.

Vaping: There are no confirmed deaths from second-hand vape.

Conclusion: Vaping is better for the air.

Issue: Ninth cause of action: Forest Fires

Smoking: Smoking is one of the leading causes of forest fires

Vaping: Vaping does not cause forest fires.

Conclusion: Vaping is not a leading cause of forest fires because it is reusable.

IV. VIOLATION OF DUE PROCESS OF LAW

Violation of due process of law, procedurally and substantively because of the establishment of presumptions without the protection guaranteed by the due process clause of the United States Constitution—protection is NOT GIVEN BY THE HEARING THAT IS PROVIDED IN ANOTHER STATUTE. The protection that is missing is the pre-termination thinking, and can be informal but must be given chance to challenge.

A Cause of Action for violation of due process in yet another way: Due Process procedurally and substantively is violated by the definitions of aspects of "flavoring" which will be the base of unlawfulness; there is no definition that does not involve discretionary application of parameters. Since this goes to the very essence of the unlawfulness, due process is violated because the city cannot give fair and adequate notice of what the city will include in the definition that will determine coverage. The due process concept of *Christopher v. SmithKline Beecham Corp.* No 11-204. 567 US, and *FCC v Fox Television Stations INC* No. 10-1293, June 21, 2012, included in FDA Law Blog, July, 2012

In the event of evidence of any violation of due process, a jury trial will be requested with damages to be set by the jury, in an amount limited only by not more than enough to deter the actor from again violating these or any other civil rights.

V. VIOLATION OF THE CIVIL RIGHTS ACT OF 1866. (because of equal protection argument) The due process violation serves as the base for the lawsuit which entitles the plaintiff to a jury trial to set damages.

VI. GOVERNMENT HAS THE BURDEN OF ASSURING IT DOES NOT DO ANYTHING TO INJURE THE PUBLIC HEALTH, OR THE PUBLIC HEALTH OF A CITIZEN.

The ordinance fails here because what it sets out to do is intended to do exactly that which the Constitutional rights of the people say it will not do.

The vaping equipment and artifacts and liquids are safer than tobacco and are not harmful to public health, as witnessed by fact that Congress did not undertake to regulate flavoring. It provides the most effective way to break addiction to combustible cigarettes, and it is the combustion that causes the health and death problems. So, by banning e-liquids, the government denies to the citizens a way to avoid deadly illness, thus is injuring the public health

VI. SEPARATE AND INDEPENDENT ACTION UNDER THE AMERICANS WITH DISABILITIES ACT AND THE CALIFORNIA UNRUH CIVIL RIGHTS ACT

<u>Plaintiffs</u>: Addicts to cigarettes are persons with disabilities under both the Americans With Disabilities Act and the Unruh Civil Rights Act of California, and are thus legally entitled to treatment and assistance. To prohibit sale of a substance abuse treatment to them violates the law and public policy of California.

<u>Cause of Action</u>: Right to assistance denied by state through the prohibition of sale of electronic vaping equipment including liquid with nicotine

<u>Cause of Action</u>: Person addicted to tobacco is protected by the federal Americans with Disability Act and by the Unruh Civil Rights Act in California. Under both, tobacco addiction constitutes a disability subject to appropriate treatment and to no discrimination.

So, the public policy of the state of California is to protect both the disabled rights to appropriate treatment and from discrimination:

(a) This section shall be known, and may be cited, as the Unruh Civil Rights Act.

SEC. 7. (a) A person may not be deprived of life, liberty, or property without due process of law or denied equal protection of the laws; provided, that nothing contained herein or elsewhere in this Constitution imposes upon the State of California or any public entity, board, or official any obligations or responsibilities which exceed those imposed by the Equal Protection Clause of the 14th Amendment to the United States Constitution with respect to the use of pupil school assignment or pupil transportation.

The California Constitution also guarantees equal protection of laws:

The Unruh Civil Rights Act in California provides that: "All persons within the jurisdiction of this state are free and equal, and no matter what their sex, race, color, religion, ancestry, national origin, disability, medical condition, genetic information, marital status, sexual orientation, citizenship, primary language, or immigration status are entitled to the full and equal accommodations, advantages, facilities, privileges, or services in all business establishments of every kind whatsoever."

VIII. CAUSE OF ACTION FOR VIOLATION OF PRIVACY OF ADULTS

Based largely and generally on the Ninth Amendment of the United States Constitution. Colloquially called the "just leave me alone" amendment, it says that we have God-given rights and are not dependent on the Constitution to state those rights. The Constitution is a limitation on government and anything not given to it there it does not have.

The Ninth gives vapers the right to engage in an activity that does not involve a dangerous product or object, that is safe and lawful, and that is not under any watch list of the government, or you would have been first to know.

IX. SPECIFIC RIGHT TO PRIVACY VIOLATION APART FROM THE NINTH AMENDMENT

A long series of United States Supreme Court cases have sustained a cause of action based on the citizen's right to be free of government intervention in his private life. The cases cover the waterfront from the right to appreciate pornography in the home to the right to buy birth control medication----choices of personal health and welfare. Fitting directly into that is the control of devices for adults. Violation of privacy rights:

Meyer v Nebraska (1923) Griswold v Connecticut (1965) Stanley v Georgia (1969) Ravin v State (1975)
Kelley v Johnson (1976)
Moore v East Cleveland (1977)
Cruzan v. Missouri Dep't. of Health (1990)
Lawrence v Texas (2003)



6/19/2017

Re: File No. 170441

Honorable Supervisors,

Many of the locally founded San Francisco enterprises that you often praise; C.R.E.A.M, Bi-Rite, Gus's, Philz Coffee, etc. were once Corner Markets. The opportunities and hard work that lead to the transformations you see today were no easy feat, yet newer immigrant store owners will not be allowed the same prospects with the current and developing restrictions and prohibitions levied on this sector. The Arab American Grocers Association, whom represents over 400 businesses, in particular, has been a consistent civic partner since its inception and through generations while at the same time upholding establishments that are vital parts of neighborhoods and treasures of a rapidly changing City. We have members who have gone out of business due to loss of lease (Rose's Market, across from SF General) and those who have tried to transition their model to a full grocer with no alcohol or tobacco, and were swiftly run out of business by formula retail and larger grocery stores (Healthy Haven, Divisadero). The factors facing this sector are many; workforce depletion via the gig economy, including online retail, automation and TNC drivers, supply chain disruptions due to Formula Retail pressuring distributors to raise minimums and street and sidewalk changes, increased State taxes, onerous fees, permits, and regulations on the City level and an environment of fear and confusion as a result of policies on the Federal level targeting a large demographic of those working in this sector.

Many store owners and workers, including more than half our membership who was able to attend the Public Safety and Neighborhood Services Committee Hearing, were not able to sit in the main Committee room due to overcrowding, and were relegated to the overflow room. We are not the Tobacco Industry, we are not being paid to do this, we are working for a living, and we should not have to continually defend the fact that we are worthy people let alone worthy U.S. Citizens, and throughout this process both have been put into question.

We feel there is still much more the Supervisors owe us in terms of an explanation of their logic. Why are we not banning labeling? There are precedents in existing law that refer to the signage and advertising discussed in Committee—we are already legally restricted from these types of advertisements and accessible table top displays of products. Why not expand this particular precedent to address the concerns of seductive packaging and access? Why are the sponsors not entertaining substantive amendments that merely give consideration to the amount of time these stores will need to default on a lease or sell off inventory they have already paid taxes on, or possibly recreate a completely different business model? Will this follow with an already drafted Ban on Filtered Cigarettes? Where is the local data in this Ordinance? There have been at least 5 laws in the past year that have sought to address the same health policy goals, including contradicting policy processes, i.e. long term phase outs like Article 19H which counteracts with immediate prohibition. Why are you disregarding the mechanisms already in place? We experience non-stop sting operations from Federal, State and local entities, and SFPD is tasked to enforce things 3-4 times over. And how do you respond to the fact that the taxes and fees we pay on our licenses goes directly to these very Departmental bodies, non-profits, and lobby organizations that are vilifying us and demanding our submission? How do you pledge to protect and retain *all* the people of San Francisco? The world is in a delicate place in which the severity of public safety and health issues are often recited as hashtags, however, to proclaim solidarity and good will, means nothing when the economic dimension is being ignored.

We urge you to consider the consequences of this type of legislation.

Sincerely,

AAGA Board and Members



BOARD MEMBERS

Altayeb Abdulrahim (President)

Samer Elbandak (Vice President)

Linda Khoury-Umili (Secretary)

Souhil Zaim (Ex Officio)

Shadi Elkarra

Ahmed Saleh

Arab Cultural and Community Center

2 Plaza Street, San Francisco, CA 94116

June 12, 2017

Honorable Supervisors,

The Arab Cultural and Community Center (ACCC) was established in 1973 in San Francisco. We serve 6,000 people a year with direct social service, youth and cultural programming. The Arab community is diverse in income, ethnicity and religion, but our programming has inevitably had to direct attention to those fleeing war since the 1990's. We are a diaspora that have found a home for generations in San Francisco and where many have become established, we still have considerable demographics of low-income residents and vulnerable populations. We have worked with the City and County over the years and collaborated with the Girls and Boys Club, SFUSD, etc. to establish programming and direct services. The Middle Eastern, Arab, Muslim, and South Asian communities have been living in a real state of fear, especially in the current climate and with laws coming down from the Federal level. One of our member trade organizations is the Arab American Grocer Association (AAGA). This industry in particular has been suffering as workers and operators fear increased criminalization of the corner market industry with increased sting operations, difficulty in understanding new laws, misunderstanding the purpose of enforcement or regulatory bodies that may be visiting their workplace, and are constantly battling restrictions in sending money to family still in their country of origin. We are writing as a Community Organization in San Francisco to express our concern and opposition to Ordinance 170441, Banning the Sale of Flavored Tobacco Products', as it will only increase this criminalization of legally operating businesses including hookah lounges, ethnic/import stores, corner markets and smoke shops, and will disproportionately affect our communities. The introduction of increased taxes and fees and ongoing difficulties to doing business including increased rents, have already adversely affected this sector and thwarted a clear path for the future for many families that are supported by this vital demographic of small businesses. This law not only shows a lack of regard for the sensitive federal climate but also the direct impact that this will have on the Arab, Muslim and Sikh communities in San Francisco.

We encourage your deep consideration before a vote on this Legislation. Additionally, we ask that the final Board vote be postponed until after the Holy Month of Ramadan, which is observed by a large majority of these store owners. A final Board vote following Committee would fall not only during a crucial breaking of fast time, but potentially also the ending Eid-al Fitr Holiday.

Altayeb Abdulrahim President of the Board of Directors 2017

Arab Cultural & Community Center
2 Plaza Street ◆ San Francisco, CA 94116 ◆ (415) 664-2200
www.arabculturecenter.org



San Francisco Council of District Merchants Associations

Henry Karnilowicz President Maryo Mogannam Vice President Vas Kiniris Secretary Keith Goldstein

SFCDMA

Member Associations

Balboa Village Merchants Association **Bayview Merchants Association** Castro Merchants Chinatown Merchants Association Clement St. Merchants Association **Dogpatch Business Association** Fillmore Merchants Association Fishermans Wharf Merchants Assn. Golden Gate Restaurant Association Glen Park Merchants Association Golden Gate Restaurant Association **Greater Geary Boulevard Merchants** & Property Owners Association Hayes Valley Merchants Association Japantown Merchants Association Marina Merchants Association Mission Creek Merchants Association Mission Merchants Association Noe Valley Merchants Association North Beach Merchants Association North East Mission Business Assn. People of Parkside Sunset Polk District Merchants Association Potrero Dogpatch Merchants Assn. Sacramento St. Merchants Association South Beach Mission Bay Business Assn. South of Market Business Association The Outer Sunset Merchant & Professional Association **Union Street Merchants** Valencia Corridor Merchants Assn.

West Portal Merchants Association

May 4, 2017

Honorable Supervisor Sandra Lee Fewer San Francisco Board of Supervisors 1 Dr. Carlton B. Goodlett Place, Room 244 San Francisco, CA 94102-4689

Dear Supervisor Fewer,

On behalf of the San Francisco Council of District Merchants Associations I am writing to express our concern and opposition to Ordinance 170441, 'Banning the Sale of Flavored Tobacco Products'.

The introduction of increased taxes and fees and ongoing regulations to doing business, have already adversely affected this sector and thwarted a clear path for the future for many families that are supported by this vital demographic of small businesses.

This law not only shows a lack of regard for the climate of increased vacancies and gentrification but also the value this mom and pop industry has as community serving businesses.

Thank you for your consideration.

Sincerely,

Henry Karnilowicz President

Cc:

Ms. Regina Dick Endrizzi - Executive Director, Office of Small Business



June 13, 2017

The Honorable Hillary Ronen, Chair Board of Supervisors Public Safety and Neighborhood Services Committee 1 Dr. Carlton B. Goodlett Place, Room 244 San Francisco, CA 94102

RE: File No. 170441, Banning Sale of Flavored Tobacco Products

Dear Supervisor Ronen:

The San Francisco Chamber of Commerce, representing over 2,500 local businesses with over 200,000 employees, urges the Public Safety and Neighborhood Services Committee to delay action on the above noted ordinance further regulating the sale of tobacco products to adults.

While the health impacts from the use of tobacco products are well known and both the State of California and City of San Francisco have taken significant steps to discourage smoking, especially underage smoking, at some point local prohibitions will constitute a "taking" of businesses selling legal products.

The pending ordinance will give retailers only a matter of a few months to adjust their flavored tobacco inventories to these new prohibitions on product sales. Beyond the issue of stock on hand, a retailer's entire business model may need to change in order to generate sufficient cash flow to meet the financial needs of his or her business. Before you threaten the livelihood of retailers in every neighborhood of the city, the Chamber urges you and your colleagues to look at other Bay Area legislation that, unlike this ordinance, takes into account the fiscal impact of tobacco sales regulations on small businesses.

Please do not lose sight of the fact that sufficient regulations are in place to control underage sale and use and funds exist to continue California's robust anti-smoking campaign. We urge you to consider the financial needs of a significant component of neighborhood retail in San Francisco before further hindering small retailers' ability to operate their businesses.

Sincerely,

Jim Lazarus

Senior Vice President of Public Policy San Francisco Chamber of Commerce

cc: Mayor Ed Lee, Clerk of the Board to be distributed to all members of the Board of Supervisors

Honorable Supervisors,

I am writing as a business owner/operator in District 10 to express my concern and opposition to Ordinance 170441, 'Banning the Sale of Flavored Tobacco Products'. The introduction of increased taxes and fees, and a restriction on ability to sell a tobacco license have already adversely affected my business and thwarted a clear path for the future. The terms of violation in the legislation are left open ended and we feel it is a premature and redundant code change given the very short window since new regulations on tobacco sales have been introduced. This law shows a lack of regard for our value as community serving businesses, as meeting and conversation spots, as outlets for accessible convenience goods that our customers want, as cornerstones of a familiar City.

Thank you for your consideration.

Double Rock Grocery 2830 Ingalls St. San Francisco, CA 94124

2743

Honorable Supervisors,

I am writing as a business owner/operator in District 10 to express my concern and opposition to Ordinance 170441, 'Banning the Sale of Flavored Tobacco Products'. The introduction of increased taxes and fees, and a restriction on ability to sell a tobacco license have already adversely affected my business and thwarted a clear path for the future. The terms of violation in the legislation are left open ended and we feel it is a premature and redundant code change given the very short window since new regulations on tobacco sales have been introduced. This law shows a lack of regard for our value as community serving businesses, as meeting and conversation spots, as outlets for accessible convenience goods that our customers want, as cornerstones of a familiar City.

Thank you for your consideration.

Bosness owner, Bayview-Hunters Print

Honorable Supervisors,

I am writing as a business owner/operator in District 10 to express my concern and opposition to Ordinance 170441, 'Banning the Sale of Flavored Tobacco Products'. The introduction of increased taxes and fees, and a restriction on ability to sell a tobacco license have already adversely affected my business and thwarted a clear path for the future. The terms of violation in the legislation are left open ended and we feel it is a premature and redundant code change given the very short window since new regulations on tobacco sales have been introduced. This law shows a lack of regard for our value as community serving businesses, as meeting and conversation spots, as outlets for accessible convenience goods that our customers want, as cornerstones of a familiar City.

Thank you for your consideration.

5/21/17

Palou Market INC 4019 3rd St San Francisco Ca auszy

COMMUNITY & CORNER STORE UNITY PLEDGE & PLATFORM

Real dialogue. Real needs.

We, the undersigned pledge to commit a process of dialogue and community informed demands that respect our collective interests as San Francisco residents, business owners, workers, customers, and advocates. We recognize the diverse interests of our communities, keeping in mind the needs of elders, young people, immigrants, natives, impacted populations, etc. We pledge to commit an effort that counters the divide and conquer politics initiated with the 'Ban on Flavored Tobacco' and create an organic and relevant process to address the concerns of the community and the livelihood of all members.

Current List of Demands:

- > Hire Local
- > Eliminate sales of drug paraphernalia
- > Revenue from tobacco and alcohol fees designated for community-serving organizations
- AAA

Name / Organization / Business		gypropyd narol og Grantosski nygolygy pygny ygirgy thiri bir blytolyton	Skanningstallangs (1778-1878) saka bagin kalaban saka bagin saka bagin saka bagin saka bagin saka bagin saka b	entre entre de la companya de la co	
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Summary of Legislation: Banning the Sale of Flavored Tobacco Products [Ordinance 170441]	The proposed ordinance (introduced April 18, 2017) amends the Health Code to prohibit local tobacco retailers from selling flavored tobacco products. The tobacco products that would be subject to the prohibition on sale would include, but not be limited to, flavored cigarettes, including menthol cigarettes, flavored cigars, flavored smokeless tobacco, flavored shisha, and flavored nicotine solutions that are used in electronic cigarettes. Violation of the ordinance would be punishable by a suspension of the retailer's tobacco license, of which notice or time determination is left open ended in the legislation.
Summary of Petition: Ask the Supervisors and Mayor to Consider Industry and Community Impact before Voting	We, the undersigned, are concerned citizens and consumers who urge our leaders to consider the punitive impact this legislation will have on our San Francisco Small Businesses. The intended health code regulation of this legislation as it is written will <i>only</i> stop the availability of flavored tobacco products to be purchased from brick and mortar San Francisco retailers but will not affect the consumers' access to said products online or from neighboring Cities. As participating citizens, we are troubled about the prohibition nature of this legislation on a legal substance and its restrictions on our consumer rights. Additionally, the failure to engage stakeholders and outreach also concerns us and falls short of fair law-making practices. San Francisco's existing Tobacco and Tobacco Sales regulations are more severe than any other City with restrictions on resale of a Tobacco Licenses, quarterly fees for street cleaning which amount to \$6 million/year (FY 15-16 Controllers Report), and a prohibition on the sale of other products as a Tobacco License holder, thus using Federal statistics as the "Findings" cited as intent for the Legislation, does not make sense.

Printed Name	Signature / /	Address	Comment	Date
Solley	Ymal Sulley	20 Canner Court 8.7. Ca 94124		5/17
JEREMY MENZIES	1-1.00.	522 Arkansas St 94107		5/23
EZZ KYS	GAMMA			
JUSTIN HARTGADO	Jan Colo	56 CAFAICHE 8 94103		5/26
SAL PAVONG	2 A	315 counties 0 Dr. Saw Drung 94060		5/22
Brandon Blackman	LARAM	249 11th St 9403		9/27
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SAGOP DEN OHE	aj	By Jones &CD		6/10
Meagan milos	-TP	337 A 10th St. SE, CA 94110		6/10

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Brandark.		1215 PlayyolAXe	Hell NO US	5/15/1
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Shelby Holt	Shelyn	oaklard		5/17/17
Jue D.		dahland	,	5/17/17
JESSCIA FAMEUN			No Hurr	5/18/17
Mike Man	Millean	135 Bresna Court		5/11/17
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Jason Deneva	Millen	1601 Sacramerto St Ant		3/14/17
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James A	garge alberties	711 Lean Worth		5/21
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Authory T.		141/Silver Ave		5/23
David D		2928 By Shu Bird		5/23
Patricio Israel	SAT	1870 Mason		5/23
TONY STEVENCON	AA	1249 Brussels	Et aint aintains	5/26
James Jaban	Ain It	101 Crestus sol a	Hen YA	5/26
Edward Dworkin	Edglis	620 Sutter St.	Been Smoking backwoods	5/26
SusieArdshir				5/26
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Gave Anderson	Ken HADD	990 Hoith Ave		maylg
Frank Pence Del		171 Red Hank Ct	We love Swishers	5/24
Tim Ekelers	July 1	645 Stockton		5301
Sarah Carlson	K Sphal	-350 TURK St	e-liquid helped me put	5/30
BASHIR MUSSA	73	280 BRIGHTON AVE	keeps me off ciggs	5/30/1
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ERIK KENTEY		1055 PINE	Segreation Enst	ingl Liture
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A Andrew P		601 Stockton St	NA	
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Andrew Rivers	and	297726th St		6/13/17
Javah Ramin	Juny 120	3915 Edgemos-p)	Sucks balls	64117
Michelle School	Widoffla	0424 Jones St. #201	~ ~ ~ ~ ~ ~ ~	0/14/17
William DEBOER	1 bh	1035 PINEST 94109		6/14/17
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ZACH GRIFFITHS	3pel)	535 Stockton St.	Ridiculous idea.	8/2	
George Ghazal	Suga Sh	56 milliam Street	you pulls are	5/3	
Zeren Emerso	n 3/2	755 Bush St.	Hello	5/3	
Antone	Attended &	2200 41=1 BUE		5/3	
David White	Dilmeti	97 Bay Wm	Let us be fre	5/2	
Ferus Kanlel	Jun /2	435 Stockton St		5/3	
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Freddy Rangel	200	3130 Oak Road	lame	515	
AND EN HOROUR		562 suffer	fight a better buttle	5/4	

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Jonathan Sullin	" "	621839 Leavenworth st #30.	This is Bacist	5/4/17
Pitakthai Dama	111	631 0' Farrill	Dont	5/4/15
MATT GOERZ		15 LINCOLD WAY	what the is the	5/4/13
Negonder Javier	Dual	1000 Van Noss Ave	Please Stop, Thank	5/4/17
KPAUS (10m)	Magg	989 Warket St.		5/4/17
BRYCE EVANS	bylined	215 SENECY AUT	DONT DO IT	5/4/17
SEREMY EVALS	TERENY EVAN	215 SENECK AVE	PLEADE NO!	5/4/7
blocking School	Vy SCA 32	1338 BATSIER	JUENSENO!	S(4/H
Vick ODA		634 pawell ST	' 1,	5/11/17
Javae Voyle	5 Oul Jee	cegoi sunkist DR	not cool	5/12/
Michael Cazores	1. //	6901 SUMLIST DE	What is the point?	5/1-11

Printed Name	Signature ,	Address	Comment	Date
Adneme UHE	1- Druf Ale	1125 East 18th St.		4/4/2017
Anthony KARRY	ANY KARR	1140 Clay st of	Whack attack Jack	W5/2017
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Sarah Morris		154 Coles St #2A	Honestly !?! No	
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Markus Pearly	Monogras	24 wentworth Pl		5/5/17
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	May Le Ceto	1790 SUNWYDALE		5/5/17
Ashley DekGue	O XIII CO	-275 Torks		\$/\$//7
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Marvin Vitable	1 Juni / Later		Not my Swishers!	5517
SunyOher	200	795 Spett the St	/	5/5/2017
Thomas Demps	ey Thomas engly	245 Rinceton St		5/5/17
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David Engel	T	427 Stockton St	Reef off my shir please! SF, CA ST	shers 51.71.7
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James Sniers	(1)	1481 De havo st	Stor Leng twats	5/5/17
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Toni Ashford	Tille	1713 Waller St.	not gonna Stop Smoti	5/8/
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SHAMPRTHAS	Sil	1520 Fillmore St.	Danit Poit!!!	5-8-17
Cynthia Soto	gothin Sto	1567162 md Ale Son Loone	to NO thanks	
Traci Cox	1- Cep	679 Pine St. S.F. CA 94/08		5/8/17
Frank C. Davis	All mos	679 Pine Sta 94108	Freedom weans your	5/9/17
Aptrew Benertd	03	955 Bush St, 94109	Freedom	5/4/17
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BEART ALEXANSON	a well	191 UNIVERSITY		5/4/17
full-e knox	MAX	417 Stockton	Gotel low set	5/9
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Michael GriAM	990) 375 Staten Ave., 6		5/11/1
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Melissa Hall	I WIS W	2021 26th St. #102, SF 941	UST STFU	5/11/17
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John Fuller		636 el camino re	ζ (> 1317

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Paul Giannini	Paul Hiennini	191 S Muglan		5/3
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Ryan Young	May of	417 Stockton St.	DO NOV 1.11	5/3/17
Marel Trojo	160	336 Bookford St.	Let it be fickers	5/3/17
Hange Wang		871 20 St CATAM	DONOT	5/4/17
Danny Bartist	DIBER	3 Depois Terroce	Don't do it.	5/11/
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Lorenzo Carbe	Complanto.	851 California St	Stop this nonsense	5/4/17
Robert Granniul-	R Drein	780 Post St.	Serrously's Un-America	5/4/17
Olison Direm		391 Seittn St	DO NOT	3/4/17
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Baldwin Dea Baldi	240 Spockton St.		3/4/1
Geben Crecy Bergerland	150 BUSH ST.	DO NOT	5-4-17
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VICK MAKAMOTO DUB NATE	636 Bush ST		94/17
Idrees Hollis Sholle	129 Majestic Ave	Don't Do It.	5/4/17
Jacky Chan John Chan	810 Dattery St. Ap+ 4804	1 No Chile	5/4//
Ken Lara 1/2-12	109 Plerce		5/4//
Alexander viver Duris So	2000 your Ness Ave	Please Stop Thinks	5/4/17
Phil Pinsley Philled	11 SANANTONIO PL		5/4/12
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Joseph Parly Quantum	4A San Antonio		
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Bassel Khoury	700/	1417 Castro		5-8-17	
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Printed Name	Signature	Address	Comment	Date
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The proposed ordinance (introduced April 18, 2017) amends the Health Code to prohibit local tobacco retailers from selling flavored tobacco products. The tobacco products that would be subject to the prohibition on sale would include, but not be limited to, flavored cigarettes, including menthol cigarettes, flavored cigars, flavored smokeless tobacco, flavored shisha, and flavored nicotine solutions that are used in electronic cigarettes.

Violation of the ordinance would be punishable by a suspension of the retailer's tobacco license, of which notice or time determination is left open ended in the legislation.

Summary of Petition: Ask the Supervisors and Mayor to Consider Industry and Community Impact before Voting We, the undersigned, are concerned business owners and operators who urge our leaders to consider the punitive impact this legislation will have on our San Francisco Small Businesses and our livelihoods.

This piece of legislation comes after a restriction on the resale of a Tobacco License (Health Code Article 19H), which is essentially a retirement value for store owners looking to sell their business, an increase in a Cigarette Litter Abatement Fee (60 cents/pack), i.e. for a convenience store with limited cigarette sales, this is a nearly \$800 check for a single quarter (revenue garnered from the Cigarette Litter Abatement Fee according to FY 15-16 Controllers Report amounts to \$6M +/- small tobacco retail license holders are paying the Department of Public Works annually). Additionally, the State Proposition 56 added \$2 to a pack of cigarettes, the BOE added 87 cents and a Floor Tax in which we have to pay the new tax on inventory held prior to the new law. The President of the Board, Supervisor Breed's Office is also looking to Ban Filtered Cigarettes altogether in a pending piece of Legislation. According to the Department of Public Health, the number of Tobacco Licenses per district is decreasing, undoubtedly this is due to loss of leases as a result of displacement and increased challenges to doing business. Stores like ours, are always the first and easiest targets in environmental and public health driven policies, and find that the bureaucracy and restrictions legislated at both State and City levels in this regard rarely account for the capacity of a small business. It saddens us that we are always juxtaposed as an enemy to the impacted communities in our City. We are part of these communities and spend every day serving these communities. San Francisco smoke shops and corner markets have not only complied, but supported Citysponsored and non-profit efforts over the past years to reduce signage, include healthier merchandising, reduce alcohol sales and availability, raise the Tobacco purchasing age to 21, etc. This Ban on Flavored Tobacco will affect ethnic and import stores, mom and pop markets, and convenient store/tobacco retailers, some of whom will be unable to sell up to 50% of their inventory or more.

2017 JUN 19 PM 4: 38

Printed Name Signature	Address	Comment	Date
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Man Firmet			
NAR FATTAIN Mentfertich	378 FILLMONEST		5/23/17
Michael Ronting	106. Chapery		5/23/17
Mohand Ahmal Schaffert	245 columbus AVE	·	5/23/217
Naji Elkhuri	35 Cambon Dr ST		5/23/17
mahmad IOUM m Stel	5155 3 RD ST		5-23-17
Pant- Boul	211 SPRUCE AVE		5-23-17
3:N Named	Same as above		5-23-17,
took Sur	3624 Balbon 94121		5/23117
Roger Kitorin Man	4692 Callan Blud		5/24
ANA D	DC 9401	<u> </u>	
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Printed Name	Signature	Address	Comment	Date
Anthonyweshap	Adlangastato	17 Dauble Rock St		427/17
Donble Rock Grocery		2830 Inealls St. 94124		4/27/17
HANNAFRE	is they	1300 Figgerald	42 K Terusalem	412717
Jamal Mohsin	Ju O	99 am Stret	3	842
Farhad Nabi	Freel	1135 market st.	National Dollar agan	zil, com
Khaldovn Madan	136	790 Silvu Ave	K madanal (2) has	5/3/17
VICTOR Care	Mil	3798 Missionst	New College Hill	Markel
AC MO	wish	201 Janus 84	084 Uguars	
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George Duran (2700	800 Valencia	geo-Duranayaha	5/4/17
Annas Kanawi -	- Church	2091 Mission St	Annaskanawi@yahoo	can 5/4/1
Ahmes Alkabha	AnonA	2007 Mission &	aatkablany agma	1. 1
SHAKIB KAWELY	1	12 Stockforth S.F.	Stopit	5/5/17
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à Koran Km	22	601 2nd AVE		5-24-201
Samle		1859 Marca.		5-24-20/
Marcos Lopez		2377 Spring ST	Don't Take them!	5/25/1-1
Sam Pah	Sub	milamatat 2200 sin		5.26.17
SAM BAR.	4/4	1700 relencie ST.		5/26/17
DAVID ZOUZOUNIS	1000	1530 Howard ST 94103		6-16-17
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Printed Name	Signature	Address	Comment	Date
Shauntis Konny	Shounts & Kong	1521 Ocean Avestica 94	No Changes 112 Needed	4-29-17
w. Michael		2290 San Bruns Wit	****	4-28-7
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The Consumer Advocates for Smoke-free Alternatives Association

www.casaa.org

4225 Fleur Drive #189, Des Moines, IA 50321

202-241-9117

June 14th, 2017

Testimony of Jennifer Berger-Coleman, CASAA Community Outreach Director San Francisco Board of Supervisors Public Safety and Neighborhoods Committee RE: Health Code - Banning the Sale of Flavored Tobacco Products (Opposed)

Chairwoman Ronin and distinguished Members of the Committee,

My name is Jennifer Berger-Coleman. I am the Community Outreach Director for The Consumer Advocates for Smoke-free Alternatives Association (CASAA). Thank you for the opportunity to speak to you today on behalf of our members in San Francisco.

CASAA has reviewed the proposed ordinance, which would prohibit the sale of flavored vapor products. We have identified a few key issues with this policy that we believe warrant the Committee's unanimous opposition to this bill.

By way of background, I started smoking when I was 15 years old--and I started long before there were any flavors on the market. My parents were both smokers and I took their Marlboro Reds. I smoked at least a pack per day for over 25 years. Over the years, I used all of the pharmaceutical options to try to quit smoking. I tried patches, gums, and anti-depressants. None of them worked. When I got my prescription of patches from my doctor, he told me to get cinnamon toothpicks and bags of fruit flavored hard candies to suck on. Flavors are important to quitting smoking no matter how you choose to do it.

20 years ago, my father was diagnosed with Buerger's Disease, a peripheral artery disease that requires a person to be a smoker as a matter of diagnosis. He was told to quit smoking, or risk limb loss. In the days before vapor products, his options were limited to nicotine patches and gum. Despite the medical threat he was facing, he could not quit smoking. He ended up losing both legs slowly over the course of many surgeries.

My doctors all told me that I had a very high likelihood of developing the same disease, as it tends to run in families and because I was a smoker. Despite this dire warning, the longest I was able to remain smoke-free was 3 days. In June 2015, I successfully made the transition completely from combustible cigarettes to vapor products.

Six months prior to switching to vapor products, I had purchased my first "cigalike" with tobacco flavoring. Not only did the taste not appeal to me, as tobacco flavoring is hard to replicate (because there is no tobacco in e-liquid), but the tobacco sensation and taste led to repeated relapses to smoking because I craved an actual cigarette even more. My success came on June 1st, 2015 after walking into my local vape shop and being allowed to sample the variety of flavors. Apple pie is the one I chose, and I haven't smoked a cigarette since.

From my own experience in my youth and as a parent--and from what we know empirically--a leading predictor of youth smoking is whether or not a parent or guardian smokes. In homes where parents smoke, young people perceive smoking as a behavioral norm. Moreover, family members who smoke, unwittingly, run the risk of becoming the primary supplier of cigarettes to youth. Denying these adults access to low-risk tobacco and vapor products that come in flavors other than tobacco creates unnecessary barriers to quitting smoking. Equally concerning, such policies perpetuate the risk that their children will initiate smoking.

As a lesbian, and LGBTQ acitivist, this issue is doubly important to me because of the disproportionately higher smoking rates in the LGBTQ community. According to the CDC, 23.9% of LGBTQ adults are smokers as opposed to 16.6% of heterosexual adults. 6.2% of San Francisco residents identify as LGBTQ--the largest percentage in the country. Historically, LGBTQ people choose to live in San Francisco because of the city's progressive policies that offer acceptance and protection and promote harm reduction strategies to improve public health.

Once again, the LGBTQ community is looking for leadership from the Board of Supervisors in addressing a public health issue that impacts us more than our heterosexual counterparts. It is vital that this committee and the rest of the Board of Supervisors consider all of the evidence regarding tobacco harm reduction and resist the urge to adopt policy based on the emotional appeal of protecting children.

The variety of flavored vapor products plays a vital role in helping adult smokers transition to a smoke-free product.

In December of 2015, CASAA conducted a survey of our membership regarding e-cigarette use. The survey results are based on over 19,000 observations from our target population of CASAA members living in the United States who were regular users of e-cigarettes, the vast majority of whom were between the ages of 26-55.

Survey participants were asked specific questions regarding the role that interesting flavors play in how they use vapor products. Overwhelmingly, 72% of respondents who have quit smoking entirely credit interesting flavors with their success (Phillips, 2016).

Prohibition of flavored vapor products from the legal marketplace will force many consumers to purchase products on a newly created black market.

CASAA's survey also asked participants to contemplate a scenario in which flavors other than tobacco and menthol were banned in the United States. Predictably, an overwhelming majority (89%) of respondents indicated that they would turn to a domestic black market to purchase products, make flavored e-liquid at home, or purchase from overseas sources.

When contemplating a ban on flavors other than tobacco and menthol, 14% of respondents who had completely quit smoking indicated they would likely start smoking again, something I think we can all agree would be a blow to genuine public health. In another survey from 2013, 37% of respondents indicated that a lack of flavor variability would make it less likely that they would successfully quit smoking. 48% of respondents indicated that restricting flavors would increase their cravings for traditional combustible cigarettes (Farsalinos, 2013).

The success of a ban on flavored tobacco and vapor products is dependent on preventing young people from initiating smoking. This law will do nothing to support smokers who might attempt to quit. In fact, this law will deny smokers access to alternatives to smoking and demand that they use products which have an established dismal success rate. Although studies show that nicotine replacement therapy (NRT) or prescription medications in combination with professional support and counseling can improve success, it is fair to note that such resources are typically employed by only the heaviest smokers. These types of resources are also not necessarily accessible to lower income smokers who make up a disproportionately higher percentage of the smoking population.

Meanwhile, traditional cigarettes remain the most visible and popular way to consume nicotine. Although retailers face serious penalties for selling cigarettes to anyone under 21, social and family sources cannot be effectively policed.

Royal College of Physicians urges public health professionals and governments to promote vapor products to adult smokers.

In April, 2016, the Royal College of Physicians (RCP) — whose groundbreaking 1962 report linking smoking to a host of diseases predated the U.S. Surgeon General's by two years —

released an extensive 200-page report on vapor products. The RCP concluded that vapor products should be promoted widely to smokers as a viable alternative to smoking. To date, the RCP report is the most comprehensive review of the the science, public policy, regulation, and ethics regarding vapor products. The RCP's conclusions include:

- "E-cigarettes are not a gateway to smoking Use of e-cigarettes is limited almost entirely to those who are already using, or have used, tobacco.
- "E-cigarettes do not result in normalisation of smoking there is no evidence that
 either nicotine replacement therapy (NRT) or e-cigarette use has resulted in
 renormalisation of smoking. None of these products has to date attracted significant
 use among adult never-smokers, or demonstrated evidence of significant gateway
 progression into smoking among young people.
- "E-cigarettes and quitting smoking among smokers, e-cigarette use is likely to lead to quit attempts that would not otherwise have happened, and in a proportion of these to successful cessation. In this way, e-cigarettes can act as a gateway from smoking.
- "E-cigarettes and long-term harm the possibility of some harm from long-term e-cigarette use cannot be dismissed due to inhalation of the ingredients other than nicotine, but is likely to be very small, and substantially smaller than that arising from tobacco smoking. With appropriate product standards to minimise exposure to the other ingredients, it should be possible to reduce risks of physical health still further. Although it is not possible to estimate the long-term health risks associated with e-cigarettes precisely, the available data suggest that they are unlikely to exceed 5% of those associated with smoked tobacco products, and may well be substantially lower than this figure." (RCP, 2016)

FDA Deeming.

The FDA deeming regulations are unjustifiably heavy handed and will result in 99% of the vapor industry being shut down. However, the agency made a conscious decision to NOT prohibit the sale of flavored vapor products. The FDA openly acknowledges that a variety of flavors may be helpful in transitioning smokers to less risky vapor products (FDA, 2016, 81 FR 29011).

Recommendation

On behalf of our members in San Francisco, CASAA urges the Committee to reject this ordinance and any legislation that would limit the variety of smoke-free tobacco and vapor product flavors. However, if the Committee is inclined to keep debate on this issue alive, we strongly urge you to follow the lead of the FDA and hold this proposal for further study.

References:

Phillips, Carl V. "CASAA Ecig Survey Results." Antithrlies.com. Carl V. Phillips, 4 Jan. 2016. Web.

Farsalinos, Konstantinos et al. "Impact of Flavour Variability on Electronic Cigarette Use Experience: An Internet Survey." IJERPH 10.12 (2013): 7272–7282. CrossRef. Web.

Royal College of Physicians. "Nicotine without smoke: Tobacco harm reduction." London: RCP, 2016.

US Food and Drug Administration. "Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products." Federal Register. National Archives and Records Administration, 10 May 2016. Web. 15 May 2016.

Members of the Board,

I have been operating a liquor and convenience stores in San Francisco for many years now and we have developed a loyal customer base at each of our locations that we hope to continue for years to come. Unfortunately, when we learned our Board of Supervisors are considering a ban on Flavored Tobacco Products and menthol cigarettes, it would seem our local government wishes to end these relationships. If we are unable to provide products like flavored tobacco and menthol cigarettes then we are no longer going to see these customers in our store, period. Consumers are going to head outside of the Bay area or get them illegally from someone who has brought the product in from somewhere else, which is a lose-lose for us and the city. Along with the loss in small cigar sales and menthol cigarettes, we will see all related sales disappear as well; no liquor, wine, beer, soda, etc. as those purchases will be made where they can buy flavored tobacco and menthol cigarettes, you are naïve to think otherwise.

I urge the Supervisors to consider the amount of product this ordinance would affect, the money the city and its businesses will lose, and then the jobs in the retail, manufacturing, and distribution of these products that would be lost as a result. I'd then ask that each Supervisor go to a retailer in your district and tell them we are taking over a third of your profits out of your store, for a cause that we have no proof will have its intended effect, and see how they react. It is legislation like this that is destroying the personal liberties that made this country great; which allowed its citizens to CHOOSE whether to do something, and relied on education, not legislation to quide the decisions we make.

Sincerely,

Tareq Manaa
Drumm Liquor & Deli
15 Drumm Street
San Francisco, CA 94111

Supervisors,

I am writing to urge you to vote against the menthol and flavor ban ordinance. It would be very bad for my business and my customers will be very upset if they can't get these products in San Francisco.

Many people have high blood pressure or high glucose levels and their doctor tells them to avoid eating salty and sugary foods. They know it is bad for them and if they keep eating salty and sugary food though it could lead to a stroke, diabetes or a number or other ailments. Does this stop them? Sadly, it does not.

The same can be said for my customers who smoke. They know that smoking is not good for their health. They know they should quit and if they don't bad things could happen to them. Just like the person who eats to much salt or sugar, they do it anyway.

If the city banned salty and sugary food, they'd just buy it somewhere else. My customers will go elsewhere to buy their cigarettes too.

While the intent of this ordinance is noble, the reality is that it will do nothing to change the behavior of smokers. The only thing this ban will definitely do is harm businesses. I urge you to vote no.

I appreciate your attention to my comments.

Sincerely,

Tareq Manaa Soma Wine and Spirits II 689 Folsom Street San Francisco, CA 94107

Supervisors,

I own several liquor store and wine shops in San Francisco that sell tobacco and I am shocked to learn that you are thinking about banning the sale of flavored tobacco and menthol cigarettes in the city.

I do not understand why the city would do this when the price of a pack of cigarettes just increased by \$2 per pack and the state raised the age to purchase to 21. Isn't that enough?

Please don't try to say that you are doing this for the children. They don't buy cigarettes from me or from any other retailers I know.

Owning and operating a viable small business is difficult. Taking legal products off my shelves makes it even more difficult to stay afloat. How will the city compensate me and other business owners for lost revenue or lost businesses due to your sales bans?

I urge you to vote NO on this unnecessary and discriminatory ordinance. Thank you.

Sincerely,

Tareq Manaa Soma Wine and Spirits 600 Folsom Street

San Francisco, CA 94107

To: San Francisco Board of Supervisors Re: Vote no on Flavored tobacco ban

I will be unable to attend the hearing on Wednesday as it is at 10:00 in the morning, probably the worst time of day for retailers to leave their stores but I want to make sure that you and other members of the Board know that I am very opposed to flavored tobacco and menthol ban you will be discussing.

I am disappointed that the city did not have the courtesy to alert businesses to let them know that this ordinance was being discussed and have it during the evening hours when more of us could attend. While you may not think this is a big deal, it is for the many storeowners that sell tobacco.

Running a small, independent business is a difficult task. Our profit margins are thin and the sales bans you are proposing in your tobacco ordinance will wreak havoc on our business.

In the past several months, we have been hit with a \$2 tax increase on cigarettes, the legal age to purchase has been raised to 21, and in July, the taxes on other tobacco products like chewing tobacco and cigars will increase. This is on top of the soda tax passed last year.

While larger stores have a greater ability to absorb these types of tax increases and sales bans, smaller stores like mine struggle to make ends meet.

Many of my customers are on fixed incomes and tax increases and sales bans have a disproportionate impact on their lives. Some of my customers do not have cars so if I am no longer able to sell the products they desire, they cannot drive to the next town to purchase what they want.

I suspect that many of these customers will have no alternative but to turn to the black market to purchase the tobacco products you propose to ban.

I urge you to remove the sales bans included this ordinance.

Regards,

Tarek Manaa Bel Clift Market 516 Geary Blvd. San Francisco 94102

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I urge you to vote NO on this unnecessary and discriminatory ordinance. Thank you.

Sincerely,

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Eddys 951 loving SF CA

Members of the Board,

I operate a convenient store in your district and was very alarmed to hear the Board of Supervisors are considering a ban on flavored tobacco products and menthol cigarettes. If this were to pass my business would take a hit that I'm not sure it could recover from. Flavored tobacco products and particularly menthol cigarettes are what get customers in the door and drive our other sales (food, drinks, etc.). Without these products, we lose those customers and everything they buy, not just tobacco.

What is the justification for removing these products which are only sold to adult consumers who are 21, (the same as alcohol) and show proper identification? I have been told that it is to keep kids from using tobacco but meanwhile kids are dying everyday from taking illegal drugs (opioids and heroin), or driving a car while intoxicated, things that kill instantly, unlike tobacco and vapor products, yet you hear nothing from our Supervisors and Health officials on these issues. Instead they want you to consider removing legal products from legitimate tax paying retailers while criminals continue to plague this area and are a much larger threat to our youth. You are basically writing a check to the criminals who will no longer be able to sell marijuana once it becomes legal next year and will thank cities like San Francisco for banning products that they can now sell on the street (menthol cigarettes and flavored tobacco) to recover what they are going to lose in illicit marijuana sales.

This ordinance is nothing more than a business killer and would cost the city valuable tax dollars, jobs, and business owners will be forced to either move or close, that is how much retailers rely on these products, as was seen recently in San Leandro.

Thank you for your time,

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150 Beecon St

SF, CA

Re: Vote no on Flavored tobacco ban

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I suspect that many of these customers will have no alternative but to turn to the black market to purchase the tobacco products you propose to ban.

I urge you to remove the sales bans included this ordinance.

Regards,

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San Prozestse

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Cigarettes For less 1053 Market St SF CA 94/03

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2/96 mission ST

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Postern Polk & Clay Liquer 1700 Polk St SF 94109.

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FREDS LIQUOR 151 SIXTH ST SAN FRANCISSED Ca 9418

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Albertino

Market

897 Lambard

S.C. OA. 92/942

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900 Post st. S.E. CA.

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Ali Elmuflihi
paradise Coffice Colomts
453 ofarrell st 51

OA 94102

Ch Mallisto

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Stagi 's Liquers 3055 16th St. SF. Ct 94103

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The Silver platter 251 Van Noss Are SI

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AVID'S FOOD STORF 612 Kearny St. St. CA 94/08

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OLLALOMA MKT.

255 PORTO CA PR. 5F. CA. 94/2)

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NEWSTAR-ELL

ASSZAN JOB MASSZA

501 PIVISODEROST -

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MATURAL

2201 PINE ST S.E CA 94115

2803

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Decomere Market pool Volencia St

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Fog Zone 5420 Coast Hwy Pacifica CA 94044

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Me OLoomy 539 haight SF 94117

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Lowell Market Gol Brunswick St

S.F CA 94112

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ROXUT

ROXU FOUD CENTER CA 94112

1901 SAN JGSIE AVE SIE CA

2808

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SF, CA 94132

Herb n' Legend 35 Cambon Dr.

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FREMIA MARPLE

1499 HONE AM S.

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Thank you for your time,

Abdeh SAADOUNE WharFliquoRs 2730 TayloR street SF. (A9A133

Supervisors,

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I urge you to vote NO on this unnecessary and discriminatory ordinance. Thank you.

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Sylvano Market 3398 Luenost

2813

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CADILLAC MILT 499 Eddy St

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Thankyou for your time,

A & N Liquors
1521 ocean Ave

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I urge you to vote NO on this unnecessary and discriminatory ordinance. Thank you.

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Daves Food Store
1601 John St SF 94107

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SHARMAN MARKET 1598 UDION ST

Re: Vote no on Flavored tobacco ban

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I am disappointed that the city did not have the courtesy to alert businesses to let them know that this ordinance was being discussed and have it during the evening hours when more of us could attend. While you may not think this is a big deal, it is for the many storeowners that sell tobacco.

Running a small, independent business is a difficult task. Our profit margins are thin and the sales bans you are proposing in your tobacco ordinance will wreak havoc on our business.

In the past several months, we have been hit with a \$2 tax increase on cigarettes, the legal age to purchase has been raised to 21, and in July, the taxes on other tobacco products like chewing tobacco and cigars will increase. This is on top of the soda tax passed last year.

While larger stores have a greater ability to absorb these types of tax increases and sales bans, smaller stores like mine struggle to make ends meet.

Many of my customers are on fixed incomes and tax increases and sales bans have a disproportionate impact on their lives. Some of my customers do not have cars so if I am no longer able to sell the products they desire, they cannot drive to the next town to purchase what they want.

I suspect that many of these customers will have no alternative but to turn to the black market to purchase the tobacco products you propose to ban.

I urge you to remove the sales bans included this ordinance.

Regards,

m-fell All Nite Pegga & Food 5155 3 RD ST SF C494124

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Mission Smoke Shop 2059 Mission St

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I urge you to remove the sales bans included this ordinance.

Regards,

SAU MORE MARK 4500 3RD Street S.F. CA 94124

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Saw S Grocery
1461 Grant Ave
S.F. CA 94133

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optown Market 684 Lankin St.

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I urge you to vote NO on this unnecessary and discriminatory ordinance. Thank you.

Sincerely, Michael Routs Cheneny Mankot

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Sincerely, 691 Periods PAINCE

Good morning Members of the Board of Supervisors....

I am Dr. Michal Foriest Settles, a SF homeowner.

The topic today is an emotional one. Your role in setting public policy is vital in this health debate.

My story goes back decades when another related public policy was established. The United States military's smoking policy at the time was for US service men to be provided chocolates and cigarettes...all issued by the US Army.

My Dad, Mark Anthony Foriest, was one of those young soldiers serving in the Korean War. Decades later my Dad died of emphysema (a condition in which the air sacs of the lungs are damaged and enlarged, causing breathlessness and ultimately the collapsing of the lungs and death) following decades

of addiction to cigarette smoking resulting from an ill- conceived public policy. He died at age 50. He did not see his children graduate from college, he did not know any of his grandchildren or great grandchildren. He did not collect a pension nor collect social security. His passing left my Mother a widow at 49 years of age.

Now you have an opportunity to set public policy as well. Please **reflect long and hard** on your decision and its impact on individuals and their children, decades later.

Please vote "YES" on this measure. It is one small step in protecting the youth we say we value. Let us show the youth of this community our words have real meaning.

Thank you.

African Ame_ican Tobacco Con_ol Platform



The African American Tobacco Control Leadership Council

45,000 African Americans continue to die each and every year from tobacco related illnesses. Yet our community has never mounted a true concerted effort to rid our community of its number one killer, tobacco! Our community faces many daunting challenges, but we cannot afford to watch another generation of our children become the replacement smokers for those who have already died.

"Stand UP!"

We have the power to create a safe, happy, healthy, and prosperous community.

The AATCLC is available to:

- > Provide community education
- Coordinate meetings with health professionals, civic leaders, and grassroots organizations
- Provide relevant expert testimony
- Conduct or stand with you in press conferences, webinars, and media events

For More Information Call 888.881.6619



WWW.SAVINGBLACKLIVES.ORG

African American Tobacco Control Platform

- 1) Protect our Children by making tobacco use and the predatory marketing of flavored tobacco products one of the top five priorities facing our community.
- Work within our own organizations and religious institutions to mount a sustained and comprehensive campaign against the tobacco industry.
- 3) Understand that predatory marketing and tobacco use perpetuate poverty in our communities.
- 4) Hold the tobacco industry responsible for the irreparable harm that has been done to our community.
- 5) With the support of elected officials, develop a comprehensive tobacco control platform that will eventually reduce tobacco related illness and improve health equity in the African American community.
- 6) Demand adequate funding for tobacco prevention programs and culturally appropriate services to help people stop smoking.
- Educate all organizations and institutions that serve African
 Americans on how to adopt a non-acceptance of tobacco industry sponsorship/contributions policy.
- 8) Support raising the price of ALL tobacco products, especially cheap unregulated tobacco products that inundate African American and Latino communities. These products include little cigars, blunt wrappers, and cigarillos such as Black N Milds, and Swisher Sweets. Increase legal age to purchase tobacco to 21.
- 9) Prohibit the sale of all flavored tobacco products, including menthol cigarettes.
- 10) Support and demand smoke free multi-unit housing and other protections against secondhand smoke exposure.

Dear Board of Supervisors,

My name is Ethan, and I am an 19 year old that vapes. I do not purchase things illegally with a fake ID or anything of that sort. However I get all the equipment with my mother purchasing the items for me. My mother had no problem with me vaping because of my academic success. I graduated High School with a 3.89 cumulative GPA and I am currently majoring in mechanical engineering with a cumulative 3.34 GPA. I started vaping as a choice, it had nothing to do with the flavors or juices or anything like that. I also personally vape a very low to no nicotine. I was never a fan of nicotine so I just vape just as something to pass the time. Taking away flavor juices is probably a huge mistake that could be made. Just because a product is flavored does not mean its main intent is to reach out towards kids or minors. If that were the case, the sales in just tobacco flavored juice would still be higher than the flavored ones. Its a flavor, like ice cream, gives people variety. People today like having options for anything.

Current SF resident, Ethan

PETITIO V

TO THE SAN FRANCISCO BOARD OF SUPERVISORS

The Petition of certain citizens of the San Francisco Bay Area draws to the attention of the San Francisco Board of Supervisors:

We, the following, are over the age of 21, taxpaying, and voting citizens who believe that it is strictly the responsibility of the retailers and parents/guardians to deny access to tobacco products to minors. We believe that clucation and awareness should be increased to prevent minors from obtaining tobacco products, however, we do not believe that denying the sales of flavored tobacco products, directly impacts youth smoking rates. We believe in freedom of choice, and this includes our consumed products tobacco and otherwise.

The Petitioners therefore request To Deny BOS File No. 170441 – Ordinance amending the Health Code to prohibit tobacco retailers from selling flavored tobacco products, including menthol cigarettes.

Name/Business	Address	City/County	Post Code	Signature
1. Dexter Taylor	2469 Son Bruno AUE	Sen Fearcisco	9,4134	Que B. Tayon
2. Tracy () mer	un 20 Papresale Are	DalyCet	194575	
3. Shawin Sun	1714 Byd Ave	Son Marcisco	Jun -	Gulwar
4. Asthray Carosofly	616 Miraway Ave	San Francisco	19412	30
5. Angus Cang	79 Dorado Terrace	San Francisco	94112	Maryton
6. TONNE MILLER	3 × × × × × × × × × × × × × × × × × × ×	SF	941112	O. A.
7. STEFAN SIMIFICH	422 VICTORIA ST.	SF	94132	
8. Brian Park	2751 42nd are	\$F	24116	Dr. Jan
9. Emma Care	77 lakeview Ave	SP	94112	Expo
10. Daniel Arangs	61- Potomac-St	SF	94117	121-4
11 Rory Timer	1942 34th ar	SF	<u> 1</u> 4116	3 1
12: Tristin Eng	32 browle sp	SF	94110	inj
13. In My Metus	352 Brishton Ave	SF	94112	Inwa
14. Matha kyhr	NO Sun Rabel Lyn	SC	94/27	h
15. Mess Enlas	576 Belllove Blod	LB	90814	Co
16. Color Parker	270 GRANADA AVE	SF	94112	Ties flavors
17. Alex Medrives	352 BRIGTONAVE	5 P	94112	Sufare 2
18. Leo Volobrynsky	2412 28th AUE, Ap+#1, SF	SF	94112	Bot
20. Jacob leterson	1460 Wave Crest ave Spot P	HMB	94019	Sacol flat

ETITION

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1. Alovon Knua	137318 Palmetto Ave	Pacifica	94094	Cuiron
2 Thomasler Gieger	42 De Montfort ave.	San fran	1.5.2.5	6/42617
3. Sonja Lyobinko	vic 145 Lisbon st	San Franc	50094112	000-94/
4. Alad GARLAND	145 LISBON ST.	SAN FRANCISA	94112	3
5. Nicole Zamignan)	727 Holloway Ave	Santrancisa	94/12	A STATE OF THE STA
6. Phillipe Favi gran	227 Holloway Ave	Sentancisco	94112	10
	58 West Portal Ave	Say Francisa	94127	Regarded Jalains
	7/859 30Th ave.	San Francis	co 94122	July -
9. AUS Lin Bran	178 R. D. Sheellave	Sanfran	94111	
10. Helen kvang		San Francisco	94134	
	379 FAXON AVE	Saw Franks	94112	
	350 Arbailo Dr. Apt IIK BEC	& Son Francisco	94135	Luin
13.Melanie Kristense	n 15939th Avenue	Santrancisco		Mound
14. Nick Lawart	239 N. Kenmove	Los Angeles	90064	
15. M. Cober	2545 45th Ap	SF.	94116	Office Co
16. Gina Gulyers	2567 21st Aue	SP	9416	fine for
17. ERICA Eappin	2562 21St Ave	SE_	9416	au
18. Sean Thomas	4021 Lincoln Way #2	5/2	94122	2
20. MACISSI SAN PEN	n 182 TRUMBULL ST SF 941	12 SE	94112	Illin Ayland
	- 20	002	Z. 34	

ETITION

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Name/ asiness	dress	City, County	Post Co. 3	Signature
1. DAN CRITES	436 CAYUGA ACE	St. St.	94112	2
2. CHANLES DELEON	Participa o	SF SF	94116	In State of the st
	777 victoria Strect	SF SF	94127	soft liter
	1101 19th Avo	SF	94132	hope Menly
	1575 26+4 Ave	SF	94122	mag.
6. STELEN JEE	1410 292 AVE	SE	94122	Styning
7 SAYR BUENAVENTURA	1213 C ALLAN BLVD	Daycog	9908	
8. Ton Within	8/3 Shields St		94132 -	
9. Bandenland	145 Kenwa02	\$	94127	
10. NI Corde	69 tairtield	<u> S/</u>	9412	As the second
11. Mak Vivent	2225 16M AV	1 SF	94/16	W Vin Mist
12. Andrew Shin	338 Staples: Ave.	SF	94112	arburgh
13 CHRIS CHANG	4114 CACIFORNIA ST	8-	94114	
14. Kun Common	1451 22nd We	85-	94122	Y
15. Andre Smith	IN Albarross G	SIF	94124	
16. DAVID SOK	491 EPINBURGH ST	SF	94112	
17. Dyan Novero	1623 25th Ave	SE	94127	Thymas
18. Zhas XL	1372 7th Arc	SF.	99122	
20. Alex Poberesta	590 464 Ave.	76	194121_	

PETITIO |

OTHE SAN FLANCISCO BOARD OF SUPERVISORS

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PETITION

TO THE SAN FRANCISCO BOARD OF SUPERVISORS

The Petition of certain citizens of the San Francisco Bay Area draws to the attention of the San Francisco Board of Supervisors:

We, the following, are over the age of 21, taxpaying, and voting citizens who believe that it is strictly the responsibility of the retailers and parents/guardians to deny access to tobacco products to minors. We believe that education and awareness should be increased to prevent minors from obtaining tobacco products, however, we do not believe that denying the sales of flavored tobacco products, directly impacts youth smoking rates. We believe in freedom of choice, and this includes our consumed products tobacco and otherwise.

The Petitioners therefore request To Deny BOS File No. 170441 – Ordinance amending the Health Code to prohibit tobacco retailers from selling flavored tobacco products, including menthal cigarettes.

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STATE OF CALIFORNIA TOBACCO EDUCATION AND RESEARCH OVERSIGHT COMMITTEE

MEMBERS:

MICHAEL ONG, M.D., Ph.D. CHAIRPERSON Assistant Professor in Residence Division of General Internal Medicine and Health Services Research Department of Medicine University of California, Los Angeles

LOURDES BAEZCONDE-GARBANATI, Ph.D., M.P.H., M.A. Professor in Preventive Medicine, Institute for Health Promotion and Disease Prevention Research Director in the Center for Health Equity in the Americas University of Southern California

RICHARD BARNES, JD Consultant

VICKI BAUMAN Prevention Director II Stanislaus County Office of Education

PATRICIA ETEM, M.P.H. Executive Consultant CIVIC Communications

ALAN HENDERSON, Dr.P.H., C.H.E.S. Professor Emeritus California State University. Long Beach

DEBRA KELLEY Advocacy Director American Lung Association in California

PAMELA LING, M.D., M.P.H. Associate Professor Department of Medicine University of California, San Francisco

WENDY MAX, Ph.D. Professor in Residence and Director Institute for Health Aging University of California, San Francisco

ROBERT OLDHAM, M.D., M.S.H.A. Public Health Officer and Public Health Division Director Placer County Department of Health and Human Services

MARY BAUM Program Manager Alcohol, Tobacco and other Drug Prevention Program Social Advocates for Youth (SAY) San Diego

CLARADINA SOTO, Ph.D., M.P.H. Assistant Professor University of Southern California Keck School of Medicine

MARK STARR, D.V.M., M.P.V.M. Deputy Director for Environmental Health California Department of Public Health

November 21 2016

President Barack Obama 1600 Pennsylvania Avenue NW Washington, DC 20500

RE: Support banning all flavors, including menthol, from tobacco products.

Dear President Obama:

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 99 tobacco tax revenues for tobacco control, prevention education, and tobacco-related research in California. TEROC advises the California Department of Public Health, the University of California, and the California Department of Education with respect to policy development, integration, and evaluation of tobacco education programs funded by Proposition 99. TEROC is also responsible for the development of a master plan for the future implementation of tobacco control and tobacco-related research, and making recommendations to the State Legislature for improving tobacco control and tobacco-related research efforts in California.

At the September 29, 2016, TEROC meeting, members became aware that the African American Tobacco Control Leadership Council (AATCLC), along with several key public health stakeholders, sent a letter to your administration asking for removal of all flavored tobacco products, including mentholated cigarettes, from the marketplace. **TEROC supports this request and urges your administration to ban all flavors, including menthol, from all tobacco products.**

Flavored tobacco products disproportionately affect certain priority populations (e.g., low-income, racial/ethnic minorities, young adults, and Lesbian Gay Bisexual and Transgender individuals) and they entice and encourage youth and young adults to use tobacco products. In 2014, an estimated 70 percent of middle and high school students who had used a tobacco product in the past 30 days had used a flavored tobacco product within this period. Additionally, menthol cigarettes are advertised more frequently and cost less in African American and in low-income neighborhoods. Not surprisingly, more than 80 percent of African American smokers smoke mentholated cigarettes compared to 26 percent higher than whites.

Flavored tobacco and menthol are a public health risk that attract new smokers and disproportionately affect certain populations. Menthol smokers show greater signs of nicotine dependence, have higher rates of quit attempts, and are less likely to successfully quit smoking than other smokers. Consequently, these smokers will have a higher risk of tobacco-related disease. Banning all flavored tobacco products would reduce prevalence of smoking and use of tobacco products among vulnerable populations, while improving health for all Americans.

President Barack Obama Page 2 November 21 2016

Although the 2016 Final Deeming Rule gave the United States Food and Drug Administration (FDA) regulatory authority over all tobacco products, including e-cigarettes, all cigars, hookah, dissolvables, and novel future tobacco products, the FDA did not include menthol in the definition of characterizing flavors. Therefore, **TEROC urges your administration as a final act to direct the FDA to issue a proposed rule to remove all flavored tobacco products, including menthol, from the market.**

Banning flavors, including menthol, from all tobacco products is consistent with TEROC's 2015-2017 Master Plan, Changing Landscape: Countering New Threats, Objective 5: Prevent Youth and Young Adults from Beginning to Use Tobacco and Objective 7: Minimize Tobacco Industry Influence and Activities. Strategies in support of Objective 5 include combating tobacco industry actions such as marketing of e-cigarettes, flavored tobacco products, and any other product that either entice or engage youth in tobacco initiation. Under Objective 5, TEROC requests that all organizations involved in tobacco control urge the FDA to ban menthol cigarettes and all other flavored tobacco products. Similarly, under Objective 7, TEROC recommends that the FDA ban all flavored and menthol tobacco products, including smokeless tobacco, cigars, and e-cigarettes containing nicotine.

Your leadership to help reduce the uptake of tobacco products and save lives by banning flavored tobacco products is greatly appreciated. If TEROC can provide further information that would facilitate your decision-making regarding this matter, please feel free to contact me directly at (310) 794-0154 or via e-mail at mong@mednet.ucla.edu.

Sincerely,

Michael Ong, M.D., Ph.D.

Chairperson

CC:

CC:

Cecilia Muñoz, Director, White House Domestic Policy Council Congressman G. K. Butterfield, Congressional Black Caucus Dr. Robert Califf, Commissioner, Food and Drug Administration Joe Biden, Vice President

Michelle Obama, First Lady

Mitch Zeller, Director, Center for Tobacco Products, Food and Drug Administration Shaun Donovan, Director, Office of Management and Budget Sylvia Mathews Burwell, Secretary of Health and Human Services



May 8, 2017

Supervisor Malia Cohen 1 Dr. Carlton B. Goodlett Place City Hall Room 244 San Francisco, CA 94102

Dear Supervisor Cohen-

We write on behalf of the San Francisco Tobacco-Free Coalition in support of the proposed ordinance that would end the sale of menthol and flavored tobacco products by amending the health code. We are grateful for your bold leadership on this issue, taking on powerful interests as you prioritize the health and well-being of San Francisco youth and adults. We continue to needlessly lose so many people to tobacco-related disease, given that there are approximately 480,000 deaths in the United States every single year related to tobacco.

According to national data and research, 90% of smokers start smoking by the age of 18. Those who start at a younger age tend to be heavier and long term smokers, which leads to higher risk of tobacco-related health problems such as cancer and heart disease. Youth who smoke are also at risk for increased blood pressure, asthma, and reduced lung growth. Exposure to and use of nicotine before 25 years of age has long-lasting negative impacts on adolescent brain development.

Menthol and flavored tobacco with colorful packaging is used by the tobacco companies to attract young people. As tobacco companies know, menthol cools and numbs the throat, reducing irritation, making menthol an appealing option for young people who are initiating tobacco use. 81% of youth who have ever tried a tobacco product report that the first tobacco product they used was flavored. Menthol, candy and fruit flavors proliferate in the marketplace.

The proposed ordinance would have a significant impact on the health of this generation of youth. Decreasing smoking rates also equates to lower direct and indirect health expenditures for individuals, families and the City and County of San Francisco. Researchers at the University of California, San Francisco estimated that the cost of smoking in San Francisco amounted to over \$380 million per year, including direct health care costs and indirect costs from lost productivity due to illness and premature death. Eliminating the sale of menthol and flavored tobacco products would be beneficial for the health and economic well-being of San Franciscans.

This ordinance would add to San Francisco's history of advanced tobacco policies which protect our youth from a lifetime of addiction, poor health, and possibly death and ensures the health of future generations. For these reasons, we are honored to support the proposed ordinance.

Tonya Williams, MPA

In Parison

Bob Gordon, MPH

Co-Chairs of the San Francisco Tobacco Free Coalition

Coalition Member Organizations: African American Tobacco Control Leadership Council (AATCLC) ·American Cancer Society Cancer Action Network (ACS CAN) · American Heart Association · American Lung Association · Americans for Nonsmokers' Rights · Bay Area Community Resources (BACR) · Breathe CA – Project E-NUFF · Bright Research Group · California LGBT Tobacco Education Partnership · Coalition of Lavender-Americans on Smoking or Health (CLASH) / The Last Drag · Freedom from Tobacco · San Francisco Cancer Initiative (SF CAN) · San Francisco University Student Health Services · San Francisco Unified School District Health Programs (SFUSD) · UCSF Center for Tobacco Research and Education · Vietnamese Youth Development Center (VYDC) · Youth Leadership Institute (YLI)



Empowering Youth. Transforming Lives.

5th May 2017

Supervisor Malia Cohen 1 Dr. Carlton B. Goodlett Place City Hall Room 244 San Francisco, CA 94102

Dear Supervisor Cohen,

I am writing to express Vietnamese Youth Development Center (VYDC)'s support for the policy impact of ending the sale of flavored tobacco in San Francisco. VYDC has a proven record of accomplishment working with the youth in the areas of tobacco use prevention, leadership, and policy advocacy. Our mission is to empower under-served Asian Pacific Islander and urban youth with knowledge and confidence to define their future and reach full potential.

Current data shows that flavored tobacco products have been especially targeted at youth of color, and menthol cigarettes harm youth across our community in the Tenderloin. Tobacco products with menthol, flavors and colorful packaging are designed to attract young people. An alarming 95% of African American teen smokers and 60% of Asian American teen smokers use menthol cigarettes. VYDC prioritizes the health and safety of our community over tobacco industry's 'special interests'. Therefore, we support the ongoing efforts leading up to policy ban, as we believe that regulating the sale of flavored tobacco will help mitigate the harmful impact of smoking on young people's lives.

I look forward to our continued partnership on this very important issue.

Sincerely,

Judy Young

Executive Director

Judyu of

Vietnamese Youth Development Center



May 25, 2017

Ending the Sale of Menthol and All Flavored Tobacco

RE: Support for San Francisco Supervisor Malia Cohen's ordinance

As an organization working for 25 years to eliminate tobacco-related harms, the Coalition of Lavender-Americans on Smoking & Health (CLASH) is pleased to sign on as a supporter of Supervisor Malia Cohen's proposed ordinance that would end the sale of all menthol and flavored tobacco products in San Francisco.

This ordinance will save lives. Menthol is training wheels for new smokers. It makes it much easier to tolerate the harshness of tobacco and pick up the habit. It also enhances the impact of nicotine and makes it harder to quit. More than 70% of smokers wish they didn't smoke and a majority of smokers support tobacco control measures in order to help them quit. If menthol is taken off the market, quit rates will rise and initiation will drop.

When Congress gave the FDA authority to regulate tobacco in 2009, menthol was initially included among all the other flavors that would be eliminated from the market because they lure kids. Philip Morris/Altria supported the bill because they saw FDA regulation as inevitable and wanted a hand in shaping it. They threatened to kill the bill if menthol was no longer available. Their "compromise" was two-fold: they were willing to allow a ban on other flavors such as vanilla and berry, representing a small market share, but not menthol which accounts for 30% of the market. Secondarily, they agreed to charge the FDA with studying the menthol issue as a first order of business after passage.

The FDA spent years gathering expert testimony and finally acknowledged that eliminating menthol would be a boon to public health. However, their efforts were thwarted by the Obama administration for reasons unclear to us, but most likely a result of tobacco industry influence behind the scenes.

Almost every tobacco control win is secured at the local or state level, where the industry has less influence. San Francisco needs to assert its leadership on this issue and be an example for other jurisdictions.

Menthol is preferred by a large majority of African American smokers, contributing to a disproportionate health burden in that community. LGBTs and young people also use menthol more than others.

Thank you,

Naphtali Offen, President

noplitali Offin

Coalition of Lavender-Americans on Smoking and Health (CLASH)

CLASH mail address: 1270 Sanchez Street, San Francisco, CA 94114

Telephone: 415-436-9182 Email: bob@lgbtpartnership.org

life is why:

2016-2017

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May 8, 2017

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Chairman of the Board

Mayor and Board of Supervisors, City of San Francisco

426 17th St, Ste 300, Oakland, CA 94612 Phone (510) 903-4050 Fax (510) 903-4049

Chris Tsakalakis

1 Dr. Carlton B. Goodlett Place

President

Alden McDonald III, MD

San Francisco, CA 94102

Chairman of the Board-Elect

Dan Smoot

Dear Mayor and Supervisors,

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Carol Ann Satler, MD, PhD Matthew Scanlan Lynne Sterrett

Cigarette smoking is the leading cause of preventable disease and death in the United States, claiming on average 480,000 lives yearly. It increases the risk for Leadership Development Chair heart disease and stroke, especially in those who are genetically predisposed. Smoking decreases our ability to exercise, increases the tendency for blood clots, and decreases good cholesterol. The best way to prevent tobacco-related illness

The American Heart Association supports Supervisor Malia Cohen's proposed

ordinance "Prohibiting the Sale of Flavored Tobacco Products," including menthol

cigarettes. This ordinance will limit access to flavored tobacco products which are

and death is to prevent people from starting to smoke in the first place.

the industry's primary method for targeting & hooking new smokers.

The tobacco industry targets young people and communities of color with flavored tobacco products. Tobacco companies have historically targeted African-American communities with aggressive marketing of mentholated tobacco products and it is no accident that 95% of African-American youth smokers report smoking menthol-flavored cigarettes. As a result, African Americans bear a disproportionate burden of tobacco-related disease and death; 47,000 African Americans die annually from smoking-related illnesses, making tobacco use the largest preventable cause of death among African Americans.

Flavors including grape, menthol, cotton candy, bubble gum and gummy bears mask the harsh taste of tobacco and are highly appealing to youth, encouraging young smokers. In California, 9.4% of young adults (18-24 years old) currently use electronic cigarettes or other vaping devices which capitalize on flavor marketing.

Policies like San Francisco's proposed ordinance "Prohibiting the Sale of Flavored Tobacco Products," protect our communities from flavored tobacco products and are crucial to preventing a lifetime of tobacco addiction. The American Heart Association respectfully asks for your support of this vital health policy. We ask that you put the health of your constituents before tobacco industry profits, and help to ensure that all residents have the healthy and prosperous lives they deserve.

Sincerely,

Alden McDonald III, MD **Board President**

Senior Vice President Maria Gonzalez Olson



April 28, 2017

Supervisor Malia Cohen 1 Dr. Carlton B. Goodlett Place City Hall Room 244 San Francisco, CA 94102

Dear Supervisor Cohen,

We write on behalf of Bay Area Community Resources to offer insight on the potential impact of prohibiting the sale of menthol and flavored tobacco products in San Francisco.

American tobacco companies mass-produce a deadly consumer product. Consequently, the San Francisco tobacco market remains a serious threat to public health. This is especially true in vulnerable communities where teens and young adults are deliberately targeted by industry marketing.

Tobacco products with menthol, flavors, and colorful packaging are designed to attract teens and young adults who are, as the tobacco industry explains, "the only source of replacement smokers." Menthol numbs the throat and reduces irritation, making it an ideal choice for beginners. Flavored products, like fruit-flavored cigarillos, provide young people an array of alternatives to the taste of pure tobacco.

Over 80% of tobacco consumers began by using flavored products—menthol or otherwise. Therefore, we are confident that regulating the sale of products designed to capture and addict new customers will effectively mitigate the tobacco industry's ability to target teens and young adults.

The Bay Area has a legacy of working hard to protect vulnerable citizens from the threat of addiction, disease, and death. Our organization commends your efforts to continue this legacy by prioritizing public health and safety over tobacco industry special interests.

Thank you,

Daniel Maggioncalda

Project Director, Tobacco Policy

Mary Jo-Williams

Chief Operating Officer

Martin Weinstein

Chief Executive Officer



1310 Bacon St, San Francisco, CA 94134-1638
Tel: 415.337.1938 Fax: 415.586.0355 Email: inquiry@gsgracenter.org
Web: www.gsgracenter.org

June 2, 2017

Core Values
Mercy
Reconciliation
Zeal
Individual Worth

Re: Support for Supervisor Cohen's flavored tobacco legislation

Dear Supervisors Breed, Cohen, Farrell, Fewer, Kim, Peskin, Ronen, Safaí, Sheehy, Tang and Yee:

Board of Directors

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Good Shepherd Guild Nora Hall President

Staff
Sr. Marguerite
Bartling, RGS
Executive Director

On behalf of **Good Shepherd Gracenter**, a Licensed Recovery Residence for Women in San Francisco, I'm writing in support of Supervisor Malia Cohen's legislation that seeks to safeguard our youth by ending the sale of flavored tobacco products in San Francisco.

The tobacco industry employs multiple methods to get kids and teens to start smoking, knowing that once they get started, many will be addicted for life. Flavored tobacco is the same deadly tobacco, only flavored like candy and fruit to attract youth. Deadly products, such as strawberry cigarillos, cherry blunt wraps, chocolate hookah, and cotton candy vape/e-cigarette liquids, are sold throughout San Francisco, especially near our schools and low-income neighborhoods. No wonder that 80% of all teen smokers started with some kind of flavored tobacco, and that 95% of African-American teen smokers, 55%-60% of Latino and Asian American teen smokers (1), and over 70% of LGBT young adult smokers use minty menthol cigarettes (2). Flavored tobacco is an issue of social justice.

The Board of Supervisors has always been a champion for our youth and their wellbeing. Healthier kids makes for more successful students, but tobacco companies are getting kids addicted by putting these favors in tobacco. We know that youth are three times more likely to start smoking traditional combustible cigarettes if they start using flavored tobacco products like e-cigarettes first (3).

The U.S. Department of Health and Human Services has launched Healthy People 2020 (www.healthypeople.gov) and one of their objectives is to reduce tobacco use by both adults and adolescents. I can tell you from first hand experience that my father, a long time smoker, died of a stroke due to smoking. As the Executive Director of a women's recovery residence, I witness every day how women struggle to choose a healthy lifestyle and desire stop smoking. Some have been successful and their health improved significant!

You have the power to improve health outcomes, reduce healthcare costs, and advanced health equity. For these reasons, **Good Shepherd Gracenter** supports Supervisor Cohen's ordinance, for the health of our children and our future.

Sincerely,

Sr. Marguerite Bartling, RGS

MSW, CATC IV Executive Director

A Woman's Recovery Begins with Grace...

Good Shepherd Gracenter is a 501(c)3 Tax Exempt organization licensed by the State of California

Federal Tax I.D. # 94-1156670





AMERICAN LUNG ASSOCIATION IN CALIFORNIA

333 HEGENBERGER ROAD, SUITE 450, OAKLAND, CA 94621 phone: 510.638.5864 | fax: 510.638.8984

May 8, 2017

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Olivia Gertz President and Chief Executive Officer The Honorable Ed Lee Members of the San Francisco Board of Supervisors 1 Dr. Carlton B. Goodlett Place City Hall, Room 244 San Francisco, CA 94102

Dear Mayor Lee and Members of the San Francisco Board of Supervisors:

On behalf of the American Lung Association in California, the leading public health organization fighting to reduce and prevent the lung disease, I am writing to express strong support for the adoption of an ordinance to prohibit the sale of all flavored tobacco products, including menthol.

Each year in California, nearly 40,000 adults die from smoking-related causes and over 12,000 kids become new daily smokers. According to a 2012 Report of the U.S. Surgeon General, tobacco companies have a long history of using flavored products to entice new, younger customers. Eight out of ten youth smokers report that they initiated tobacco use with a flavored tobacco product, and the younger a person is the more likely they will be to use a flavored tobacco product. All of the product of the

Despite the FDA's 2009 ban on the sale of flavored cigarettes, the market for other types of flavored tobacco products such as cigars and e-cigarettes is growing rapidly.⁴ Additionally, menthol flavors were excluded from the FDA ban despite the evidence that menthol is also driving factor in tobacco initiation.

The American Lung Association stands in strong support of the proposed ordinance's inclusion of menthol products. These products present a unique set of challenges, both in their health risks and in the populations they affect. Menthol tobacco is disproportionately used by certain populations, with over 80% of African American smokers and over 70% of LGBT smokers choosing these products. ^{5,6} Furthermore, we know that menthol users tend to be more addicted and less able to quit smoking than non-menthol users. ⁷

For these reasons, we urge the Board to move forward with the ordinance which will prohibit the sale of all flavored and menthol tobacco products.





By eliminating the flavored products that attract young tobacco users, the proposed ordinance will take an important step toward reducing to tobacco use in San Francisco.

Thank you for your leadership and we hope that San Francisco will continue to set a healthy example for other Californian communities by supporting innovative, effective tobacco control policies.

Sincerely,

Vanessa Marvin

VP Public Policy and Advocacy

Vanessa Marri

1 U.S. Department of Health and Human Services. Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2012. | 2 Ambrose, BK, et al., "Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014," Journal of the American Medical Association, published online October 26, 2015. | 3 Villanti, AC, et al., "Flavored Tobacco Product Use Among U.S. Young Adults," American Journal of Preventive Medicine 44(4):388-391, 2013. | 4 Campaign for Tobacco-Free Kids. Flavored Tobacco Products Fact Sheet.

https://www.tobaccofreekids.org/research/factsheets/pdf/0383.pdf | 5 Substance Abuse and Mental Health Services Administration, The NSDU Report: Use of Menthol Cigarettes. 2009: Rockville, MD. | 6 National Youth Advocacy Coalition, Coming Out about Smoking: A Report from the National LGBTQ Young Adult Tobacco Project 2010: Washington, DC. | 7 U.S. Food and Drug Administration, Preliminary scientific evaluation of the possible public health effects of menthol versus non-menthol cigarettes. July 2013.



Here for you

P.O. Box 194247 San Francisco, CA 94119 1(415) 547-7800 1(415) 547-7821 FAX www.sfhp.org

May 25, 2017

Supervisor Malia Cohen 1 Dr. Carlton B. Goodlett Place San Francisco, CA 94102-4689

Dear Supervisor Cohen:

I write in support of your efforts to reduce youth tobacco use. As San Francisco's public Medi-Cal managed care plan whose mission is to improve the health of San Francisco's low income residents and to support the safety net providers who care for them, the San Francisco Health Plan (SFHP) is concerned about the significant impact flavored tobacco products have had on overall smoking rates, but particularly amongst low income, minority youth who make up a large portion of SFHP's members. SFHP strongly supports reducing access to flavored tobacco products in San Francisco.

Please let us know how we may be of assistance to you and this legislation.

Sincerely,

Jøhn F. Grgurina, Jr.

CEO, San Francisco Health Plan

cc: Members of the Board of Supervisors

London Breed, President

Mark Farrell

Sandra Lee Fewer

Jane Kim

Aaron Peskin

Hillary Ronen

Ahsha Safai

Jeff Sheehy

Katy Tang

Norman Yee

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May 18th, 2017

Supervisor Malia Cohen 1 Dr. Carlton B. Goodlett Place City Hall Room 244 San Francisco, CA 94102

Dear Supervisor Cohen,

I am writing on behalf of the Youth Leadership Institute (YLI) to offer education and insight on ending sales of menthol and flavored tobacco products in San Francisco. We have been serving the San Francisco community for over 20 years we believe that cultivating engaged and dynamic young people today will lead to a more just, equitable, and sustainable society tomorrow. YLI supports and engages "non-traditional" youth leaders – particularly those from low-income communities of color – in becoming civic leaders. We are dedicated to working with and building the skills of young people so they can confidently address and break down the social, economic, and environmental inequities in their communities.

These youth leaders are the fabric and the future of San Francisco, investing in their health is critical and we know that the leading cause for African American premature death is due to tobacco related issues. Countless youth we have developed at YLI have expressed that their peers and family members would not have started smoking if it were not for the flavored options such as menthols that remain accessible and bombarded with messages to consume these deadly products.

The industry targets youth, communities of color and the LGBT community as they desperately attempt to evolve to find the next generation of clients. San Francisco under your leadership is poised to take another strategic public health stand that will not only protect our most vulnerable communities but also set the tone for other to follow, as our beloved city continues to be a leader in social justice efforts that focus on health equity.

YLI has been a leader in addressing health inequities and is excited to continue to build on over a decade of our tobacco prevention efforts in youth leadership, research, and community change in San Francisco and throughout the state.

Sincerely,

Fahad Qurashi,

Bay Area Director of Programs fqurashi@yli.org, (408) 805-0553



1400 EYE STREET, N.W. • SUITE 1200 • WASHINGTON, DC 20005 PHONE (202) 296-5469 • FAX (202) 296-5427

May 18, 2017

Mayor and Board of Supervisors City and County of San Francisco 1 Dr. Carlton B. Goodlett Place San Francisco, CA 94102

Dear Mayor Lee and members of the Board of Supervisors:

The Campaign for Tobacco-Free Kids Action Fund supports amending the Health Code by adding Article 19Q, "Prohibiting the Sale of Flavored Tobacco Products," to end the sale of all flavored tobacco products, including menthol, in the City and County of San Francisco.

Prohibiting the sale of flavored tobacco, including menthol cigarettes, is an important step in protecting San Francisco children from the unrelenting efforts of the tobacco industry to hook them to a deadly addiction. For decades, tobacco companies have used flavorings to improve the taste and reduce the harshness of their products to make them more appealing to new users, almost all of whom are under age 18. A government study found that 81 percent of kids who have ever used tobacco products started with a flavored product¹. The evidence is clear that menthol cigarettes and flavored tobacco products have a direct appeal to youth and make it easier for them to start smoking. Prohibiting the sale of menthol cigarettes and other flavored tobacco products will help reduce tobacco use and its devastating toll.

In recent years, there has been an explosion of sweet-flavored tobacco products, especially e-cigarettes and cigars. These products are available in a wide assortment of flavors that seem like they belong in a candy store or ice cream parlor – like gummy bear and cotton candy, wild berry and lemonade. A 2014 study identified more than 7,700 unique e-cigarette flavors, with an average of more than 240 new flavors being added per month. Sales of flavored cigars, meanwhile, have increased by nearly 50 percent since 2008, and flavored cigars made up more than half (52.1 percent) of the U.S. cigar market in 2015, according to Nielsen convenience store market scanner data.

These sweet products have fueled the popularity of e-cigarettes and cigars among youth. Youth cite flavors as a major reason for their current use of non-cigarette tobacco products, with 81.5 percent of youth e-cigarette users and 73.8 percent of youth cigar users saying they used the product "because they come in flavors I like." Across all tobacco products, the data is clear: flavored tobacco products are overwhelmingly used by youth as a starter product, and preference for flavors declines with age.

Tobacco companies have a long history of targeting and marketing flavored tobacco products to specific populations and subgroups. Tobacco industry marketing, often targeted at minority communities, has been instrumental in increasing the use of menthol products and in the disproportionate use of menthol products by minority groups and youth. As a result, 85 percent of African-American smokers smoke menthol cigarettes, compared to 29 percent of white smokers. Menthol cigarettes are particularly popular among youth: more than half of youth smokers use menthol cigarettes, including seven out of ten African-American youth smokers. The FDA's Tobacco Products Scientific Advisory Committee (TPSAC) estimated that by 2020, 4,700 excess deaths in the African-American community will be attributable to menthol in cigarettes, and over 460,000 African Americans will have started smoking because of menthol in

cigarettes. TPSAC further concluded that "Removal of menthol cigarettes from the marketplace would benefit public health in the United States." ⁶

There is also a long history of the tobacco industry targeting the LGBTQ population. For more than 20 years, the tobacco industry has targeted the LGBTQ market through direct advertisements, sponsorships and promotional events. The most infamous example of this targeted marketing of the LGBTQ community is "Project SCUM" (subculture urban marketing), a 1995 marketing plan developed by R.J. Reynolds to target the gay community in the Castro District of San Francisco.

The scientific evidence leaves no doubt that flavored tobacco products – including menthol – have a profound adverse impact on public health in the United States, resulting in more smoking and subsequently more death and disease from tobacco use. The research also demonstrates that the tobacco industry is responsible for the harm caused by menthol cigarettes because of its targeted marketing to children and African-American communities and its manipulation of menthol cigarettes to appeal to specific target markets. Prohibiting the sale of flavored tobacco products, including menthol cigarettes, will help counter these industry tactics.

By adding Article 19Q, "Prohibiting the Sale of Flavored Tobacco Products" to the Health Code, you will place the health of San Francisco's kids before tobacco industry profits. Thank you for your leadership protecting San Francisco youth from the harmful effects of tobacco use.

Sincerely,

William P. Lee

Executive Vice President, US Programs

¹ Ambrose, BK, et al., "Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014," *Journal of the American Medical Association*, published online October 26, 2015.

² Zhu, S-H, et al., "Four Hundred and Sixty Brands of E-cigarettes and Counting: Implications for Product Regulation," *Tobacco Control*, 23(Suppl 3):iii3-iii9, 2014.

³ Delnevo, CD, et al., "Changes in the mass-merchandise cigar market since the Tobacco Control Act," *Tobacco Regulatory Science*, 3(2 Suppl 1): S8-S16, 2017.

⁴ Ambrose, BK, et al., "Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014," *Journal of the American Medical Association*, published online October 26, 2015.

⁵ Villanti, A., et al., "Changes in the prevalence and correlates of menthol cigarette use in the USA, 2004–2014," *Tobacco Control*, published online October 20, 2016.

⁶ Tobacco Products Scientific Advisory Committee, Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations, July 21, 2011

http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM2 69697.pdf

⁷ Goebel, K, et al., "Lesbians and gays face tobacco targeting," *Tobacco Control*, 3: 65-67, 1994.

⁸ RJ Reynolds. Project SCUM. Legacy Tobacco Documents Library. December 12, 1995. Access Date: October 19, 2002. Bates No.: 518021121/1129. http://legacy.library.ucsf.edu/tid/mum76d00.

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Phone: (650) 994-5868 Fax: (415) 445-3000 Email: info@ggbreathe.org Web: www.ggbreathe.org

Since 1908, Breathe California has fought for clean air, healthy lungs and the elimination of lung disease in the San Francisco Bay Area.

A member of the **Breathe America** TM Alliance

May 10, 2017

San Francisco Board of Supervisors 1 Dr. Carlton B. Goodlett Place City Hall, Room 244 San Francisco, CA 94102-4689



Dear Supervisors Breed, Cohen, Farrell, Fewer, Kim, Peskin, Ronen, Safaí, Sheehy, Tang and Yee:

On behalf of Breathe California's Board of Directors and staff I would like to thank Supervisor Cohen for the incredible leadership she has shown introducing legislation to end the sale of flavored tobacco products in San Francisco. As the CEO of a lung and environmental health nonprofit organization founded in San Francisco over 100 years ago I am proud to stand and work with you to ensure the health of our residents comes before corporate or other interests.

Lung disease is the 2nd leading cause of death in the United States and tobacco is the #1 preventable cause of death¹. Chronic obstructive pulmonary disease (COPD)—deeply debilitating and primarily caused by tobacco use¹¹—is the 3rd leading cause of death alone. Over 90% of smokers began smoking before age 18¹¹¹ and 80% of teen smokers started with a flavored tobacco product such as menthol cigarettes, fruit-flavored cigars, or candy-flavored vapes/e-cigarettes. IV Breathe California has been educating our San Francisco communities about the dangers of tobacco for decades. Over the last two years, by surveying high school students, conducting focus groups, and providing education to our communities, our team of youth advocates has worked to draw attention to how the tobacco industry uses flavors to target young people.

Flavored tobacco is similar to the inclusion of toys in fast food children's meals: just like the very presence of the toy encourages children to choose unhealthy food, flavors in tobacco draw youth into smoking. Flavored tobacco products' bright packaging and low price mimic those of candy, which makes flavored tobacco incredibly attractive to youth. We have met countless community members who mistook our display of flavored tobacco products as candy at our presentations and events; parents are especially horrified when they realize it isn't candy at all! The San Francisco Board of Supervisors has already restricted the inclusion of toys from fast food meals to protect youth health. We urge you to prohibit the sale of flavored tobacco products as well.

This is an issue not only of youth health, but also of social justice. Menthol cigarette users, especially younger smokers and people of color, have a harder time quitting. Youth menthol cigarette smokers are disproportionately African American, Asian American, LGBT, and from low-income communities already significantly impacted by lung disease in.

Breathe California believes no one should ever struggle to breathe and we fight lung disease each day through advocacy, grassroots programs and direct services. We work with individuals, families, and communities fighting to improve the quality of their lives and we know how painful, isolating, and hopeless many people feel when they are struggling with tobacco addiction and tobacco-related disease. For decades Breathe California has worked in partnership with the Board of Supervisors, to prohibit the sale of single cigarettes (1991), establish smoke-free workplaces that pre-date California law (1994), smoke-free bars (1998), smoke-free playgrounds (2002), tobacco retailer licenses (2003), smoke-free parks (2005), tobacco-free pharmacies

2851

(2008), smoke-free events (2013), and e-cigarette regulations (2014).

Youth often don't understand that the health impacts from tobacco may not be felt for decades. My father is a good example of this; he first began smoking as a teenager and although he hasn't smoked since 1989 he was diagnosed with lung cancer just last month. Having already lost two uncles to tobacco-related lung disease, in addition to working with people battling lung disease every day, I know how agonizing it is to watch people you love struggle with oxygen tanks, tests, treatments, and surgeries - all due to tobacco use. Your action passing this legislation will help protect the next generation of San Franciscans, and their families, from suffering the same way.

The San Francisco Board of Supervisors has always been a champion for the wellbeing of our youth and San Francisco has consistently provided new models for community health for the nation to follow. You are in a powerful position to save lives! You now have the opportunity to do something no other city has done before - you can advance health equity by eliminating the sale of flavored tobacco.

Thank you for helping ensure the health of all San Franciscans. I urge you to prioritize the health of our most vulnerable communities and take this bold step to eliminate the sale of flavored tobacco products.

With respect and gratitude,

Tanya Stevenson, EdD, MPH

President & CEO

i Carter B, et al., "Smoking and Mortality – Beyond Established Causes", New England Journal of Medicine, 2015:372:631-40.

ⁱⁱ Centers for Disease Control and Prevention. Annual smoking-attributable mortality, years of potential life lost, and productivity losses—United States, 1997–2001. *MMWR*. 2005;54(250):625-628.

iii US Department of Health and Human Services. 2012. Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General.

iv Ambrose BK, et al., "Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014". JAMA 2015; 314(17): 1871-1873.

v Foulds J, et al. 2010. Do Smokers of Menthol Cigarettes Find It Harder to Quit Smoking? Nicotine Tob Res (2010) 12 (suppl_2): S102-S109.

vi Giovino GA, et al., "Differential trends in cigarette smoking in the USA: is menthol slowing progress?" Tobacco Control 2015; 24: 28-37.

vii San Francisco Health Improvement Program. 2017. Community Health Dashboard data available at www.sfhip.org.



May 2, 2017

The Honorable Ed Lee 1 Dr. Carlton B. Goodlett Place City Hall, Room 244 San Francisco, CA 94102

Dear Mayor Lee and Members of the San Francisco Board of Supervisors:

The American Cancer Society Cancer Action Network is committed to protecting the health and well-being of the citizens of San Francisco through evidence-based policy and legislative solutions designed to eliminate cancer as a major health problem. As such, we are writing to support passage of the proposed amendment to the San Francisco tobacco retail license (TRL), which will prohibit sales of flavored tobacco products.

The 2014 Surgeon General's Report found that more than 43 million Americans still smoke, and tobacco will cause an estimated 480,000 deaths this year in the U.S. Of the 9 million youth currently living in our state, nearly 1.4 million of them will become smokers, and approximately 440,000 of those kids will die prematurely as a result of tobacco use.

In 2009, Congress, prohibited the sale of cigarettes with flavors other than tobacco or menthol. Tobacco companies responded by expanding the types of non-cigarette flavored tobacco products they offer, and now make most of those products available in a growing array of kidfriendly flavors. Little cigars, smokeless tobacco, and e-cigarettes are marketed in a wide array of sweet flavors and colorful packaging that appeals to youth. According to the California Department of Public Health, young people are much more likely to use candy and fruit flavored products than adults. Prohibiting the sale of flavored tobacco products, including menthol cigarettes, helps to remove some of the appeal of these products to beginning smokers.

Adolescents are still going through critical periods of brain growth and development, and they are especially vulnerable to the toxic effects of nicotine. Both opponents of smoking and purveyors of cigarettes have long recognized the significance of adolescence as the period during which smoking behaviors are typically developed. Tobacco companies have a long

American Cancer Society Cancer Action Network 700 Main Street, Suite 102 • Fairfield CA 94533 • 707.290.0003 history of marketing to vulnerable populations, and target youth with imagery and by marketing appealing flavors. This has been particularly true in the African American population. In African American communities, the tobacco industry has aggressively marketed menthol flavored tobacco products to youth. More than 80% of African American smokers smoke menthol cigarettes, and African American men have the highest death rates from lung cancer, when compared to other demographic groups. The anesthetizing effect of menthol masks the harshness of tobacco, making menthol cigarettes more appealing to beginning smokers, and menthol smokers demonstrate greater dependence, and are less likely to quit.

While cigarette smoking has declined in the U.S., sales of menthol cigarettes have steadily increased in recent years, especially among young people and new smokers. Prohibiting the sale of flavored tobacco products can help to keep kids from ever starting to smoke, and can encourage those who do smoke to quit. We should be doing everything we can to protect young people from ever establishing this deadly addiction, and the cancer it causes, as well as supporting those who are trying to quit. ACS CAN appreciates San Francisco's leadership in bringing this issue forward, and we encourage the Board of Supervisors to pass this amendment to prohibit the sale of all flavored tobacco products in the City of San Francisco.

Sincerely,

Cassie Ray

Cassie Ray

Government Relations Director, Northern California American Cancer Society Cancer Action Network



June 6, 2017

Re: Support for Supervisor Cohen's flavored tobacco legislation

Dear Supervisors Breed, Cohen, Farrell, Fewer, Kim, Peskin, Ronen, Safaí, Sheehy, Tang and Yee:

On behalf of Donaldina Cameron House I'm writing in support of Supervisor Malia Cohen's legislation which seeks to safeguard our youth by ending the sale of flavored tobacco products in San Francisco.

The tobacco industry employs multiple methods to get kids and teens to start smoking, knowing that once they get started, many will be addicted for life. Flavored tobacco is the same deadly tobacco, only flavored like candy and fruit to attract youth. Tobacco companies specifically package tobacco in bright colors at price points targeted to teens, such as selling double packs of chocolate flavored little cigars for \$.99 throughout San Francisco.

These deadly products, such as strawberry cigarillos, cherry blunt wraps, chocolate hookah, and cotton candy vape/e-cigarette liquids, are sold throughout San Francisco, especially near our schools and low-income neighborhoods. No wonder that 80% of all teen smokers started with some kind of flavored tobacco, and that 95% of African-American teen smokers, 55%-60% of Latino and Asian American teen smokers (1), and over 70% of LGBT young adult smokers use minty menthol cigarettes (2). Flavored tobacco is an issue of social justice.

The Board of Supervisors has always been a champion for our youth and their wellbeing. Tobacco companies are getting kids addicted by putting these favors in tobacco. We also know that youth are three times more likely to start smoking traditional combustible cigarettes if they start using flavored tobacco products like e-cigarettes first (3).

As an anchor institution in Chinatown serving vulnerable, low-income immigrant youth and families, our experiences has been that the Asian population we serve have limited access to healthy food and face many medical issues, including cancer. We try our best to keep youth from developing smoking habits will negatively affect their wellbeing.

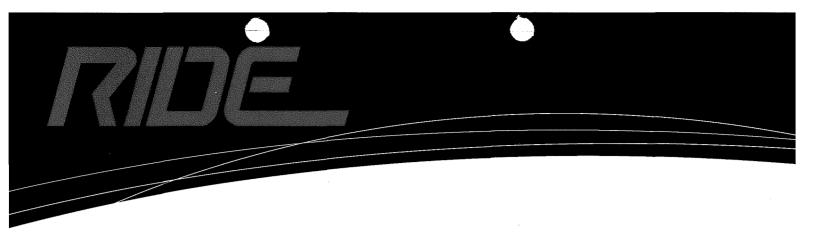
Decreasing access to tobacco products will make San Francisco a leader across the nation. Together we can close this loophole in San Francisco so that tobacco companies can't get our kids, especially minority, disadvantaged, and low income youth, addicted to life-threatening flavored tobacco. You have the power to improve health outcomes, reduce healthcare costs, and advanced health equity. For these reasons, Donaldina Cameron House supports Supervisor Cohen's ordinance.

For the health of our children and our future,

May Leong

Executive Director

- 1. Ambrose BK, et al., "Flavored Tobacco Product Use Among US Youth Aged 12 17 Years, 2013-2014." JAMA 2015; 314(17): 1871-1873.
- 2. National Youth Advocacy Coalition. 2010. "Coming Out About Smoking: A Report from the National LGBTQ Young Adult Tobacco Project.
- 3. Primack BA, et al. 2015. Progression to Traditional Cigarette Smoking After Electronic Cigarette Use Among US Adolescents and Young Adults. JAMA Pediatrics 169(11): 1018 -1023.



Dear San Francisco Board of Supervisors

It is important that we protect youth from addiction and death by stopping the sale of flavored tobacco products. As leaders, we are role models for the youth and can have a positive effect on their lives by creating an environment that reduces their access to deadly addictive products.

RIDE is an organization that began nearly 15 years ago to counter the marketing of tobacco products to youth involved within the racing and car show scene. We achieve this through youth leadership development, policy adoption and education campaigns.

In the past, RIDE documented sampling and giveaways of tobacco products to youth that resemble candy and fruit like products at car shows. This includes car shows within the city and county of San Francisco. The racing and car show scene attracted large numbers of youth, some of which were hosted by tobacco product retailers. These vendors often market tobacco, including e-cigarette, products that have fruit and menthol flavorings. Studies show that widespread use and availability of menthol and flavored tobacco products promote the initiation and use of tobacco among youth. The fact is, over 80% of youth started tobacco use that had flavored products in them.

Menthol and flavored tobacco is the vehicle used to deliver these poisons and hook our youth to nicotine addiction. San Francisco led the nation in amazing public health work and it our hope that we will continue leading the nation by creating safe spaces that protect our youth from predatory and poisonous flavored and mentholated tobacco products.

Thank you,

Rosalyn Moya, MPH

Project Director-Project RIDE (RIDE)

fromlyn hir Moya



June 6, 2017

Board of Supervisors 1 Dr. Carlton B. Goodlett Place City Hall, Room 244 San Francisco, Ca. 94102-4689

Re: Support for Supervisor Cohen's flavored tobacco legislation

Dear Supervisor Breed, Supervisor Cohen, Supervisor Farrell, Supervisor Fewer, Supervisor Kim, Supervisor Peskin, Supervisor Ronen, Supervisor Safaí, Supervisor Sheehy, Supervisor Tang and Supervisor Yee,

On behalf of Boys & Girls Clubs of San Francisco, I am writing in support of Supervisor Malia Cohen's legislation which seeks to safeguard our youth by ending the sale of flavored tobacco products in San Francisco.

The tobacco industry employs multiple methods to get kids and teens to start smoking, knowing that once they get started, many will be addicted for life. Flavored tobacco is the same deadly tobacco, only flavored like candy and fruit to attract youth. Tobacco companies specifically package tobacco in bright colors at price points targeted to teens, such as selling double packs of chocolate flavored little cigars for \$.99 throughout San Francisco.

These deadly products, such as strawberry cigarillos, cherry blunt wraps, chocolate hookah, and cotton candy vape/e-cigarette liquids, are sold throughout San Francisco, especially near our Clubs in low-income neighborhoods. No wonder that 80% of all teen smokers started with some kind of flavored tobacco; and that 95% of African-American teen smokers, 55%-60% of Latino and Asian-American teen smokers¹, and over 70% of LGBT young adult smokers use minty menthol cigarettes². Flavored tobacco is an issue of social justice.

The Board of Supervisors has always been a champion for our youth and their well-being. Healthier kids make for more successful students and more engaged Club kids, but tobacco companies are getting kids addicted by putting these flavors in tobacco. We also know that youth are three times more likely to start smoking traditional combustible cigarettes if they start using flavored-tobacco products like e-cigarettes first³.

¹ Ambrose BK, et al., "Flavored Tobacco Product Use Among US Youth Aged 12 - 17 Years, 2013-2014." JAMA 2015; 314(17): 1871-1873.

National Youth Advocacy Coalition. 2010. "Coming Out About Smoking: A Report from the National LGBTQ Young Adult Tobacco Project.

Primack BA, et al. 2015. Progression to Traditional Cigarette Smoking After Electronic Cigarette Use Among US Adolescents and Young Adults. JAMA Pediatrics 169(11): 1018 -1023.

Teens from three of our Clubhouses (Excelsior, Tenderloin, and the Willie Mays Club at Hunters Point) participated in Breathe California's Project E-NUFF in the fall of 2015. Our Club members were among the 150 San Francisco high school students who were surveyed and were part of the finding that flavors play a key role in tobacco use among San Francisco youth.

Decreasing access to tobacco products will make San Francisco a leader across the nation. Together, we can close this loophole in San Francisco, so that tobacco companies can't get our kids, especially minority, disadvantaged, and low income youth, addicted to life-threatening flavored tobacco. You have the ability to improve health outcomes, reduce healthcare costs, and advance health equity. For these reasons, Boys & Girls Clubs of San Francisco supports Supervisor Cohen's ordinance.

Sincerely,

Rob Connolly

President

Boys & Girls Clubs of San Francisco

Defending your right to breathe smokefree air since 1976

May 12, 2017

Mayor and Board of Supervisors City and County of San Francisco 1 Dr. Carlton B. Goodlett Place San Francisco, CA 94102

Dear Mayor Lee and members of the Board of Supervisors:

On behalf of our members in San Francisco, Americans for Nonsmokers' Rights supports amending the Health Code by adding Article 19Q, "Prohibiting the Sale of Flavored Tobacco Products," from Supervisor Malia Cohen that would end the sale of all flavored tobacco products, including menthol, in the City and County of San Francisco.

The Centers for Disease Control and Prevention (CDC) recommends *Best Practices for Comprehensive Tobacco Control Programs* that have a proven track record in helping to reduce tobacco-related disease and death in our communities. The CDC's three best practices are to 1) eliminate exposure to secondhand smoke, 2) promote tobacco use cessation, and 3) prevent tobacco use initiation among youth and young adults, which includes addressing access to tobacco products via stronger local laws directed at retailers.

San Francisco has a long history of leadership in tobacco prevention to reduce the deadly impact of tobacco use and exposure. Communities have the right and responsibility to hold tobacco and e-cigarette retailers accountable for not being part of the tobacco epidemic by selling these addictive and deadly products in flavors that are very appealing to youth and young adults. It is important to take strong action because the tobacco and e-cigarette industries continue the deceptive and targeted marketing of their products to youth and young adults, African-Americans, the LGBTQ community, and other vulnerable populations.

The evidence is clear that menthol tobacco products are more heavily marketed to African-Americans, and more than 80% of African-American smokers are menthol smokers (compared to 30% of Latinos and 20% of Caucasians). While the tobacco industry's history of targeting the African-American community is often cloaked by its generous community contributions, scholarship initiatives, and other forms of "corporate responsibility," it is no secret that the health of African-Americans is most impacted by cancer, heart disease, and stroke—all of which are associated with smoking and secondhand smoke exposure.

Tobacco companies have everything to gain from addicting young people, given research showing that the earlier a person starts using tobacco, the higher the risk of addiction, and the harder it becomes to quit. The tobacco industry's long and well-documented history of profiling and targeting the African-American community for economic profits comes at the expense of individuals' lives. When it comes to industry tactics, some things never change.

San Francisco should put the health of the community ahead of tobacco company and retailer profits.

Given these facts, Americans for Nonsmokers' Rights urges the San Francisco Board of Supervisors to adopt the proposed Article 19Q, "Prohibiting the Sale of Flavored Tobacco Products," to prohibit the sale of flavored tobacco products, including menthol.

Thank you for your leadership and desire to make San Francisco the best place to live, work, and visit. Please feel free to contact us at 510-841-3032 if you have any questions, comments, or feedback.

Sincerely,

Cynthia Hallett, MPH President and CEO

Cynthia Hallett

Americans for Nonsmokers' Rights is a national, member-based, not-for-profit organization based in Berkeley, CA that is dedicated to helping nonsmokers breathe smokefree air since 1976.



June 9, 2017

RE: Sale of Flavored Tobacco Products;

Sponsors: Cohen; Safai, Breed, Farrell, Sheehy, Tang and Yee.

Dear Supervisors:

The San Francisco Marin Medical society strongly supports a ban on sale of flavored tobacco products, including menthol, being sold in San Francisco.

In fact, we have supported such a policy for years, and convinced the California Medical Association to do likewise: our proposal to them resulted in their statement that "CMA supports a full ban on menthol additives in tobacco products in order to curb smoking."

You will no doubt hear the many reasons why this is an important public health policy. We want you to know that the medical community is very much in agreement that this is a policy whose time has come.

For the health of San Franciscans, we urge you to adopt this proposed ordinance, which is firmly in line with our city's long history of minimizing harm from tobacco.

Thank you very much.

Sincerely,

Man-Kit Leung, MD President School Health Programs Department San Francisco Unified School District 1515 Quintara St. San Francisco, CA 94116



June 1, 2017

Dear Supervisors Breed, Cohen, Farrell, Fewer, Kim, Peskin, Ronen, Safaí, Sheehy, Tang and Yee:

On behalf of San Francisco Unified School District, I'm writing in support of Supervisor Malia Cohen's legislation which seeks to safeguard our youth by ending the sale of flavored tobacco products in San Francisco. This proposed law would result in healthier outcomes for youth, as well as more successful students, with better grades and improved attendance. SFUSD has worked to make health education a rite of passage for students in grades K to 12 (https://sfusdhealtheducation.org/) and is a leader in the Tobacco Use Prevention Education with Youth Outreach Workers educating their peers against the dangers of e-cigarette use through school-wide events, classroom presentations and public service announcements (check out student work at: https://sfwellness.org/2017-anti-tobaccovape-psa-contest-winners/)

However, tobacco companies are getting kids addicted by putting these favors in tobacco. These deadly products, such as strawberry cigarillos, cherry blunt wraps, chocolate hookah, and cotton candy vape/e-cigarette liquids, are sold throughout San Francisco, especially near our schools and low-income neighborhoods. 80% of all teen smokers started with some kind of flavored tobacco, and that 95% of African-American teen smokers, 55%-60% of Latino and Asian American teen smokers (1), and over 70% of LGBT young adult smokers use minty menthol cigarettes (2). Flavored tobacco is an issue of social justice. We also know that youth are three times more likely to start smoking traditional combustible cigarettes if they start using flavored tobacco products like e-cigarettes first (3).

Decreasing access to tobacco products will make San Francisco a leader across the nation. Together we can close this loophole in San Francisco so that tobacco companies can't get our kids, especially minority, disadvantaged, and low income youth, addicted to life-threatening flavored tobacco. You have the power to improve health outcomes, reduce healthcare costs, and advanced health equity. For these reasons, San Francisco Unified School District supports Supervisor Cohen's ordinance.

Sincerely,

Quarry Pak, MSW

Program Administrator and SFUSD Tobacco Use Prevention Education Program Coordinator

- 1. Ambrose BK, et al., "Flavored Tobacco Product Use Among US Youth Aged 12 17 Years, 2013-2014." JAMA 2015; 314(17): 1871-1873.
- 2. National Youth Advocacy Coalition. 2010. "Coming Out About Smoking: A Report from the National LGBTQ Young Adult Tobacco Project.
- 3. Primack BA, et al. 2015. Progression to Traditional Cigarette Smoking After Electronic Cigarette Use Among US Adolescents and Young Adults. JAMA Pediatrics 169(11): 1018 -1023.



1090 Vermont Avenue, NW | Suite 850 Washington, DC 20005

Esteemed Supervisors:

San Francisco's proposed ban on flavored vaping products comes a year after England's <u>Royal College of Physicians</u> reported that e-cigarettes are at least 95 percent less harmful than traditional tobacco cigarettes, largely because users inhale vapor instead of smoke heavy with the carcinogenic byproducts of burning. By failing to differentiate between combustible tobacco products like cigarettes and cigars, and smokeless e-cigarettes and vapor products (which don't actually contain tobacco but *are* almost exclusively flavored), San Francisco's ban threatens to undermine current smokers' ability to reduce the burden tobacco wields over their lives.

Unfortunately for the LGBT community, who out-smoke other Californians <u>2-to-1</u>, the tobacco issue has City Hall convinced that preaching abstinence and crossing their fingers is the best way to combat tobacco addiction.

It's a shocking change of tune for a city known for proudly outpacing the rest of the nation by fighting public health crises through "harm reduction" strategies. In the early 1980s, as rumors surfaced that AIDS spread through sex, volunteers with the AIDS & KS Foundation (now the San Francisco AIDS Foundation) began handing out free condoms. Before New York City had even spent a dime addressing their own burgeoning epidemic, Castro Street activists predicted what we know to be true today: Harm reduction alternatives can mean the difference between life and death.

When roughly $\underline{1}$ in $\underline{250}$ of San Francisco's intravenous drug users were diagnosed with AIDS, Bay Area activists responded by supplying them with clean syringes in violation of California state law. Their effort, dubbed " $\underline{Prevention\ Point}$," caught the attention of then-Mayor Frank Jordan, who committed almost \$140,000 to support the needle exchange program. Today, the rate of HIV among intravenous drug users in San Francisco is $\underline{roughly\ half}$ that of the rest of the country.

Risk reduction has served our community well: HIV diagnoses in San Francisco have dropped by 48% in the last decade and HIV no longer reigns as the number one killer in American's gay community. Tobacco has assumed that grim throne, claiming more than 30,000 LGBT lives each year — twice the number lost to complications of HIV. In fact, those undergoing antiretroviral therapy are now far more likely to die from their cigarettes than from complications of the virus.

But while many in the medical community acknowledge vaping and e-cigarettes as unconventional tools to combat tobacco harm — the <u>American Heart</u> <u>Association</u> even discourages physicians from rejecting a patient's decision to use e-cigarettes when other cessation methods fail — it appears City Hall is content to buck the Bay Area's proud legacy of harm reduction.

This debate couldn't have come at a less opportune time: The U.S. Centers for Disease Control (CDC) recently reported that <u>more than a third</u> of smokers utilize ecigarettes to quit, far more than the number turning to nicotine replacement therapies like the patch, gum, or drugs like Chantix or Zyban.

Tobacco harm reduction isn't a perfect solution; e-cigarettes still contain nicotine, formaldehyde, and other chemicals which impact health. But even the director of UC San Francisco's Center for Tobacco Control Research and Education, <u>Stanton</u> <u>Glantz</u>, notes "There's no question that a puff on an e-cigarette is less toxic than a puff on a regular cigarette."

With studies reporting that e-cigarette use can help current smokers <u>reduce their tobacco consumption</u> or eliminate it entirely, it can't hurt to embrace e-cigarettes as smoking's less harmful alternative. That's why it's so urgent that members of the LGBT community — and every other group burdened by the health harms of tobacco — have access to risk-reducing alternatives like flavored e-cigarettes and vapor products.

If passed, San Francisco's blanket ban on flavored smoking products will ensure that one in ten of its citizens — and nearly one in four members of its LGBT community — remain at an increased risk of cancer and heart and lung diseases that accompany chronic cigarette smoking.

I implore the San Francisco Board of Supervisors to quit the habit of making the perfect the enemy of the good, and embrace — rather than betray — the longstanding legacy of this fair city as a leader in harm reduction alternatives.

Gregory T. Angelo is the president of Log Cabin Republicans, the nation's premier organization representing LGBT conservatives and straight allies.

Good morning members of the San Francisco Board of Supervisor's Public Safety & Neighborhood Services Committee. Thank you for the opportunity to testify here today.

My name is Manuel Cosme and I am a business owner who provides tax consulting services for small businesses for over 30 years, many of which are the very local retailers impacted by this proposed tobacco ordinance.

I have also advocated for the rights of small business owners who continue to be the backbone of the California economy and have participated various leadership roles to include: the past Chairman of the California National Federation of Independent Businesses (NFIB), the immediate past Chairman of the California Hispanic Chambers of Commerce (CHCC) and past-president of both the Napa and Solono Hispanic Chambers of Commerce.

Today, I stand in solidarity with my fellow local small business owners and community members here today that are strongly opposed to this proposed ordinance because of the real and documented negative impact that it will have on the city of San Francisco.

Many of these local community markets provide vital foods like fresh fruits, vegetables, water, snacks, gas and other essentials. The stores provide jobs, support local charities, and sponsor youth sports teams. These business owners and retail stores are a vital part of the local community. They are rooted in San Francisco and should not be forced out.

I strongly believe this ordinance will jeopardize public safety. A total ban on almost all flavored tobacco products creates the conditions for the illicit sale of these products right here in San Francisco.

These small business owners spend time and money making sure employees are properly trained on how to check ID's. The criminal elements that will move in and sell tobacco illegally here will not comply with the law and won't think twice about not verifying the legal age of anyone who desires to buy tobacco products.

It will destroy independent and minority-owned retail businesses that generate sales tax revenue for the city and provide local jobs. If the ordinance goes into effect, it is also our concern that the County will lose valuable sales tax revenues to neighboring jurisdictions that do not have similar product bans in place. The policy has far-reaching unintended consequences and deserves closer scrutiny, especially given the City's projected budget deficit and \$5.5 billion in pension liabilities.

What is good for small business, is good for California! I urge you to VOTE NO on this ordinance.



125th Anniversary 1892-2017 ADMINISTRATION
210 Cottonwood Avenue

Harrland, WI 53029 Phone (262) 367-2714 Fax (262) 367-2430 www.villageofhartland.com

jeffreyp@villageofhartland.com

May 22, 2017

Department of Health and Human Services Thomas E. Price, M.D., Secretary 200 Independence Avenue, SW Washington, DC 20201

Food and Drug Administration—United States Government Scott Gottlieb, M.D., Commissioner 10903 New Hampshire Avenue Silver Spring, MD 20993-0002

Chairperson Council on Environmental Quality White House 1600 Pennsylvania Ave NW Washington, DC 20500

As indicated in our previous letter dated April 18, 2017, the Village of Hartland conducted a three day hearing, April 27-29, 2017 regarding the Department's failure to coordinate regarding the impact of the Deeming Regulations. A spokesman for the FDA telephoned and left a voice message that it would not be able to have someone attend but a letter would be sent regarding our concerns. We have not as yet received that letter.

Attached to this letter of transmittal are the Findings and Conclusions entered by the Hartland Hearing Board at the conclusion of the hearings. This letter contains references to Executive Orders that President Trump has issued that provides reasons why you should withdraw the Deeming Regulations and begin coordination with our agency.

We note that you and your Department are under direction from President Trump to review all departmental regulations in order to determine whether any of them have adverse impact on jobs and on other aspects of our local needs.

In that same Executive Order issued in February, 2017, the President ordered that you review your regulations in light of President Clinton's federalism executive order 12866 both of which executive orders give specific grounds for you to withdraw the Regulations until they could hopefully, with local government input and industry input, bring about resolution of the deep conflict between local



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government and the national government on this issue. Following are excerpts from President Trump's executive orders and executive order 12866:

From the President's order to you issued in February of 2017:

"At a minimum, each Regulatory Reform Task Force shall attempt to identify regulations that:

(i) <u>eliminate jobs, or inhibit job creation;</u>

The evidence before Hartland shows beyond any doubt, not just reasonable doubt, that jobs will be eliminated and no new jobs will be created as a result of the adverse impact of the regulations for the reasons stated in our findings. So your Deeming Regulations are among the first that should be identified as eliminating jobs and put on hold so that no lives be ruined by elimination of jobs and job opportunities.

e) In performing the evaluation described in subsection (d) of this section, each Regulatory Reform Task Force shall seek input and other assistance, as permitted by law, from entities significantly affected by Federal regulations, including State, local, and tribal governments, small businesses, consumers, non-governmental organizations, and trade associations.

This provision is joined with the following from President Clinton's 12866 as to the requirement that you seek our participation.

e) In performing the evaluation described in subsection (d) of this section, each Regulatory Reform Task Force <u>shall seek input and other assistance</u>, <u>as permitted by law, from entities significantly affected by Federal regulations, including State, local, and tribal governments, small businesses, consumers, non-governmental organizations, and trade associations.</u>

Your department has not sought our input, but we are giving the first of our hopefully many communications with you through these Findings. We look forward to your coordinating with us pursuant to instructions from President Trump and the laws of the United States so that we can help resolve the issues and save an industry that saves lives.

From 12866 again:

The Regulatory Philosophy. Federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling public need, such as material failures of private markets to protect or improve the health and safety of the public, the environment, or the well-being of the American people.

The overwhelming evidence presented to us, as you will see from the Findings, shows that the private market has done an outstanding job of protecting and improving the health and safety of the public---from providing the most effective and safe substitute for smoking combustible cigarettes to establishing their own safety regulations in the manufacture of products. They are a self-regulating industry which has developed self-imposed standards in the absence of any included in the Deeming Regulations. SO, UNDER THE PRESIDENT'S SPECIFIC LANGUAGE THE DEEMING REGULATIONS SHOULD BE WITHDRAWN.

Again from 12866:

a. In deciding whether and how to regulate, agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating. Costs and benefits shall be understood to include both quantifiable measures (to the fullest extent that these can be usefully estimated) and qualitative measures of costs and benefits that are difficult to quantify, but nevertheless essential to consider. *Further, in choosing among alternative regulatory approaches, agencies should select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity)*, unless a statute requires another regulatory approach.

Again, the evidence was overwhelming that your agency did not do a cost analysis, did not consider and try to minimize the adverse impact on small communities like Hartland that will occur from loss of Johnson Creek Enterprises or even a deep cut in their business which your Regulations will bring about. The economic losses to Hartland as well as all of Wisconsin will be enormous and your Department's attitude so far has been "oh well." As for the environmental impact, your Regulations have taken into account not at all the human environment as defined by the Council on Environmental Quality. Our record, which you will have both by audio and video, will detail for you the losses to the human environment which your Regulations will bring about. Again, the evidence calls for withdrawal under your President's directive to you.

Another provision from 12866:

1. <u>Each agency shall base its decisions on the best reasonably obtainable scientific, technical, economic, and other information concerning the need for, and consequences of, the intended regulation.</u>

Your Regulations ignore the Royal Academy study, as well as the opinions of virtually every medical expert including Dr. John Dunn who testified in our hearing that the vaping industry provides a safe alternative to health destructive smoking. The consequences of the Regulations will be the destruction of an industry that offers serious relief to the vast wasteland of health care for the smoker. Again,

under the President's Executive Order language, the Regulations should be withdrawn.

From 12866:

2. <u>Each agency shall identify and assess alternative forms of regulation and shall, to the extent feasible, specify performance objectives</u>, rather than specifying the behavior or manner of compliance that regulated entities must adopt.

Your Regulations provide no "performance objectives" with regard to the industry which will have to submit applications for approval of products. They are playing at a guessing game to determine what you want, what you need, and by what standard you will act in granting or rejecting approval.

From 12866:

"Each agency shall tailor its regulations to impose the least burden on society, including individuals, businesses of differing sizes, and other <u>entities (including small communities and governmental entities)</u>, <u>consistent with obtaining the regulatory objectives</u>, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations."

A careful reading of our Findings will demonstrate to you that you have not fulfilled the President's Order about imposing the "least burden" on our small local community. The vaping industry makes up a very important part of our lifestyle and our economy, our social cohesiveness. The impact on our community if we lose Johnson Enterprises and the individual vape shops will be astronomical---a loss that is staggering in dollar amounts as well as a loss of our citizens and the important role they play in our interchange of information.

Ultimate provisions re local input:

1. Wherever feasible, agencies shall seek views of appropriate State, local, and tribal officials before imposing regulatory requirements that might significantly or uniquely affect those governmental entities. Each agency shall assess the effects of Federal regulations on State, local, and tribal governments, including specifically the availability of resources to carry out those mandates, and seek to minimize those burdens that uniquely or significantly affect such governmental entities, consistent with achieving regulatory objectives. In addition, as appropriate, agencies shall seek to harmonize Federal regulatory actions with related State, local, and tribal regulatory and other governmental functions.

The Deeming Regulations fall so far afield from the President's directions to you that it hardly needs our comment that the Regulations are out of sync with this Executive Order and should be withdrawn. You in no way sought our views, the

views of the County or the State of Wisconsin legislators who testified at our hearing through written statements. You did not seek our input, either with us all or with those of us in local government, with information to others to follow.

Because of the failure to coordinate and because of the statutory and constitutional flaws in the content of the Regulations, we call on you to arrange to meet with us personally or through an authorized representative to discuss what should be done about the regulations.

Our preference, of course, would be for you to rescind the Regulations in order to start over with drafting new regulations with input from Hartland and the experts who testified during our hearing.

We await your response and the beginning of coordination.

Cordially,

Jeffrey Pfannerstill Village President

Village of Hartland, Wisconsin

IN RE THE FINDINGS AND CONCLUSIONS OF THE VILLAGE OF HARTLAND, WISCONSIN RE COORDINATION WITH THE FOOD AND DRUG ADMINISTRATION AS TO ITS DEEMING REGULATIONS RESTRICTING THE ELECTRONIC VAPING INDUSTRY

ON APRIL 27 - MAY 1, 2017

THE LAWS THAT GOVERN THE COORDINATION PROCESS

PREPARED BY HEARING OFFICER FRED KELLY GRANT----April 27, 2017

The process of "coordination" as set forth in federal statutes requires all levels of government to "coordinate" with the lowest level, that nearest the people, nearest the problems to be solved, before deciding on policies, plans or actions. It is not a concept or process foreign to our American way of thinking or governing. From the time our nation was born, local government was vital, and most decisions affecting citizens were made in town meetings---raucous in New England---gentile, at least on the surface, in the South--wild and rough in the West. As our settlements moved westward toward our Manifest Destiny, local governments were the first established. Most services that are enjoyed by citizens are furnished by local government. Local government is the level at which individual voices can be heard, and at the local level there is far less skepticism about whether our elected and appointed officials will give our interests priority.

In the early 1990s it was at the local level in Owyhee County that we set out to save livestock ranching from a powerful lobby that influenced the Secretary of the Interior to end a traditional use of the rangelands in the west. "Coordination" as set forth in federal statutes won out for rocal citizens against sheer national power and money and special interests. Since that time, the process has brought relief to local governments and their citizens from South Dakota to Texas---even stopping the first leg of the NAFTA Superhighway through action by four tiny towns with a total population of 6,000.

Faced with destruction of an industry by the Food and Drug Administration—an industry that brings hope to individuals who want to escape the clutches of addicting tobacco, the Electronic Vaping Coalition of America, through its Founder Mark Block and co-Founder Linda Hansen, called for a hearing by the Village of Hartland for the purpose of establishing whether Food and Drug would coordinate with the village as it is required to do.

The Coalition is vividly aware of the fact that since at least November 10, 1961 Presidents of the United States, who have direct authority over all agencies in the Executive Branch of Government, have directed that the agencies make the effort to "coordinate" with local governments.

Congress added its voice to the need for coordination when in the passage of NEPA it required that all federal agencies cooperate with local governments in coordinating programs for the benefit of the human environment, and in the Federal Land Policy Management Act which defined the term.

Mr. Block pointed to and relied upon the actions of Presidents John Fitzgerald Kennedy, Ronald Reagan, William Clinton and Barack Obama to show the importance to the people of the nation the need for federal agencies to coordinate their activities with local governments that most directly represent the citizens, those governments that actually deliver services to the citizens of the United States of America.

PRESIDENTIAL MEMORANDUM FROM JOHN FITZGERALD KENNEDY:

On November 10, 1961 President John Fitzgerald Kennedy issued a Presidential Memorandum Directive that ordered federal agencies to organize the structure for reaching out to citizens at the local level to coordinate government services and understanding of citizens needs as to 'economic problems, natural resources development, protection of equal rights and urban development efforts." The Directive provided as follows:

John F. Kennedy November 10, 1961

465 Memorandum on the Need for Greater Coordination of Regional and Field Activities of the Government.

Memorandum for Heads of Department and Agencies

As an integral part of present steps to increase the effectiveness and economy of Federal agencies, I want coordination of government activities outside of Washington significantly strengthened. That is to include improvement of the management and direction of Federal offices throughout the country by the chief departmental officials in Washington, and provision for an interagency working group for closer coordination across department and agency lines in important centers of Federal activity outside of the National Capital area.

More than ninety percent of all Federal employees work outside of the Washington area. Decisions affecting the expenditure of tens of billions of

dollars are made in the field. Federal programs have their impact on State and local governments largely through the actions of regional and local representatives of our departments and agencies. Most important, Federal officials outside of Washington provide the principal day-to-day contact of the Government with the citizens of this country and generally constitute the actual point of contact for Federal programs with the economy and other phases of our national life.

In the international assistance programs, previously separate U.S. efforts are being brought together in order to provide a common focus on the needs and problems of individual countries. Here at home we must similarly bring more closely together the many activities of the Federal Government in individual states and communities throughout the nation.

Although each Executive agency and its field organization have a special mission, there are many matters on which the work of the departments converge. Among them are management and budgetary procedures, personnel policies, recruitment efforts, office space uses, procurement activities, public information duties, and similar matters. There are opportunities to pool experience and resources, and to accomplish savings. In substantive programs, there are also opportunities for a more closely coordinated approach in many activities, as on economic problems, natural resources development, protection of equal rights, and urban development efforts.

As a first step in bringing Federal officials outside of Washington closer together, I have directed the Chairman of the <u>Civil Service Commission</u> to arrange for the establishment of a Board of Federal Executives in each of the Commission's administrative regions. Where associations of Federal regional officials exist in other regional centers they will be continued. Each Executive department and agency is directed to arrange for personal participation by the heads of its field offices and installations in the work of these <u>Federal Executive Boards</u>. These activities are not to require additional personnel but provide means for closer coordination of Federal activities at the regional level.

The cooperative activities of Federal Executive Boards must be undertaken primarily through the initiative of the head of our field activities. The Chairman of the Civil Service Commission and the Director of the <u>Bureau of the Budget</u> will furnish the Boards from time to time with guides on official goals and objectives in the management field and will arrange for periodic briefings by national executives of the government. Each of the Boards will consider management matters and interdepartmental cooperation and establish liaison with State and local government officials in their regions. A clearinghouse will be provided in the office of the Chairman of the Civil Service Commission on problems and recommendations submitted by the regional Boards.

Following a reasonable period for evaluation on these initial steps, recommendations are to be prepared by the Chairman of the Civil Service Commission and the Director of the Bureau of the Budget for continuing improvement of the management and coordination of Federal activities.

Within each department, I want the chief officers of each agency, particularly the chief operating officials for administrative matters, to make critical appraisal of pending field management procedures with the principal

regional officers of that agency. The Director of the Bureau of the Budget shall provide guidance to department and agency heads on their internal appraisals of field management. Over all, new emphasis shall be placed on management skills in support of improved economy, efficiency, and the substantive effectiveness of the Executive Branch of the Government.

JOHN F. KENNEDY

EXECUTIVE ORDER DIRECTING COORDINATION BY PRESIDENT RONALD REAGAN:

On the official birth day of the Republic, July 4, 1982, President Ronald Reagan ordered that all federal agencies conduct a review of our federal system thorough coordination with local governments:

Executive Order 12372--Intergovernmental review of Federal programs

Source: The provisions of Executive Order 12372 of July 14, 1982, appear at 47 FR 30959, 3 CFR, 1982 Comp., p. 197, unless otherwise noted.

By the authority vested in me as President by the Constitution and laws of the United States of America, including Section 401(a) of the Intergovernmental Cooperation Act of 1968 (42 U.S.C. 4231(a)), Section 204 of the Demonstration Cities and Metropolitan Development Act of 1966 (42 U.S.C. 3334) and Section 301 of Title 3 of the United States Code, and in order to foster an intergovernmental partnership and a strengthened federalism by relying on State and local processes for the State and local government coordination and review of proposed Federal financial assistance and direct Federal development, it is hereby ordered as follows: [Preamble amended by Executive Order 12416 of Apr. 8, 1983, 48 FR 15587, 3 CFR, 1983 Comp., p. 186]

Section 1. Federal agencies shall provide opportunities for consultation by elected officials of those State and local governments that would provide the non-Federal funds for, or that would be directly affected by, proposed Federal financial assistance or direct Federal development.

- Sec. 2. To the extent the States, in consultation with local general purpose governments, and local special purpose governments they consider appropriate, develop their own processes or refine existing processes for State and local elected officials to review and coordinate proposed Federal financial assistance and direct Federal development, the Federal agencies shall, to the extent permitted by law: (a) Utilize the State process to determine official views of State and local elected officials.
- (b) Communicate with State and local elected officials as early in the program planning cycle as is reasonably feasible to explain specific plans and actions. (c) Make efforts to accommodate State and local elected officials' concerns with proposed Federal financial assistance and direct Federal development that are communicated through the designated State process. For those cases where the concerns cannot be accommodated, Federal officials shall explain the bases for their decision in a timely manner.
- (d) Allow the States to simplify and consolidate existing Federally required Stateplan submissions. Where State planning and budgeting systems are sufficient and where permitted by law, the substitution of State plans for Federally required State plans shall be encouraged by the agencies.
- (e) Seek the coordination of views of affected State and local elected officials in oneState with those of another State when proposed Federal financial assistance or direct Federal development has an impact on interstate metropolitan urban centers or other interstate areas. Existing interstate mechanisms that are redesignated as part of the State process may be used for this purpose.
- (f) Support State and local governments by discouraging the reauthorization orcreation of any planning organization which is Federally-funded, which has a Federally-prescribed membership, which is established for a limited purpose, and which is not adequately representative of, or accountable to, State or local elected officials.
- Sec. 3. (a) The State process referred to in Section 2 shall include those where States delegate, in specific

instances, to local elected officials the review, coordination, and communication with Federal agencies.

- (b) At the discretion of the State and local elected officials, the State process may exclude certain Federal programs from review and comment.
- Sec. 4. The Office of Management and Budget (OMB) shall maintain a list of official State entities designated by the States to review and coordinate proposed Federal financial assistance and direct Federal development. The Office of Management and Budget shall disseminate such lists to the Federal agencies.
- Sec. 5. (a) Agencies shall propose rules and regulations governing the formulation, evaluation, and review of proposed Federal financial assistance and direct Federal development pursuant to this Order, to be submitted to the Office of Management and Budget for approval. (b) The rules and regulations which result from the process indicated in Section 5(a) above shall replace any current rules and regulations and become effective September 30, 1983.

[Sec. 5 amended by Executive Order 12416 of Apr. 8, 1983, 48 FR 15587, 3 CFR, 1983 Comp., p. 1861

Sec. 6. The Director of the Office of Management and Budget is authorized to prescribe such rules and regulations, if any, as he deems appropriate for the effective implementation and administration of this Order and the Intergovernmental Cooperation Act of 1968. The Director is also authorized to exercise the authority vested in the President by Section 401(a) of that Act (42 U.S.C. 4231(a)), in a manner consistent with this Order.

Sec. 7. The Memorandum of November 8, 1968, is terminated (33 Fed. Reg. 16487, November 13, 1968). The Director of the Office of Management and Budget shall revoke OMB Circular A-95, which was issued pursuant to that Memorandum. However, Federal agencies shall continue to comply

with the rules and regulations issued pursuant to that

Memorandum, including those issued by the Office of Management and Budget, until new rules and regulations have been issued in accord with this Order.

Sec. 8. The Director of the Office of Management and Budget shall report to the President by September 30, 1984 on Federal agency compliance with this Order. The views of State and local elected officials on their experiences with these policies, along with any suggestions for improvement, will be included in the Director's report. [Sec. 8 amended by Executive Order 12416 of Apr. 8, 1983, 48 FR 15587, 3 CFR, 1983 Comp., p. 186]

/s/ RONALD REAGAN

The White House July 14, 1982

Federal Register

Vol. 64, No. 153

[Filed with the Office of the Federal Register, 3:18 p.m., July 14, 1982]

AGAIN FEDERAL AGENCIES WERE ORDERED TO COORDINATE WITH LOCAL GOVERNMENT BY THE 'FEDERALISM' EXECUTIVE ORDER ISSUED BY WILLIAM CLINTON:

On August 10, 1999 President William Clinton ordered in a "Federalism" Executive order that all federal agencies develop a coordination regime with local governments:

•	Executive order 13132 of August 4, 1777
Tuesday, August 10,	Federalism
1999	
	By the authority vested in me as President by the
Title 3— The	Constitution and the laws of the United States of America,
President	and in order to guarantee the division of governmental

Presidential Documents

Executive Order 13132 of August 4, 1999

responsibilities between the national government and the States that was intended by the Framers of the Constitution, to ensure that the principles of federalism established by the Framers auide the executive departments and agencies in the formulation implementation of policies, and to further the policies of the Unfunded Mandates Reform Act, it is hereby ordered as follows: Section 1. Definitions. For purposes of this order:

"Policies (a) that have federalism implications" refers to regulations, legislative comments or proposed legislation, and other policy

statements or actions that have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

- (b) "State" or "States" refer to the States of the United States of America, individually or collectively, and, where relevant, to State governments, including units of local government and other political subdivisions established by the States.
- (c) "Agency" means any authority of the United States that is an "agency"under 44 U.S.C. 3502(1), other than those considered to be independent regulatory agencies, as defined in 44 U.S.C. 3502(5).
- (d) "State and local officials" means elected officials of State and localgovernments or their representative national organizations.
- Sec. 2. Fundamental Federalism Principles. In formulating and implementing policies that have federalism implications, agencies shall be guided by the following fundamental federalism principles:
- (a) Federalism is rooted in the belief that issues that are not nationalin scope or significance are most appropriately addressed by the level of government closest to the people.
- (b) The people of the States created the national government and delegated to it enumerated governmental powers. All other sovereign powers, save those expressly prohibited the States by the Constitution, are reserved to the States or to the people.
- (c) The constitutional relationship among sovereign governments, Stateand national, is inherent in the very structure of the Constitution and is formalized in and protected by the Tenth Amendment to the Constitution.
- (d) The people of the States are free, subject only to restrictions in the Constitution itself or in constitutionally authorized Acts of Congress, to define the moral, political, and legal character of their lives.
- (e) The Framers recognized that the States possess unique authorities, qualities, and abilities to meet the needs of the people and should function as laboratories of democracy.

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- (f) The nature of our constitutional system encourages a healthy diversityin the public policies adopted by the people of the several States according to their own conditions, needs, and desires. In the search for enlightened public policy, individual States and communities are free to experiment with a variety of approaches to public issues. One-size-fits-all approaches to public policy problems can inhibit the creation of effective solutions to those problems.
- (g) Acts of the national government—whether legislative, executive, orjudicial in nature—that exceed the enumerated powers of that government under the Constitution violate the principle of federalism established by the Framers.
- (h) Policies of the national government should recognize the responsibility of—and should encourage opportunities for—individuals, families, neighborhoods, local governments, and private associations to achieve their personal, social, and economic objectives through cooperative effort.
- (i) The national government should be deferential to the States whentaking action that affects the policymaking discretion of the States and should act only with the greatest caution where State or local governments have identified uncertainties regarding the constitutional or statutory authority of the national government.
- Sec. 3. Federalism Policymaking Criteria. In addition to adhering to the fundamental federalism principles set forth in section 2, agencies shall adhere, to the extent permitted by law, to the following criteria when formulating and implementing policies that have federalism implications:
- (a) There shall be strict adherence to constitutional principles. Agencies shall closely examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and shall carefully assess the necessity for such action. To

the extent practicable, State and local officials shall be consulted before any such action is implemented. Executive Order 12372 of July 14, 1982 ("Intergovernmental Review of Federal Programs") remains in effect for the programs and activities to which it is applicable.

- (b) National action limiting the policymaking discretion of the States shallbe taken only where there is constitutional and statutory authority for the action and the national activity is appropriate in light of the presence of a problem of national significance. Where there are significant uncertainties as to whether national action is authorized or appropriate, agencies shall consult with appropriate State and local officials to determine whether Federal objectives can be attained by other means.
- (c) With respect to Federal statutes and regulations administered by theStates, the national government shall grant the States the maximum administrative discretion possible. Intrusive Federal oversight of State administration is neither necessary nor desirable.
- (d) When undertaking to formulate and implement policies that havefederalism implications, agencies shall:
 - (1) encourage States to develop their own policies to achieve programobjectives and to work with appropriate officials in other States;
 - (2) where possible, defer to the States to establish standards;
 - (3) in determining whether to establish uniform national standards, consult with appropriate State and local officials as to the need for national standards and any alternatives that would limit the scope of national standards or otherwise preserve State prerogatives and authority; and
 - (4) where national standards are required by Federal statutes, consultwith appropriate State and local officials in developing those standards.

- Sec. 4. Special Requirements for Preemption. Agencies, in taking action that preempts State law, shall act in strict accordance with governing law.
- (a) Agencies shall construe, in regulations and otherwise, a Federal statuteto preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.
- Federal statute Where a does not (b) preempt State law (as addressedin subsection (a). of this section), agencies shall construe any authorization in the statute for the issuance of regulations as authorizing preemption of State law by rulemaking only when the exercise of State authority directly conflicts with the exercise of Federal authority under the Federal statute or there is clear evidence to conclude that the Congress intended the agency to have the authority to preempt State law.
- (c) Any regulatory preemption of State law shall be restricted to theminimum level necessary to achieve the objectives of the statute pursuant to which the regulations are promulgated.
- (d) When an agency foresees the possibility of a conflict between Statelaw and Federally protected interests within its area of regulatory responsibility, the agency shall consult, to the extent practicable, with appropriate State and local officials in an effort to avoid such a conflict.
- (e) When an agency proposes to act through adjudication or rulemakingto preempt State law, the agency shall provide all affected State and local officials notice and an opportunity for appropriate participation in the proceedings.
- Sec. 5. Special Requirements for Legislative Proposals. Agencies shall not submit to the Congress legislation that would:
- (a) directly regulate the States in ways that would either interfere withfunctions essential to the States' separate and independent existence or

be inconsistent with the fundamental federalism principles in section 2;

- (b) attach to Federal grants conditions that are not reasonably related to the purpose of the grant; or
- (c) preempt State law, unless preemption is consistent with the fundamental federalism principles set forth in section 2, and unless a clearly legitimate national purpose, consistent with the federalism policymaking criteria set forth in section 3, cannot otherwise be met.

Sec. 6. Consultation.

- (a) Each agency shall have an accountable process to ensure meaningfuland timely input by State and local officials in the development of regulatory policies that have federalism implications. Within 90 days after the effective date of this order, the head of each agency shall designate an official with principal responsibility for the agency's implementation of this order and that designated official shall submit to the Office of Management and Budget a description of the agency's consultation process.
- (b) To the extent practicable and permitted by law, no agency shall promulgate any regulation that has federalism implications, that imposes substantial direct compliance costs on State and local governments, and that is not required by statute, unless:
 - (1) funds necessary to pay the direct costs incurred by the State and local governments in complying with the regulation are provided by the

Federal Government; or

- (2) the agency, prior to the formal promulgation of the regulation,
 - (A) consulted with State and local officials early in the process of developing the proposed regulation;

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- (B) in a separately identified portion of the preamble to the regulation as it is to be issued in the Federal Register, provides to the Director of the Office of Management and Budaet federalism summary а statement, which consists of a description of the extent of the agency's prior consultation with State and local officials, a summary of the nature of their concerns and the agency's position supporting the need to issue the regulation, and a statement of the extent to which the concerns of State and local officials have been met; and
- (C) makes available to the Director of the Office of Management and Budget any written communications submitted to the agency by State and local officials.
- (c) To the extent practicable and permitted by law, no agency shall promulgate any regulation that has federalism implications and that preempts State law, unless the agency, prior to the formal promulgation of the regulation,
 - (1) consulted with State and local officials early in the process of developing the proposed regulation;
- (2) in a separately identified portion of the preamble to the regulationas it is to be issued in the Federal Register, provides to the Director of the Office of Management and Budget a federalism summary impact statement, which consists of a description of the extent of the agency's prior consultation with State and local officials, a summary of the nature of their concerns and the agency's position supporting the need to issue the regulation, and a statement of the extent to which the concerns of State and local officials have been met; and
 - (3) makes available to the Director of the Office of Management andBudget any written communications submitted to the agency by State and local officials.

Sec. 7. Increasing Flexibility for State and Local Waivers.

- (a) Agencies shall review the processes under which State and local governments apply for waivers of statutory and regulatory requirements and take appropriate steps to streamline those processes.
- (b) Each agency shall, to the extent practicable and permitted by law, consider any application by a State for a waiver of statutory or regulatory requirements in connection with any program administered by that agency with a general view toward increasing opportunities for utilizing flexible policy approaches at the State or local level in cases in which the proposed waiver is consistent with applicable Federal policy objectives and is otherwise appropriate.
- (c) Each agency shall, to the extent practicable and permitted by law,render a decision upon a complete application for a waiver within 120 days of receipt of such application by the agency. If the application for a waiver is not granted, the agency shall provide the applicant with timely written notice of the decision and the reasons therefor.
- (d) This section applies only to statutory or regulatory requirements that are discretionary and subject to waiver by the agency.

Sec. 8. Accountability.

- (a) In transmitting any draft final regulation that has federalism implications to the Office of Management and Budget pursuant to Executive Order 12866 of September 30, 1993, each agency shall include a certification from the official designated to ensure compliance with this order stating that the requirements of this order have been met in a meaningful and timely manner.
- (b) In transmitting proposed legislation that has federalism implications to the Office of Management and Budget, each agency shall include a certification from the official designated to ensure compliance with this order that all relevant requirements of this order have been met.

- (c) Within 180 days after the effective date of this order, the Directorof the Office of Management and Budget and the Assistant to the President for Intergovernmental Affairs shall confer with State and local officials to ensure that this order is being properly and effectively implemented.
- Sec. 9. Independent Agencies. Independent regulatory agencies are encouraged to comply with the provisions of this order.

Sec. 10. General Provisions.

- (a) This order shall supplement but not supersede the requirements contained in Executive Order 12372 ("Intergovernmental Review of Federal Programs"), Executive Order 12866 ("Regulatory Planning and Review"), Executive Order 12988 ("Civil Justice Reform"), and OMB Circular A-19.
- (b) Executive Order 12612 ("Federalism"), Executive Order 12875 ("Enhancing the Intergovernmental Partnership"), Executive Order 13083 ("Federalism"), and Executive Order 13095 ("Suspension of Executive Order 13083") are revoked.
- (c) This order shall be effective 90 days after the date of this order.Sec. 11. Judicial Review. This order is intended only to improve the internal management of the executive branch, and is not intended to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, its

officers, or any person. THE WHITE HOUSE,

August 4, 1999.

[FR Doc. 99–20729 Filed 8–9–99; 8:45 am] Billing code 3195–01–P THE DIRECT ORDERING OF COORDINATION
CONTINUED WITH PRESIDENT BARACK OBAMA WHO
ISSUED AN EXECUTIVE ORDER ON JUNE 9, 2011 AGAIN
ORDERING ALL FEDERAL AGENCIES TO COORDINATE
WITH LOCAL GOVERNMENTS.

On June 9, 2011, President Barack Obama ordered the creation of a Rural Council for the purposes of all federal agencies coordinating with local governments:

EXECUTIVE ORDER - - - - - ESTABLISHMENT OF THE WHITE HOUSE RURAL COUNCIL By the authority vested in me as President by the Constitution and the laws of the United States of America and in order to enhance Federal engagement with rural communities, it is hereby ordered as follows: Section 1. Policy. Sixteen percent of the American population lives in rural counties. Strong, sustainable rural communities are essential to winning the future and ensuring American competitiveness in the years ahead. These communities supply our food, fiber, and energy, safeguard our natural resources, and are essential in the development of science and innovation. Though rural communities face numerous challenges, they also present enormous economic potential. The Federal Government has an important role to play in order to expand access to the capital necessary for economic growth, promote innovation, improve access to health care and education, and expand outdoor recreational activities on public lands. To enhance the Federal Government's efforts to address the needs of rural America, this order establishes a council to better coordinate Federal programs and maximize the impact of Federal investment to promote economic prosperity and quality of life in our rural communities. Sec. 2. Establishment. There is established a White House Rural Council (Council). Sec. 3. Membership. (a) The Secretary of Agriculture shall serve as the Chair of the Council, which shall also include the heads of the following executive branch departments, agencies, and offices: (1) the

Department of the Treasury; (2) the Department of Defense; (3) the Department of Justice; (4) the Department of the Interior; (5) the Department of Commerce; (6) the Department of Labor; (7) the Department of Health and Human Services; (8) the Department of Housing and Urban Development; 2 (9) the Department of Transportation; (10) the Department of Energy; (11) the Department of Education; (12) the Department of Veterans Affairs; (13) the Department of Homeland Security; (14) the Environmental Protection Agency; (15) the Federal Communications Commission; (16) the Office of Management and Budget; (17) the Office of Science and Technology Policy; (18) the Office of National Drug Control Policy; (19) the Council of Economic Advisers; (20) the Domestic Policy Council; (21) the National Economic Council; (22) the Small Business Administration; (23) the Council on Environmental Quality; (24) the White House Office of Public Engagement and Intergovernmental Affairs; (25) the White House Office of Cabinet Affairs; and such other executive branch departments, agencies, and offices as the President or the Secretary of Agriculture may, from time to time, designate. (b) A member of the Council may designate, to perform the Council functions of the member, a senior-level official who is part of the member's department, agency, or office, and who is a full-time officer or employee of the Federal Government. (c) The Department of Agriculture shall provide funding and administrative support for the Council to the extent permitted by law and within existing appropriations. (d) The Council shall coordinate its policy development through the Domestic Policy Council and the National Economic Council. Sec. 4. Mission and Function of the Council. The Council shall work across executive departments, agencies, and offices to coordinate development of policy recommendations to promote economic prosperity and quality of life in rural America, and shall coordinate my Administration's engagement with rural communities. Sec. 5. General Provisions. (a) The heads of executive departments and agencies shall assist and provide information to the Council, consistent with applicable law, as may be necessary to carry out the functions of the Council. Each executive department

and agency shall bear its own expense for participating in the Council. (b) Nothing in this order shall be construed to impair or otherwise affect: (i) authority granted by law to an executive department, agency, or the head thereof; or (ii) functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals. (c) This order shall be implemented consistent with applicable law and subject to the availability of appropriations. (d) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person. BARACK OBAMA THE WHITE HOUSE, June 9, 2011.

As you can see from this virtually uninterrupted string of Presidential orders, the process of coordination is not new, it is not unknown, and the fact that it is ignored is not acceptable to local governments.

So, Hartland invoked coordination upon request by Block and Hansen in order to assist its local business Johnson Creek Enterprises maintain viability in the face of economic ruin threatened by the Food and Drug Administration.

Congress has joined with Presidents Kennedy, Reagan, Clinton and Obama in ordering that coordination occur between federal agencies and local governments.

The Food and Drug Administration is a federal agency that is subject to , and not immune from, the National Environmental Policy Act

THE WISCONSIN AND FEDERAL CONSTITUTIONAL AND STATUTORY REQUIREMENTS ON COORDINATION TO IMPLEMENT THE PRIOR EXECUTIVE ORDERS DIRECTING THE AGENCIES TO COORDINATE

Written by Fred Kelly Grant, Esq.

April 27, 2017

The Food and Drug Administration is a federal agency that is subject to, and not immune from, the National Environmental Policy Act, which applies to ALL FEDERAL AGENCIES. It is an agency within the Department of Health and Human Services, under the direction of the Secretary of Health and Human Services, appointed by the President. That is a department and secretary with the Executive branch of the government under the direct supervision and direction of the President of the United States. The Department was created by, and its duties are set by Congress as are all members of the Cabinet.

The Secretary has delegated responsibility for supervision over the Food and Drug Administration to a Commissioner who is named by the President and must be confirmed by the Congress. So, the immediate superior to the Food and Drug regulatory program is the Commissioner.

The Food and Drug Administration is not an independent, stand alone agency of government with unlimited power. It is a part of the Executive branch of government, and is responsible for compliance with statutes, and with Executive Orders issued by the President. Of course, it is not immune from the Constitution of the United States of America.

The Village of Hartland is a unit of local government within the county of Waukesha, and the state of Wisconsin. It has all the authority granted to villages by the legislature of Wisconsin under the constitution and statutes of Wisconsin. It also has all the authority granted to local governments by the Tenth Amendment to the United States Constitution, and its citizens and elected officials have all the rights guaranteed by the Ninth and Fourteenth Amendments to the United States Constitution.

Under the Tenth Amendment, Hartland is authorized to exercise the "police powers" of a local government that include, according to the United States and Wisconsin Supreme Courts, law enforcement and public health and safety.

As pointed out in Hartland's Resolution number 02/13/2017-02 Hartland exercises home rule to promote "the general welfare, peace, good order, and prosperity" of its citizens, and to care for the "commercial benefit and for the health, safety, welfare, and convenience of the public." Art. XI Section 3 Wisconsin Constitution; Wisconsin Statutes 61.34 (5)

At the end of the 1960s and the beginning of the 1970s the national government was beginning to move into an era of legislating and controlling the environment of

America, and that means environment in its overall sense. In the Merriam Webster dictionary, Environment is defined as the "circumstances, objects, or conditions by which one is surrounded the complex of physical, chemical, and biotic factors (such as climate, soil, and living things) that act upon an organism or an ecological community and ultimately determine its form and survival: the aggregate of social and cultural conditions that influence the life of an individual or community"

As one of the protections of local government and its authority at this time of national expansion, Congress passed the National Environmental Policy Act, and in it required that EVERY AGENCY OF THE NATIONAL GOVERNMENT recognize it had a duty to work in coordination with local governments. To that end, Congress ordered that every agency "in cooperation with...local governments...to use all practicable means and measures, including financial and technical assistance, in a manner calculated to foster and promote the general welfare, to create and maintain conditions under which man and nature can exist in productive harmony, and fulfill the social, economic, and other requirements of present and future generations of Americans to improve and coordinate Federal plans, functions use all practicable means and measures.... to improve and coordinate Federal plans, functions, programs and resources..."

Further, Congress ordered that every agency "to the fullest extent possible" interpret and administer all regulations, polices and laws of the United States in accordance with the stated policy.

So, it is the law of the United States, binding to the Food and Drug Administration, that it coordinates its regulations with local governments, such as the Village of Hartland.

So, what does "coordination" require? Well, it is clear that Congress knows the difference between cooperate, consult, collaborate, and coordinate because it uses the words in different ways in the same statutes. For example, In the Tobacco Control Act it provided in section 914 that the Chairman of the Federal Trade Commission shall "coordinate" a duty with the Secretary, and the Secretary shall "consult" with the Chairman on a duty. So, clearly Congress does not use the words interchangeably. So what does it mean when it uses the word "coordination"?

Well, the law is that when a word of common usage is used in a statute and not defined, it is to be taken to mean what the dictionary says it means. And the dictionary definitions of "coordination"" all are pretty much the same in that they require some "equal type" working together.

Virtually all dictionary definitions contain the concept of equal, not subordinate and harmonious discussions and resolutions of conflicts.

And the dictionary definition are consistent with what Congress was thinking when it passed the National Environmental Policy Act.

In the exercise of its local government authority, the Hartland Village Board should have been involved in a coordinated effort with the Food and Drug Administration before the set of Deeming Regulations were developed and issued purportedly to implement the Family Smoking Prevention and Tobacco Control Act. Section 916 of that Act preserves to Hartland the authority and right "to enact, adopt, promulgate, and enforce any law, rule, regulation, or other measure with respect to tobacco products that is in addition to, or more stringent than, requirements established under this chapter, including a law, rule, regulation, or other measure relating to or prohibiting the sale, distribution, possession, exposure to, access to, advertising and promotion of, or use of tobacco products by individuals of any age, information reporting to the State, or measures relating to fire safety standards for tobacco products" or to tax "tobacco products".

Clearly Congress did not think it was granting that authority to Hartland; Rather, Congress recognized that Hartland already had that authority because it styled the section 916 as "Preservation" of authority, acknowledging that such authority already existed.

The existence of such local authority, traditional in our nation, as recognized by the Tenth Amendment, makes it apparent why Congress ordered executive agencies to "coordinate" with local governments before rushing off to regulate the lives of citizens of the local governments. It was important to do so to maintain the federal republic structure that is established by the Constitution.

The Tobacco situation presents a good example of why Congress ordered all national agencies to coordinate with local governments in the National Environmental Policy Act (NEPA). Local governments like Hartland have the police power to enact law enforcement and health laws that would impact tobacco smoking and allowable age; that power and authority has been traditional and that is why the United States Supreme Court has said that the Tenth Amendment reserved the police powers. Since local governments had and have that power, it is only logical, but more than logical, it is legally required, that coordination in an equal participation basis be conducted with local government before a non-elected agency of the national government imposes regulations that might adversely impact the power and authority of the local government.

At the time NEPA was passed, there was a whole host of environmental laws in the mix in the nation's capital: the Clean Water Act, the Clean Air Act, the Endangered Species Act, the Federal Land Policy and Management Act and the National Forest Management Act. Human health was in the limelight as President Nixon proposed an affordable care health insurance program, so NEPA did not concern just land and earth, and of all the environmental acts, Congress chose the comparable Federal Land Policy and Management Act to define coordination. These were all environmental Acts; they had to do with the natural environment and the human environment that includes economic, cultural, and social considerations. Under the statutory interpretation doctrine of IN PARA MATERI, when the Congress defines a term in one statute and then uses

the term in comparable statutes, but does not redefine it, it intends that the definition be the same.

In the case of Coordination, whether you look to the dictionary definition or to the Congressional definition, you reach the same conclusion: Congress intends that the agencies work together equally with local government to resolve conflicts in policy.

As a matter of first order, the Food and Drug Administration is directed by President Donald Trump to coordinate with local governments such as Hartland. One of his first orders was for every department to review its regulations and hold up on enforcing any one that had an adverse impact on jobs, employment, or economic gain. That order directly involves the Deeming Regulations.

When the Deeming Regulations were developed, the Food and Drug Administration was also under direction from President Barack Obama to coordinate with local governments such as Hartland in Executive Order establishing the Rural Council.

This direction to coordinate with local government is not something new and unique. It has been a direction to executive agencies since President John Fitzgerald Kennedy ordered it in a Presidential Memorandum dated November 10, 1961.

President Ronald Reagan, in Executive Order 12372, continued the direction to coordinate.

Furthermore, it was again directed by President Clinton. In Executive Order 13132 he directs the agencies to leave states and communities "free to experiment with a variety of approaches to public issues. One size fits all approaches to public policy problems can inhibit the creation of effective solutions to those problems." He directed agencies that national policies should "encourage opportunities for...local governments...to achieve their personal, social, and economic objectives through cooperative effort....The national government should be deferential [where] local governments have identified uncertainties regarding the constitutional or statutory authority of the national government."

Consistent with directions from Presidents Kennedy and Reagan, the Congress mandated that federal agencies coordinate their programs, policies, and actions with local governments when the National Environmental Policy Act was passed and signed into law in 1969. That act, commonly known as NEPA provides: it is the continuing responsibility of the Federal Government to use all practicable means, consistent with other essential considerations of national policy, to improve and *coordinate* Federal plans, functions, programs and resources; (2) assure for all Americans safe, *healthful*, productive, and esthetically, and culturally pleasing surroundings; in cooperation with State and local governments to use all practicable means and measures, including financial and technical assistance, in a manner calculated to foster and promote the general welfare.

Many times we tend to overlook the true meaning of the National Environmental Policy Act, and push it aside unless we are discussing some attribute of the natural environment---the

forests, the desert, the mountains, the coastline. But it is designed for far more than that. In fact, the very first sentence of the Act makes it clear that Congress' prime point of interest is "man" and "his" environment, not the natural environment. Congress opened the Act with a declaration of "national policy" to "encourage productive and enjoyable harmony between man and his environment," and of intent to "stimulate the health and welfare of man." The Council on Environmental Quality was established by the Act as the overseer of the activities taking place to put the Act into effect. One of its first acts was to define the terms to be used. The term "human environment" is set forth as explanation of this provision of the law, and makes it clear that the environment of man should be what the Council has defined as the "human environment."

In 40 CFR 1508.14 "human environment" is defined as:

'Human environment' shall be interpreted comprehensively to include the natural and physical environment and the relationship of people with that environment (see the definition of 'effects' 1508.8) This means that economic or social effects are not intended by themselves to require preparation of an environmental impact statement. When an environmental impact statement is prepared, and economic or social and natural or physical environmental effects are interrelated, then the environmental impact statement will discuss all of these effects on the human environment."

The term "effects" to which we are referred is defined by 1508.8 to include:

"effects includes ecological (such as the effects on natural resources and on the components, structures, and functioning of affected ecosystems) aesthetic, historic, cultural, economic, social, or health, whether direct, indirect or cumulative."

So, clearly, it is the direction of the Council that the Congress intended that NEPA analysis occur when necessary to determine the impact of an action on the economy, social structure, and cultural structure of man in a community, and to further determine impact on the health of man, which is consistent with the stated policy of encouraging stimulation of health in man.

Congress in 2009 enacted the Family Smoking Prevention and Tobacco Control Act.

Development of and issuance of a set of regulations is a major federal action as defined by the Council on Environmental Quality, created by the National Environmental Policy Act, and seated in the office of the President.

On every "major federal action" there must be NEPA study. And "major federal action" is defined as including:

"actions with effects that may be major and which are potentially subject to federal control and responsibility....Actions include new and continuing activities, including projects and programs entirely or partly financed, assisted, conducted, regulated, or approved by federal agencies; new or revised agency rules, regulations, plans policies or procedures...; Federal

actions tend to fall within one of the two following categories: (1) adoption of official policy, such as rules, regulations, and interpretations adopted pursuant to the Administrative Procedure Act..."

Here in Hartland, the Village is considering a set of regulations issued by a federal agency; therefore it is considering an action that by definition is a major federal action.

So, what is the agency's responsibility as to that action? The Council has said It must "insure that environmental information [remember that includes the "human" environment which includes economic, social, cultural, and health and safety concerns and elements] is available to public officials and citizens before decisions are made and before actions are taken. The information must be of high quality. Accurate scientific analysis, expert agency comments and public scrutiny are essential in implementing NEPA. " 40 CFR 1500.1 (b)

In implementing that insurance, the Council mandated that "Federal agencies shall to the fullest extent possible: Interpret and administer the policies, regulations and public laws of the United States in accordance with the policies set forth in the Act and in these regulations....integrate the requirements of NEPA with other planning and environmental review procedures required by law or by agency practice so that all such procedures run concurrently rather than consecutively....encourage and facilitate public involvement in decisions which affect the quality of the human environment...use the NEPA process to identify and assess the reasonable alternatives to proposed actions that will avoid or minimize adverse effects of these actions upon the quality of the human environment...use all practicable means, consistent with the requirements of the act and other essential considerations of national policy, to restore and enhance the quality of the human environment and avoid or minimize any possible adverse effects of their actions upon the quality of the human environment." 1500.2

The Council explained what it meant by the phrase "to the fullest extent possible: "each agency of the federal government shall comply with this section unless existing law applicable to the agency's operations expressly prohibits or makes compliance impossible."

The Council also mandates that the NEPA process be put into place at the earliest possible time during: "Agencies shall integrate the NEPA process with other planning at the earliest possible time to insure that planning and decisions reflect environmental values, to avoid delays later in the process and to head off potential conflicts." Among the many earliest possible actions would be to "identify environmental effect [economic, social, cultural, aesthetic] in adequate detail so they can be compared to economic and technical analyses." Also among the earliest possible tasks is to "study, develop and describe appropriate alternatives to recommended courses of action in any proposal which involves unresolved conflicts concerning alternative uses of available resources..." The Council also overlooks to see that the agency "consults early with state and local agencies and Indian tribes and with interested private persons and organizations when it own involvement is reasonably foreseeable."

§25.1 Purpose.

The National Environmental Policy Act of 1969 (NEPA), as amended, directs that, to the fullest extent possible, the policies, regulations, and public laws of the United States shall be interpreted and administered in accordance with the policies set forth in NEPA. All agencies of the Federal Government shall comply with the procedures in section 102(2) of NEPA except where compliance would be inconsistent with other statutory requirements. The regulations in this part implement section 102(2) of NEPA in a manner that is consistent with FDA's authority under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act. This part also supplements the regulations for implementing the procedural provisions of NEPA that were published by the Council on Environmental Quality (CEQ) in 40 CFR parts 1500 through 1508 and the procedures included in the "HHS General Administration Manual, part 30: Environmental Protection" 45 FR 76519 to 76534, November 19, 1980

§25.10 Policies and NEPA planning.

- (a) All FDA's policies and programs will be planned, developed, and implemented to achieve the policies declared by NEPA and required by CEQ's regulations to ensure responsible stewardship of the environment for present and future generations.
- (b) Assessment of environmental factors continues throughout planning and is integrated with other program planning at the earliest possible time to ensure that planning and decisions reflect environmental values, to avoid delays later in the process, and to avoid potential conflicts.
- (c) For actions initiated by the agency, the NEPA process will begin when the agency action under consideration is first identified. For actions initiated by applicants or petitioners, NEPA planning begins when FDA receives from an applicant or petitioner an EA or a claim that a categorical exclusion applies, or when FDA personnel consult with applicants or petitioners on the NEPA-related aspects of their requested actions. FDA may issue a public call for environmental data or otherwise consult with affected individuals or groups when a contemplated action in which it is or may be involved poses potential significant environmental effects.

§25.40 Environmental assessments.

(a) As defined by CEQ in 40 CFR 1508.9, an EA is a concise public document that serves to provide sufficient evidence and analysis for an agency to determine whether to prepare an EIS or a FONSI. The EA shall include brief discussions of the need for the proposal, of alternatives as required by section 102(2)(E) of NEPA, of the environmental impacts of the proposed action and alternatives, and a listing of agencies and persons consulted. An EA shall be prepared for each action not categorically excluded in §25.30, §25.31, §25.32, §25.33, or §25.34, or §25.35. The EA shall focus on relevant environmental issues relating to the use and disposal from use of

FDA-regulated articles and shall be a concise, objective, and well-balanced document that allows the public to understand the agency's decision. If potentially adverse environmental impacts are identified for an action or a group of related actions, the EA shall discuss any reasonable alternative course of action that offers less environmental risk or that is environmentally preferable to the proposed action. The use of a scientifically justified tiered testing approach, in which testing may be stopped when the results suggest that no significant impact will occur, is an acceptable approach.

BEFORE THE VILLAGE BOARD OF TRUSTEES OF HARTLAND, WISCONSIN

A PUBLIC COORDINATION HEARING REGARDING THE DEEMING REGULATIONS¹ ISSUED BY THE FOOD AND DRUG ADMINISTRATION

On April 27 through 29, 2017, a Hearing Board² appointed by the Hartland, Wisconsin Village Board of Trustees³ heard evidence in a fact finding coordination hearing, and then concluded the Hearing on May 1, 2017 with a decision that the Food and Drug Administration failed to coordinate its Deeming Regulations regarding the e-liquid industry⁴ with the Village of Hartland. The Deeming Regulations refers to the set of regulations placed in the Code of Federal Regulations by the Food and Drug Administration. The decision will be presented to the Commissioner of the Food and Drug Administration with an urgent request that the regulations be stayed, shelved, withdrawn, or rescinded outright because they were developed and imposed in violation of multiple statutes and laws, as will be set forth herein.

BACKGROUND

On February 13, 2017, the Board of Trustees resolved to request that the Food and Drug Administration enter into coordination with it regarding the Deeming Regulations, which the Trustees understood to contain provisions that would endanger survival of a thriving business in the Hartland community, Johnson Creek Enterprises. The issue was brought to the Village's attention by Mark Block, Founder and Director of the Electronic Vaping Coalition of America (EVCA), and Linda J. Hansen, Strategic Consultant and Co-Founder of EVCA. (See Attachment 1) These two presented the Board with authorities showing that there is a duty on the part of federal agencies to coordinate with local governments. The request was memorialized in Resolution 02/13/2017-01; in a second Resolution, enacted the same date, Hartland set forth its understanding of the duty of federal agencies to coordinate regulations and rule making with local governments. See Resolution 02/13/2017-02

¹ The Board will use the term "Deeming Regulations" to refer to the regulations issued by the Food and Drug

² Herein, "Hearing Board" or "Board" will refer to the Hearing Board appointed by the Hartland Village Board of Trustees.

³ The Hartland Village Board of Trustees will be referred to as "Trustees"

⁴ The Board will use the term "e-liquid" to refer to any and all equipment, supplies and devices that are used by the industry and are in widespread use of what many call "vaping" or "electronic cigarettes" or "e-cigarettes" or "vaping devices"; the Board finds that none of those terms do justice to the entire industry and following and so will simply refer to them as "e-liquid".

For two months, the Food and Drug Administration⁵ had still not coordinated, so on April 18, 2017, the Trustees set a public hearing for April 27 through 29, 2017 to hear evidence related to the Deeming Regulations and the e-liquid industry. Notice of the hearing went to the Secretary of Health and Human Services who is the overall supervisor of the Food and Drug Administration, since it is situated within his cabinet department, and to Stephen Ostroff, the Acting Commissioner of the FDA office in Silver Spring, MD, and to the Milwaukee office of the FDA.

The Board designated Fred Kelly Grant, Esq., to serve as a Hearing Officer. Grant's curriculum vitae is attached as Board's Attachment 2. The two Resolutions of the Board relating to coordination are attached as Exhibits 1 and 2, and the letter setting and notifying the Food and Drug Administration of the date of the hearing is attached as Exhibit 3.

The official hearing notice was prepared by and executed by Village Administrator, David Cox, and is attached hereto as Exhibit 4, and the instructions of the Hearing Officer to witnesses is attached as Exhibit 5.

The hearing was held beginning at 5:30 pm Central Standard Time on April 27, recessed at approximately 9:00 pm, resumed at 9:30 am on April 28, recessed at approximately 5:00 pm, and resumed at 9:00 am on April 29, and recessed at approximately 2:00 pm, to reconvene at 5:00 pm on Monday, May 1, 2017 to consider and make this decision.

At the commencement of this hearing, the Hearing Officer presented a statement of the laws applicable to the proceedings.

At the conclusion of the evidence presentations on April 29, the Board answered general questions put to it by the Hearing Officer. The answers to those questions provided the guidance for the drafting of these Findings and Conclusions by the staff of the Hearing Officer.

The questions, all of which were answered unanimously are as follows:

Has there been coordination with the County or the Village? (Unanimously answered, "No")

Will the Deeming Regulations have an adverse impact on the Village of Hartland? (Unanimously answered, "Yes")

Is Johnson Creek Enterprises a reputable business in the community? (Unanimously answered, 'Yes")

Would the Deeming Regulations put Johnson Creek Enterprises out of business? (Unanimously answered, "Yes")

⁵ Herein, Food and Drug Administration may be referred to as Food and Drug or as FDA

Is there a danger from the industry that would justify implementation of the Deeming Regulations that run the risk of putting the industry out of business? (Unanimously answered "No")

Is there sound basis for regulations that are harsher than those imposed on combustible cigarettes?

(Unanimously answered, "No")

Is there sound basis for saying the e-liquid or vaping business is a dangerous business? (Unanimously answered, "No")

Is there evidence that the FDA did analysis of cost or provided alternatives that would allow the e-liquid vaping industry to stay in business? (Unanimously answered, "No")

The unanimous answers form the basis for these Findings, calling on the Commissioner to rescind the Deeming Regulations.

The Board will see that its decision reaches the Commissioner of the Food and Drug Administration and the Secretary of Health and Human Services. The Board submits its decision with a most earnest request that this terribly flawed set of regulations be withdrawn. Representative Duncan Hunter (R-CA) has introduced H.R. 2194, which would replace the Deeming Regulations. For that Bill to be successful the Commissioner must halt or rescind the current Deeming Regulations or there will be no industry to be saved by the Bill. The Board finds within this decision that the current Deeming Regulations will destroy the eliquid industry, an industry that lends solace and alternatives to a vast number of Americans, including many in Hartland, who are addicted to nicotine and rely on dangerous combustible cigarettes for relief, a reliance which leads to death for 480,000 people per year.

This nation is committed to protecting and preserving species of animals that are on an "endangered species" list (Under the Endangered Species Act). Once a species is on such list, it is protected against harm by every department of our federal government. Yet, 480,000 discernable Americans are doomed to die this year from smoking combustible cigarettes, and instead of protecting them, the Food and Drug Administration will doom them by enforcing the Deeming Regulations that will destroy an effective alternative to smoking. This Board finds it unacceptable that a government committed to protecting endangered species of animals would intentionally destroy an industry that offers protection to a doomed sub-group of human beings.

The Tenth Amendment, which reserves police powers to the Village of Hartland as a local unit of state government, dictates that we do all we can to protect the public health of our citizens.

From that position of protection, we urge the Commissioner to do what is right, what is Constitutionally called for, what is dictated by plain old Hartland common sense! Stop the insanity that is embedded in these regulations!

FINDINGS AND CONCLUSIONS

As a preliminary observation: Most of the members of the Board had no experience with the eliquid industry, so the testimony as to the industry, and its effectiveness and safety as an alternative to traditional smoking was a true wake-up. Moreover, the Board had no idea that the Food and Drug Administration was so determined to put this industry out of business. We live in a troubled world, where the bad news stories come so blended in with the good news stories, and all blended in to fit a 30 minute newscast, that a story as deep as the one presented to this Board during the hearing is simply not told, or is told in such abbreviated fashion that the true meaning is never revealed. The Findings which the Board makes include a Finding that the Deeming Regulations are ill conceived because they will result in destroying an industry committed to, and doing, outstanding work in converting people away from deadly tobacco smoking; the Board further has found that this industry should be looked to by the Food and Drug Administration as an example of how the free market system of small businesses can work and create the American dream. It is disingenuous for the United States government and state governments to be taking money from the tobacco companies at the same time that the federal government is trying to put the industry that can stop smoking deaths out of business. The Secretary of Health and Human Services, who is responsible for this department, should take action immediately if the newly appointed commissioner of Food and Drug does not. If the Secretary does not, then the President of the United States ought to pay special heed to the fact that he could save as many as 480,000 people from death this year by stepping in and putting a stop to enforcement of the Deeming Regulations.

- I. PURSUANT TO OUR GENERAL INTRODUCTION, ALL OF WHICH SHOULD BE TAKEN AS FINDINGS OF FACT, WE MAKE THE FOLLOWING SPECIFIC FINDINGS. THE COMISSIONER OF THE FOOD AND DRUG ADMINISTRATION FAILED TO COORDINATE WITH THE VILLAGE OF HARTLAND AND WITH WAUKESHA COUNTY, AND WITH THE STATE OF WISCONSIN, AND AS A RESULT, THE REGULATIONS MUST BE SET ASIDE PENDING RE-ISSUANCE.
- 1. The Board finds from the testimony of Village Administrator David Cox that the Food and Drug Administration did not ever coordinate with Hartland, Wisconsin regarding the Deeming Regulations or any other issue. On the day prior to the commencement of this hearing, a spokesperson for the Food and Drug Administration left a voicemail message for Administrator Cox, stating they would be unable to attend the hearing but would respond by letter to Hartland's concerns. No letter has yet been received.

- 2. The Board finds from the testimony of Paul Farrow, County Executive of Waukesha County, Wisconsin, that the Food and Drug Administration did not ever coordinate with the County regarding the development or enforcement of the Deeming Regulations.
- 3. State Senator Chris Kapenga offered a statement that is admitted in evidence as Exhibit 6. In it he states: "Despite my role as an elected official in state government tasked with overseeing federal issues, I never received any contact from FDA pertaining to the Deeming Regulations. At no point did anyone from the FDA contact me to coordinate with state government to ensure there would be no negative economic impact on our communities as a result of the deeming regulations."
- 4. The failure to coordinate with Hartland is critical because the Deeming Regulations threaten a specific business, Johnson Creek Enterprises, with going out of business. Johnson Creek Enterprises is one of the largest manufacturers in the industry. If it goes down, all small companies will surely fail. The Board agrees with Senator Kapenga in that he stated:

"I believe the FDA failed to comply with the coordination requirement under federal law. Had the FDA coordinated with local governments, I would have explained the significant negative economic impact the Deeming Regulations will have on Hartland and the surrounding communities. Within my district there are several small and medium sized businesses that operate within the field the Deeming Regulations seeks to regulate. The increased regulation to bring a product to market and to maintain compliance will cost our economy jobs and income. In addition, many of my constituents utilize the products regulated by the Deeming Regulations as an effective means of tobacco harm reduction. If the FDA regulates these materials as tobacco is regulated, these individuals will likely have limited access to products that are far less harmful than tobacco."

The Board finds that the Senator has hit the issue squarely and finds with him that these regulations will hamstring any effort to persuade smokers in our communities to abandon smoking for the e-liquid devices.

5. State Senator Leah Vukmir, testified in writing that, "It is clear that the deeming regulations from the FDA that treat vaping products similarly to tobacco products are overly burdensome to the vaping industry. Because of the presence of Johnson Creek Enterprises, these new rules disproportionately affect Hartland—and the state of Wisconsin—and may cause many to lose their jobs. Additionally, I struggle to see how overregulating an industry which provides a product many use to gain independence from tobacco is helpful for the public health of our country." The Senator's statement is Exhibit 7.

The Board agrees with the Senator's misgivings, and finds that there is no sound reason why the Deeming Regulations should have been developed without coordination during which the economic damage could be pointed out with the plan for a legal alternative.

United States Senator, Ron Johnson, (R-WI), is Chairman of the Senate Homeland Security and Governmental Affairs Committee, with oversight of the FDA. He has written several letters to the FDA seeking rescission of the Deeming Regulations, for reasons consistent with our Findings. If the FDA does not feel compelled to talk with, to coordinate with, the Chair of their oversight committee, then it is no wonder they have failed to coordinate with the Village of Hartland.

As a result of the failure to coordinate, Hartland was deprived of the opportunity to point out the specific losses that will be felt. Within the structure of coordination there is a place for constructive disunion to set the base for reaching consistency between the goal of the federal agency and goal for the Village. The failure to coordinate renders these regulations invalid as far as Hartland is concerned, and pursuant to the remedies applied in <u>California Resources Agency v. USDA</u>, northern district of California, and <u>Uintah County v. Norton</u>, district court for district of Utah, the regulation should be set aside, and the agency must begin again after proper coordination.

II. E-LIQUID INDUSTRY PROVIDES A SAFE, EFFECTIVE ALTERNATIVE TO THOSE WHO SMOKE TRADITIONAL CIGARETTES AND FACE SERIOUS ILLNESS AND DEATH AND THE INTERESTS OF HARTLAND IN PROTECTING THE PUBLIC HEALTH CALL FOR RESCISION OF THE OFFENDING REGULATIONS

1. The Board finds that at least 480,000 preventable human deaths will occur this year as a result of smoking of combustible traditional cigarettes. The illness and deaths that result from such smoking come from the by products of the combustion, not from the tobacco product, i.e., nicotine which is the addictive portion of tobacco.

Jeff Stier, Senior Fellow at the National Center for Public Policy Research, has devoted considerable time for the past twenty years studying the problem created for the public health system of the nation by the vast number of sick and dying smokers. He testified, and the Board finds that smoking of combustible cigarettes is the number one preventable cause of death in this country. He pointed out to the Board how the Food and Drug Administration tried to regulate this industry out of existence once before and was stopped by court intervention, when the court pointed out that the agency had no authorization from Congress to enforce a law against tobacco products. He testified that, ironically, the Court outlined for Food and Drug how they could accomplish regulation after obtaining Congressional authorization. He testified, and the Board finds, that the Deeming Regulations impose such a formidable dollar cost on the application process that few, if any of the current industrial entities will be able to afford the cost. He also testified as to the irony of the fact that Food and Drug, created for the purpose of protecting the public health, seems determined to destroy an industry that offers the only effective method for transforming smokers of combustible cigarettes to a way of life that will save their lives. The public health can best be affected by the FDA promoting, rather than destroying, the e-liquid industry.

- 2. Stier testified that the Royal College of Physicians, one of the most, if not the most, distinguished and revered forums of medical experts in the world recommended this industry as offering the best means of greatly reducing the methods of smoking. He testified that this group contends that the e-liquid uses are safe and effective as an anti-smoking diversion. The Board credits his testimony and the opinion of the Royal College and finds consistently that the industry does provide a safe alternative.
- 3. Stier also testified as to how the regulations ban any efforts on the part of people in the industry from telling the public, by label or otherwise, that this is a safe----or even a less harmful---means of obtaining nicotine. The Board finds such effort at curtailing speech a violation of the First Amendment, which states that the government should not abridge anyone's freedom of speech. The amendment does not have an addendum that says "except for speech regarding safety of alternatives to smoking." The Board finds that the efforts to curtail speech violate the First Amendment and should be abandoned immediately. If the First Amendment can protect the release of the Pentagon Papers with the damage they did to a war effort, it surely protects the ability to warn a person that combustible cigarettes kill and e-liquid saves lives.

The Board finds from his testimony that the e-liquid industry indirectly would make inroads on the high cost to society of tobacco abuse. He testified that the combustible cigarette is the top priority health issue in America. The Center for Disease Control says the cost to society is 300 billion dollars yearly, yet the FDA sets out to regulate the industry that reduces, not increases, medical costs. He points out that it seems the FDA has set a goal to punish those who would escape tobacco damage and death in favor of a far less harmful, safe use of nicotine.

The e-liquid industry hardly existed, if at all, when the Family Smoking Prevention and Tobacco Control Act of 2009 was passed, yet it is the object of the regulatory ban to purportedly implement the Act. The Board finds that the Deeming Regulations were developed without direction to the FDA from the Congress.

The Board finds that the Deeming Regulations are evidence of government overreach designed to accomplish a special interest and bias, and have no place in the Code of Federal Regulations.

He testified that it is his opinion that the Deeming Regulations constitute a de-facto ban on the e-liquid industry. The Board agrees and finds that such ban is contrary to what Congress ordered and therefore should be rendered null and void. To give these ultra vires regulations effect would be to endow the FDA with legislative authority. This authority to regulate must be limited to the four corners of the statute passed by Congress. The statute authorized no ban.

4. Dr. John Dunn, M.D., J.D., an experienced and well qualified medical expert in toxicology and epidemiology, testified that the e-liquid industry is safe and provides the most effective means of converting people from the combustible cigarette habit. He explained that the ceremony of smoking a cigarette is important to the user; that the taking out of the cigarette from the package, lighting it up, is what gives the smoker relief even though the nicotine itself is a

Closed-system non-refillable

Open-systen
Refillable-tank
Glass with 316
(surgical)
Stainless steel
Device is 4th
generation with
Safety features
like short-circuit
protection
over/under-charge
protection and
smart charging



stimulant. The ceremony with the e-liquid device and the flavor offer the same type of selfmoving ceremony. So even as to that aspect of use, the e-liquid industry provides an effective means of diverting from smoking combustible cigarettes. Dr. Dunn testified, and the Board finds, that the e-liquid industry provides a safe alternative to smoking of combustible cigarettes and to the death path that such smokers are on when they choose to use traditional combustible cigarettes. He explained that the flavoring provides variety that adds to the ceremonial experience. Dr. Dunn said it as plain as could be: Combustible cigarettes kill; e-liquid does not. He now teaches emergency room physicians and provides emergency room service to the Army Hospital at Fort Hood, Texas, where he sees tobacco damage every day. He testified and the Board finds that the pharmaceutical companies will fight the e-liquid industry to the end because e-liquid is more effective than the nicotine replacement therapies made by the pharmaceutical companies. Sales of those nicotine replacements make a fortune for pharmaceutical companies, and they will resist to the bitter end. He pointed out the addictive features of nicotine, yet the FDA did not attempt to control it and certainly did nothing to harm sales of the nicotine replacements therapies. Rather, it sets out to control the non-addictive hardware and software of the e-liquid industry - which has no addictive powers and does no harm of any kind. The controls within the Deeming Regulations are designed only to protect special interests, not the people who seek to save their lives from combustible cigarettes.

Dr. Dunn spoke of what he believes is a culture of hate directed against anything that even looks like smoking. He contends that the FDA will continue its effort against vaping because it looks like cigarette smoking. He contends the FDA has gone off the rails in retroactively regulating safe products, contending that its job should be restrictively regulating dangerous products. He concludes that if the FDA really wanted to protect the public it would favor the eliquid products because of their safety.

5. Lou Ritter, Founder and President of the E-Research Foundation and President Emeritus and Co-Founder of the American E-Liquids Manufacturing Standards Association (AEMSA), testified as to how the e-liquid industry is consumer driven, made up of small businesses with the desire to be innovative in creating new devices and flavors in order to provide the variety that helps keep people from ever reverting to smoking combustible cigarettes. He demonstrated to the Board how each component of an e-liquid vaping device is a non-tobacco item, but when put together the Food and Drug Administration then "deems" the product to be tobacco even though it is not, and then regulates it in a fashion that will outlaw its use. The elements presented were the battery, the coil, the mouthpiece, and the case. Such convoluted government logic, or rather lack of logic, is one of the major issues we need to take on directly.

Lou Ritter agreed with the testimony of Jeff Stier that current Deeming Regulations constitute a de-facto ban of the industry.

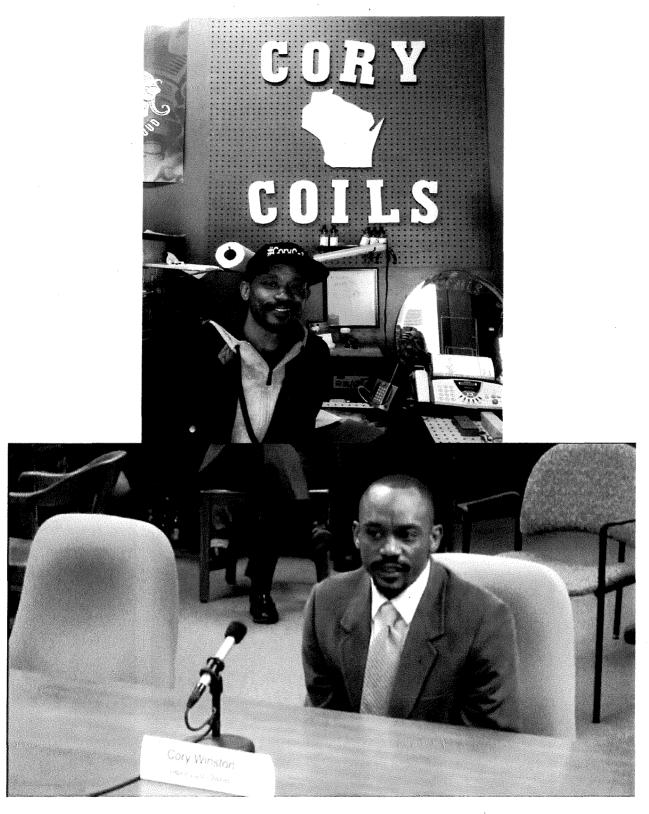
The Board finds that it is against the public interest of Hartland to have e-liquid deemed out of business, and the village will do whatever it can to try to avoid and evade such government waste and destructiveness. With these findings, we urge the Commissioner to begin

coordination with us and with other localities where the industry is present, and do so at once before it is too late for the industry. The evidence is clear, and the Board finds that these preventable deaths could be prevented if smokers would all turn to the e-liquid industry and switch from combustive cigarettes to e-liquid products. The industry will not be there to offer alternatives if these regulations are enforced.

6. Azim Chowdury testified as a witness in order to assist the Board to understand technicalities in the Act and regulations. He explained terms and pointed out that the FDA is treating e-liquid products unfairly in comparison to tobacco companies – the grandfather clause gives traditional combustible cigarettes an advantage. Without the harsh grandfather rule, e-liquid products would go through a much less onerous approval of a pre-existing product. It was not the intent of Congress to ban e-liquid products, as they were not an issue in 2007-2009. Congress told the FDA to promote "less harmful alternatives" to tobacco, and the FDA created a de-facto ban instead.

Bill Godshall, of Smoke-Free Pennsylvania, testified that only the big tobacco companies would be able to afford the cost to file the required Pre-Market Tobacco Application (PMTA) costs. He also pointed out that there is no guarantee the FDA will consider the PMTA once it is filed. So, a company faces the possibility that it will pay the high cost of preparing and filing a PMTA, only to have the FDA refuse to consider it. He also testified as to the extent that opponents will go to discredit the e-liquid industry. He told of a Portland State study that said vaping products contain formaldehyde. It later was found that the study results were fraudulent because excessive heat had been used in order to produce a negative report, referring to the futility of expecting fair and objective analysis and treatment from the FDA. He pointed out that Sweden has the lowest rate of lung and heart disease in the world, and the lowest risk products in the world. Yet, an application submitted from there for a Modified Risk Tobacco Product to the FDA, was rejected.

7. An e-liquid store owner and operator from Milwaukee, Cory Winston, testified that he quit smoking combustible cigarettes when his four year old daughter asked him one day, "When are you going to die, Daddy?" He said he was staggered and shocked by the question and he asked her where she got the idea he was a going to die. She told him that in school she heard about smoking and that it killed people. He took his daughter in his arms and decided he had to quit. He turned his life around, and for the past year has not been smoking, but is using an e-liquid device; he tried other ways to quit smoking, but this was the only effective way to do it. He testified as to how he recovered his taste for foods and his sense of smell, and when he realized just how bad everything smelled from smoke he called everyone in his phone log and apologized for subjecting them to second hand smoke for all the years he had smoked. He owns and operates an e-liquid shop in a neighborhood in Milwaukee where he serves an inner city clientele that will be disparately impacted by outlawing the e-liquid devices because so many of them are without transportation to go out of state or to some area of the states where they could get the devices or the liquid with nicotine.



Cory Winston, Owner of Vapor Lust, Milwaukee, Wisconsin

Cory also sells tobacco products in his shop. He does this for two reasons: his shop serves people who are in the inner city with no way to really travel around as do many in our cities. They walk to shop, they walk wherever they go, and all stores in the neighborhood carry extra items for the convenience of these folks. The second reason is that it gives him a chance to talk to the tobacco smokers about the e-liquid products and try to get them switched off the combustible cigarettes. He feels an obligation to do as Michael McCrary said, "pay it forward" and share with others the blessings they have received from being free of tobacco's clutches.

Cory has expertise in technical matters, and because of that, he enjoys working on the coils for e-liquid devices. However, if he does, he is then considered a manufacturer and is subject to the restrictive and expensive FDA requirements. He expressed frustration at the fact that the Deeming Regulations do not allow him to do repairs to client's devices and they are then forced to simply buy a replacement product. Cory also testified that his client's find flavorings to be very effective in helping them to switch from combustible cigarettes to e-liquid products.

The Board finds that these deeming regulations will put Cory Winston's Vapor Lust shop out of business, and that will put an unconscionably disparate impact on citizens of a city neighborhood. The Board finds this is exemplary of the shop owners who testified and the Board finds they are doing a public service by not only selling the e-liquid devices, but by becoming and serving as missionaries to convert those who are smoking combustible cigarettes. Every shop owner who testified told of the community service and commitment they have to try to get the word to smokers of the danger they can avoid by switching to the e-liquid device. The Board commends the shop owners for their commitment to public health, and finds that the Commissioner of Food and Drug could and would do well to follow the lead of the shop owners in trying to eliminate combustible cigarette smoking.

Antonio Lauria is owner of a manufacturing facility and a shop, both located in southeastern Wisconsin. He testified that the businesses will be going out of business if the Deeming Regulations remain in effect. Sixteen employees depend on his business; they and their families will have to relocate, and the result on the small towns will be as harsh as it will on Hartland if they lose Johnson Creek Enterprises. He testified that the PMTA process would destroy his business; even if he could afford the cost, the subjectivity of the "moving target" as the Johnson Creek CEO called it, puts the future of his business in the same light as if it depended on him winning on a lottery ticket. He objects to being told he must sell a zero nicotine product labeled as, "this is a tobacco product"; he resents being forced to falsely label a product, and to be restrained by law from even orally advising a person that it is not a tobacco product. He testified that the FDA has turned the vaping industry into a pariah---even many banks would not work with him, and so he opened his accounts with small local banks. He, as the other owners, treat his and his wife's customers as clients, and offer them a quality service. The FDA, he says and the Board agrees and finds as fact, has stifled innovation and safety concerns through the Deeming Regulations. He is prevented by the regulations from even changing by improvement any of his products; he cannot even switch suppliers if he is let

down on quality because to switch would subject him to one of the costly procedures for seeking permission.

Charlie Bilek, Michael McCrary, and Gary Fluaitt---McCrary from Ohio and the others from Wisconsin, all testified as to how they quit smoking through the e-liquid methods when all other types of prevention had failed. They all testified as to how the shops are social spots where those seeking to escape the binds of tobacco can come and visit and find out about the new flavors and the benefits of e-liquid. All said that if the regulations stayed in place, the industry would be lost. All agreed that users would then either go to the black market for products where there would be no quality controls, or go back to smoking combustible cigarettes. They all agreed that flavors are critical as variety for people to try until they find just the right product to help them. They agreed with Dr. Dunn's testimony that trying the flavors is part of the important "ceremony."

Jeff Steinbock owns Uhle's Cigar shop in Milwaukee, an old and traditional cigar and pipe shop. The blending of tobacco is what makes his business, and blending subjects him to the regulations and to destruction of his business because he will not be able to afford the processes. He serves 100 to 120 customers a day and is one of the last of the pipe and cigar stores. The FDA has already warned that blends will have to be subjected to the PMTA process, but cannot tell anything about the cost even though the Office of Management and Budget (OMB) and the Regulatory Flexibility Act require that they know and state the cost before putting the regulations into effect. He has studied documents, records and news reports and is certain that big pharmaceutical companies are the beneficiaries who have paid for their benefits from the regulations. They know, he said, that their "cash cow" in the nicotine patches and replacements---that sell for hundreds times more than they cost--will be lost if the e-liquid products are available. Without flavors, pipe smoking will end because all pipe tobacco is flavored. Once the base line is set, whenever he experiments with a new mixture of flavors, he becomes a manufacturer, and he believes this harms his rights. He agrees with the concept put forward by Aaron Biebert, that corruption runs rampant in favor of big tobacco and big pharmaceuticals---they have the money to buy the influence.

Matthew Wiener, co-owner of Wolfpack Wholesale in Plano, Texas, testified that they will have to move out of America if the Deeming Regulations stay in place, and they are already planning the move even though he doesn't want to do so. He is a veteran of the United States Armed Forces and after fighting for his country, is saddened by the loss of freedoms imposed by the government. He has 250 employees with their jobs at stake, and he hires with preference for veterans and their families. (He has been forced to lay off employees since the implementation of the Deeming Regulations.) His business spends over \$100,000 per month just on shipping and shipping supplies. He believes in a "second chance" mentality in hiring, giving people a second chance when they have had trouble making it previously. In addition, they are actively engaged as a business in providing training and guidance, especially to female veterans, who

need help to become acclimated to civilian life after service. He and his wife got into the business to fight against cigarette smoking.

The Board has noted and finds as fact that the majority of all the owners who appeared got into the e-liquid business to end smoking after they were able to quit by using the products. All agreed that if the regulations stay in place, users will go to the black market, and we will have another version of prohibition, which was not a successful venture for our nation.

8. Shaun Casey, President of FlavourArt North America, is in the business of developing and selling flavors all over the world. He testified that flavors in the e-liquid are very important because they do give the person the benefit of variety that is not present in the smoking of the traditional combustible cigarettes. He testified, and the Board credits his testimony, that it is not flavors that attract kids to the market; it is the advertising. The flavors actually provide variety that helps keep people from relapsing back into their smoking habit. He testified, as did others, that flavors are important to the diversion from smoking, so they should not be curtailed. The Board agrees and so finds. The high cost of seeking preliminary approval will limit the ability of a manufacturer to secure approval of mass flavors, thus will lessen the protective nature of the e-liquid industry. To ban flavors would lessen the appeal to e-liquid product users.

The Act prohibits the banning of cigarettes, "all smokeless tobacco products," cigars, pipe tobacco, and "roll-your-own" tobacco. It also prohibited reduction of nicotine yields of a tobacco product to zero. 21 U.S.C. 387

More importantly, Congress instructed the FDA to determine how best to "encourage the development of innovative products and treatments (including nicotine and non-nicotine products and treatments) to better achieve, in a manner that best protects and promotes the public health —

- A) total abstinence from tobacco use;
- B) reduction in consumption of tobacco and
- C) reduction in the harm associated with continued tobacco use."
- 9. The Family Smoking Prevention and Tobacco Control Act does contain the provision that Congress encourages the development of a product that is less harmful than tobacco. By developing and establishing the Deeming Regulations, the Food and Drug Administration has done just the opposite of what Congress ordered in the statute. As an inconsistent set of regulations designed to reach a conclusion opposite from the goal of the statute, these regulations must not be enforced. The Board finds that to enforce these regulations would provide for results not called for by Congress, and in fact would be in direct opposition to what Congress mandated.

III. THE BOARD FINDS THERE IS EVIDENCE THE U.S. FOOD AND DRUG ADMINISTRATION IS ACTIVELY PROMOTING BAD SCIENCE REGARDING THE E-LIQUID INDUSTRY; AND FURTHER THAT THE FDA BEHAVIOR CONSTITUTES A THREAT TO PUBLIC HEALTH. PROMOTION OF BAD SCIENCE IS VIOLATION OF THE SPIRIT OF THE DATA QUALITY ACT.

The board agrees with testimony from several witnesses and many expert analyses that the FDA's premarket tobacco application (PMTA) process will require each e-liquid manufacturer to submit many dozens (and potentially hundreds) of separate PMTAs for every combination of product, flavor and formula they create.

- The Board finds from evidence presented that each PMTA will cost a minimum of \$300,000 (based on FDA projections), and plausibly more than \$1 million (according to Jeff Stier, Lou Ritter, and Bill Godshall), leading to cumulative approval costs exceeding tens of millions of dollars or more for every e-liquid manufacturer.
- The Board finds from evidence presented that the PMTA process presents potential
 applicants with neither objective criteria by which products will be judged for approval,
 nor sufficient assurance that approval will be granted or denied in a timely manner.
- The Board agrees with evidence presented that the excessive cost and uncertainty of the PMTA process will cause all e-liquid manufacturers to severely reduce the number of flavors and product options on the market; AND will drive nearly all manufacturers out of the market; AND that the severe reduction of product options on the market will drive most e-liquid retailers out of the market as well.
- The Board strongly agrees with testimony and evidence presented that the variety of flavors and product options currently on the market is a significant reason for traditional cigarette smokers to switch to much safer e-liquid products; AND THE BOARD FINDS that a severe restriction of flavors and options resulting from subjecting the e-liquid industry to the PMTA process and <u>FDA policy will lead inevitably and immorally to e-</u> liquid consumers switching back to using vastly more dangerous traditional cigarettes.
- The Board also agrees with testimony and evidence presented that the FDA's Deeming Regulations regarding e-liquid products require manufacturers and retailers to conceal the considerable health improvements available to traditional cigarette smokers who switch to e-liquid products. The Board also finds that the manufacturers and retailers are prohibited from saying their product is less harmful than traditional tobacco. That prohibition is an immoral, offensive violation of the First Amendment Freedom of Speech protection. THE BOARD FINDS this FDA policy to be both a severe threat to public health and a violation of the manufacturer and retailer's rights under the U.S. Constitution's First Amendment guarantee of free speech.

IV. THE BOARD FINDS THAT JOHNSON CREEK ENTERPRISES PROVIDES AN ECONOMIC BENEFIT AND SOCIAL COHESIVENESS TO THE COMMUNITY.

Johnson Creek Enterprises is an industry within the Village of Hartland and was established in 2008.

It manufactures and sells four brands of vaping products in forty-three flavors to businesses and consumers in the United States and worldwide. The company recently began selling third party brands online as well. Under the regulations, their companies would have to go through PMTA, and so their businesses would be lost to Johnson Creek Enterprises.

Payroll and benefits total \$1.2 million per year for 20 employees; however the company has employed more people at different times. The numbers of employees and the overall payroll have fluctuated over the years, depending on season and demand. At times they have employed as many as 70 people.

The company's business drives other local economic activity as well. For instance, 85 percent to 90 percent of shipping for e-commerce sales goes through the Hartland Post Office. Larger scale customers sometimes opt for other carriers such as Fed-Ex, UPS, or other shipping companies.

The company supplies 60-70 retail stores, just in Wisconsin. The target customer for the company's online sales is a current e-liquid product user.

Management and workers are involved in many volunteer efforts in the community either individually or as a team, such as the Make-a-Wish Foundation and Feeding America - Southeast Wisconsin, with \$11,000 and 2,000 pounds of food, Donate Life - Wisconsin, Special Olympics of Wisconsin, ATI Foundation, Extra Life benefitting Children's Miracle Network Hospitals. Johnson Enterprises President and COO, Heidi Braun, testified that employees are granted time off to volunteer where they wish. In one instance, three employees played video games for 24 hours straight, in exchange for donations that went to the Children's Miracle Network Hospitals. So, if the company goes out of business, the community will suffer in more ways than just economically.

Johnson Creek Enterprises Director of Business Development, Tom Pangborn, testified that he is a longtime Hartland resident, attended the local Arrowhead High School, and currently lives in the community with his wife, who works in a nearby community, and two children, one of whom attends a public school and another who attends a local day care.

President and COO, Heidi Braun, said that if the company goes out of business all of the employees and their families would likely have to relocate outside the area to find

comparable jobs. So, the local communities would lose a substantial number of valuable citizens.

Witnesses agreed when asked by the Hearing Officer that everything the business does affect business in the community and Wisconsin.

V. THE BOARD FINDS THAT THE FULL IMPLEMENTATION OF THE FDA DEEMING REGULATIONS WOULD PUT JOHNSON CREEK ENTERPRISES OUT OF BUSINESS.

- The FDA Deeming Regulation requires a Pre-Market Tobacco Application (PMTA) for each e-liquid product manufactured by Johnson Creek Enterprises. The company makes 43 flavors of e-liquid across four brands, and provides different nicotine levels for each flavor, which means PMTAs for more than 240 different products.
- The PMTA cost estimate ranges from \$330,000 to \$1 million per application. Mr. Pangborn testified that if the Deeming Regulation is upheld, Johnson Creek Enterprises would potentially have to get rid of a lot of their flavors, which would dramatically drop sales: "If we were to pare down our 43 flavors, even down to five, we'd only be reaching that audience who only liked those five flavors."
- Johnson Creek Enterprises Director of Business Development, Tom Pangborn, President and COO Heidi Braun, and Director of Operations Shanelle Bolling, testified that their company does not have the same size staff as a big tobacco company such as R.J. Reynolds, that it could take five people to complete the PMTA process, and they would probably have to hire an outside consultant to help. The advantage is to R.J. Reynolds (and similar companies) that have hundreds of people to put to the task and mega dollars to spend.
- The witnesses also testified that the FDA has only communicated with them via a general email list, and offered no assistance in the PMTA process nor did the FDA offer any objective standard to base their application on, leaving the approval process of such application to be totally subjective and ill-defined. Heidi Braun, President and COO of Johnson Creek Enterprises, said they had been provided a "moving target."
- The first milestone in the deeming regulation was completing the product registrations.
 The witnesses testified that it was very time consuming and costly to submit the registration for the "SKUs" (FDA required stock-keeping units) over 240 flavors.
- The Board finds as stated by Hartland Trustee Ann Wallschlager, that Johnson Creek Enterprises has been "an outstanding business in our community, whenever we go to you for help or donations, you've always helped." Loss of the company would disrupt

and harm the cohesiveness of the community and would harm the human environment that is protected by the National Environmental Policy Act.

VI. THE FDA VIOLATED THE REGULATORY FLEXIBILITY ACT BY FAILING TO PERFORM AN ADEQUATE COST ANALYSIS VIS A VIS SMALL ENTITIES OF GOVERNMENT AND SMALL BUSINESSES AND FAILING TO OFFER ALTERNATIVES TO AVOID ADVERSE ECONOMIC HARM

Under the Regulatory Flexibility Act, every government agency is required to conduct a cost analysis before any regulation is put into place. That analysis is supposed to detect and avoid adverse, harmful economic damage to small government entities under 50,000 in population and to small businesses. The agency is supposed to offer alternatives to avoid adverse economic impact.

Hartland is under 50,000 in population, and Johnson Creek Enterprises is a small business for purposes of the Act. Yet, the Food and Drug Administration (FDA) did not study the impact of the regulations on either. The evidence is beyond dispute that Johnson Creek Enterprises will go out of business if the high cost of the preliminary applications turns out to be correct. Even if it is not, at the lower cost, the company can only afford to seek approval for 4 or 5 of its flavors which will deeply cut into its business. The FDA shows no concern for that, in fact never has contacted Johnson Creek Enterprises to see what impact there will be to the business.

The FDA has not coordinated with Hartland, so the FDA has no idea of the economic impact and has not a clue as to whether there is an alternative that would avoid it.

Stephen Moore, Senior Fellow in Economics for the Heritage Foundation, produced evidence that if a company with employees in 25 range, like Johnson Creek Enterprises, goes out of business, a wage loss of \$1 million dollars occurs. (This is corroborated by the fact that Johnson Creek Enterprises has a payroll of \$1.2 million.) He estimates that the loss to the community would be at least \$1.5 million per year. He pointed out that small businesses account for 60-70 percent of all new jobs in America, and the "spinal cord" of local communities. He said regulations cost small businesses an estimated \$1-2 trillion a year and excessive regulations do put small businesses out of business.

The Board finds that Moore's opinions are born out here and that the Deeming Regulations are examples of the excessive regulations that will eliminate business and jobs in this community.

A Heartland Institute study shows that one to two businesses close a day in Pennsylvania because of strangling regulations, and that the only reason some are staying open is that they cannot get out of their building leases, so must hold on for dear life. Michael McCrary, a store operator in the Cleveland, Ohio area, testified as to the economic gloom facing him and others in that area, and there is nothing in the record here or anywhere to our knowledge or the knowledge of the very skillful researchers who appeared here to show that FDA knows it, has done anything about it, or even cares about it. However, that would be true only in a make

believe world. In the real world, the FDA knows it and intends for it to be that way---adverse economic impact to drive the industry out of business.

The FDA itself acknowledges that the cost for a Pre-Market Tobacco Application (PMTA) will be a minimum of \$300,000 to 330,000, and more expert witnesses say the cost will be from \$1 to 2 million dollars. Each flavor of each brand must be submitted for the testing and scrutiny, so it seems beyond question that most will go out of business.

Yet, the FDA blithely goes along, preparing for processing PMTAs without acknowledging and admitting that the cost will be prohibitive. To make such admission would mean that they would have to comply with the Regulatory Flexibility Act, and by not doing the math they can pretend the Act will not be broken.

Under the Regulatory Flexibility Act, no regulation should be put into place when there is such a danger of deep, deep economic harm, and should never be enforced until the cost is verified and alternatives are explored. But all that would interfere in FDA 's movement to put e-liquid out of business. So, when compliance would spoil the departmental intent, the department ignores the law. That is what has happened here. **Under the Regulatory Flexibility Act, the regulations should be set aside and never implemented or enforced.**

The Heartland Institute economic study in Pennsylvania turned up no Regulatory Flexibility Act study, and none of the other witnesses who testified as to the economic harm were aware of any Regulatory Flexibility Act study or attempt to gather information. Bill Godshall is from Pennsylvania and he heads Smoke Free Pennsylvania. He spoke of no Regulatory Flexibility Study, and it is the Board's opinion that he is so thorough with his research work that he would have reported had there been one.

Because of the violation of the Regulatory Flexibility Act the commissioner should stay, and then rescind the regulations.

VII. THE DEEMING REGULATIONS ARE ARBITRARY AND CAPRICIOUS; NO BASE STANDARDS ARE IDENTIFIED; THEY SET NO STANDARDS FOR THE CONDUCT THEY MANDATE; THEY PROVIDE NO GUIDANCE AS TO PARAMETERS WITHIN WHICH CONDUCT AND PERFORMANCE MUST BE CHANNELED; THEY CONTAIN A REGULATORY SCHEME DESIGNED TO OVERSEE FAILURE AND DESTRUCTION OF THE E-LIQUID INDUSTRY. AS SUCH THEY VIOLATE DUE PROCESS OF LAW PROCEDURALLY AND SUBSTANTIVELY AND ARE INVALID.

1. The evidence is clear that, without a doubt, the Deeming Regulations will result in huge business loss in the e-liquid industry. First, the regulations establish an arbitrary baseline for what is necessary to permit a device without the extraordinary cost of the preliminary analysis and testing. They establish a predicate date that eliminates most all currently in use devices. As a result, the regulations force the industry to consider devices that have been in use for six to seven years as "new" devices subject to the required preliminary analysis, study and

certification. This creates an extraordinary unbalanced benefit to traditional combustible type cigarettes, most of which were in use prior to the "grandfather date". According to the evidence, most of the e-liquid devices that are the most effective as diversions from dangerous combustible cigarette smoking will be banned unless the manufacturer can afford the cost of the preliminary testing. So, the Food and Drug Administration has set up a system that will categorically destroy the most effective alternative for those who would make the effort to quit traditional smoking of combustible cigarettes and save their lives.

- 2. There is no element of proof of science, economics or policy to support the deadly result outlined in the preceding Finding. There is nothing that even begins to justify the arbitrary determination of the predicate date. It is simply a date picked from the air, as far as the Record shows. The cost of submitting a product for testing, analysis and certification will be enormous. The evidence shows that the FDA acknowledged that the cost would be as much as \$300,000. But, witnesses, like Jeff Stier and Bill Godshall, estimate the cost will be closer to a million and a half or two million dollars per product. A successful business will have many, many flavored products, all of which will have to undergo the testing. For example, Johnson Creek has 43 flavors in 4 brands. To test them all would require the cost times 172, prohibitive even at the \$300,000 mark. And even if they could afford that cost, there is no guarantee that certification could be completed. There are no standards in the regulations as to what will lead to approval. In other words, the manufacturer is not told what state of performance his product must reach to be approved. It is, as the CEO of Johnson Creek said, "a moving target" which could change moment by moment. Neither is there any time limit provided for the agency review. Submission of paperwork by the due date does not guarantee that agency action will be completed prior to the drop-dead date on which all currently operable devices must cease operation. So, it is completely within the discretion of the agency as to when to begin analysis of the submissions, when to end it, and to what standards to submit it.
- 3. The objective of these Regulations, designed to control without bounds as to cost or performance, is to doom an industry----an industry that provides an effective alternative to smokers. The John K. MacIver Institute for Public Policy report points out that the regulations "are likely to destroy the budding vapor industry" because of the exorbitant cost for a standard less review. The MacIver report states:

"The FDA, using authority granted to it under the Tobacco Control Act, has seemingly arbitrarily picked February 15, 2007 as the 'predicate date' for the new rules. Any product, even products that consumers have been using for years, that entered the market after that date will be subject to the stringent new requirements, including the byzantine approval process and the massive price tag that it costs these small businesses to seek permission from the FDA to sell a product." (See Exhibit 8)

No wonder the prediction by every witness that the regulations will drive out of business virtually every manufacturer now producing these life saving devices.

- 4. In May, 2016, a year ago, the FDA advertised for comments as to development of "Guidance for Industry" as to the premarket tobacco product application, but the FDA has not issued any such guidelines. To this day, nothing has ever been issued regarding setting such guidance or providing any objective standards to be met by applicants. There is nothing that identifies any standards by which the FDA staff will do the analysis and make the decision as to whether the product being tested will pass or not. The Board sees no evidence that the FDA has any intent of making this testing procedure efficient enough to allow any device now in existence and use to continue so after August of 2018. Bill Godshall testified that the FDA originally has estimated that only 25 PMTAs will be processed. He also said that the FDA estimated that there were 1600 products on the market. The witness said that number is woefully low, indicating the FDA has no clue to the depth of the industry. But this figure shows that they expect to ban 99 percent of products.
- 5. Public Health policy has not been considered in any way by the FDA and as a result, a purely discretionary, non-objective, non-measurable system of review has been set up that will permit FDA to deny clearance to every e-liquid device on the market today without even stating a reason for doing so.
- 6. Clearly, this process denies due process of law. See *Goldberg v. Kelly*, 397 U.S. 254 (1970); Mackey v. Munry, 443 U.S. 1; Fuentes v. Shevin, 407 US 67; Cleveland bd of ed v. loudemiller 470 U.S. 532 all of which would hold this regulatory scheme unconstitutional. They stand for the proposition that whenever a person must submit to this type of testing these factors must be present:
- A) The government must provide notice of what the person must meet or do
- B) The government must be able to show that there is an **articulated (non-vague) standard** of conduct that has caused the person to have to respond (here there is a real problem as to that, because no one has or probably can show why a life saving body of work must fail.)
- C) The government must provide an **opportunity to rebut a case against one in a meaningful way and at a meaningful time** (the "hearing requirement").
- D) In order to sustain its position (i.e., its deprivation of liberty or property), the government must establish--at a minimum--that there is **substantial and credible evidence supporting its action**
- E) The government must provide some **explanation** to the individual for the basis of any adverse finding.

The process in this case does not meet any of the five tests, thus it is unconstitutional and should not be carried forth.

7. Greg Troutman, attorney for a major manufacturer in Kentucky, testified that the regulatory scheme also blocks all future innovativeness within an industry noted for mom and pop stores and manufacturers who have developed an innovative, creative industry. "The immediate effect of the FDA Deeming Regulation is that it froze the e-vapor as of August 8, 2016. The Regulation allowed all e-vapor products on the market as of August 8, 2016 to remain on the

market until the two year Pre-Market Application deadline. The introduction of new e-vapor products is prohibited after August 8, 2016 unless they clear the pre-market application process. It has been estimated that 99 percent of the e-vapor industry will have to shutter as of August 8, 2018 if they cannot submit Pre-Market applications."

He points out that "most manufacturers simply will not be able to comply with the Pre-Market application process for two reasons: (1) the two year time period is woefully insufficient, and (2) the cost of compliance." He points out further that the time element is being analyzed right now by Judge Jackson, a United States District Judge in the District of Columbia. He said that, in a very recent oral argument Judge Jackson remarked to an attorney for the government that it appeared that this regulatory scheme had been "set up...to fail." (Right to Be Smoke Free Coalition v. Food and Drug Administration, Civ. No. 1:16-cv-0878-ABJ)

8. Troutman's testimony provides a picture of an industry that started on a shoe-string, (for example, Johnson Creek started in its Founder's basement) and has grown to great heights. Steve Hong provided expert opinion in the Legato Vapors case in the Indiana United States District Court, that at the end of 2015 the industry had consisted of approximately 8500 retail stores, accounting for approximately \$4 billion of product sales----certainly a competitor that the big tobacco companies would like to be rid of. (Hong is a consulting researcher with Roebling Research LLC, in New York City, AND has a Master's Degree in Business Administration from the University of Virginia.) From that standpoint, it is no surprise that FDA used the Tobacco Control Act as a means to regulate out of business big tobacco's biggest competitor. Now the current e-liquid gathering is facing big pharmaceutical companies that control the sales of prior alternatives such as the nicotine patch. The Board sees evidence that money and influence are being used to try to drive manufacturers and retailers out of business. The testimony of Jeff Stier, Dr. Dunn, Bill Godshall, Jeff Steinbock, and common sense underlie our Finding.

The Regulations not only deprive the industry of due process of law as to the procedures, they also deprive of due process substantively. The Supreme Court cases defining the parameters of the due process clause of the 5th and 14th amendments hold when a statute adversely affects economic interest, as this clearly does, there must be some rational relationship between the law and a "legitimate [government] interest." <u>City of Cleburne v. Cleburne Living Ctr.</u> 473 US 432. There cannot possibly be a legitimate interest of the government in preserving and protecting regulations that will put out of business the most effective reduction of tobacco related illness and death. But even if there were such rational relationship between putting out of business the e-liquid industry and the regulations, there must also be a rational relationship between the legitimate interest and "the means chosen…to accomplish it." <u>Casket Royale, Inc. vl Mississippi</u>, 124 F. sup. 2d at 434. <u>Cornwell v. Hamilton</u>, 80 F. Supp. 2d 1101, <u>St. Joseph Abby v. Castille</u>, 712 F.3d 215. In other words, if there was a legitimate interest in curbing the use of e-liquid products, there must also be a rational relationship to the means used, that is, regulations by the FDA. And there is none. Congress should be the power that puts e-liquid out

of business if that is a legitimate interest, not the FDA. Since Congress directed, by statute, that less dangerous products be encouraged, it is not appropriate for the FDA to regulate or to discourage use of such products. So, the means used violates substantive due process of law.

In <u>Casket Royale</u>, 124 F. Supp. 2d at 440 it is held that not only must the means rationally relate to the government's interest, the law fails if it appears that the law actually diminishes the government's interest. The government's interest should be the public health, which will be diminished by this regulation. Here it appears that the government's regulations will put out of business the industry that has been most successful in fighting smoking. In should be in the government's best interests to fight smoking, if the government were really interested in the public good and the public health.

Had the FDA coordinated with Hartland, all these elements of due process would have been on the table and perhaps they could have arrived at a better solution. The FDA had an opportunity to meet and try to do that. Having failed, it seems bent to destroy an industry that deserves plaudits, not threats.

On the basis of the 4th and 14th amendments to the United States Constitution the regulations must fail – they must be set aside by the Commissioner, the Secretary, the President, or by a Court. To the Commissioner we say: Stick with the Constitution. You can't go wrong that way!

VIII. THE BOARD FINDS THERE IS NO SOUND BASIS FOR THE U.S. FOOD AND DRUG ADMINISTRATION'S DECISION TO USE THE DEEMING REGULATIONS TO TREAT THE E-LIQUID INDUSTRY AS A COLLECTION OF DANGEROUS BUSINESSES THAT IMPERIL PUBLIC HEALTH AND SAFETY.

- The Board agrees with Dr. John Dunn, with the study by Dr. Brad Rodu, Matthew Glans, and fellow witness, Lindsey Stroud, of the Heartland Institute, and reputable studies from the Royal College of Physicians that e-liquids present (at very most) only 5 percent of the risk of smoking traditional cigarettes.
- The Board finds from the testimony of many expert witnesses including Dr. Dunn, that the inhaling of smoke from burning tobacco rather than the ingestion of nicotine is the primary cause of traditional smoking hazards. The Board further finds that this opinion is shared by numerous independent credentialed scientific researchers, many of whom are interviewed in the documentary film, A Billion Lives, produced by Aaron Biebert.
- The Board finds from the testimony and agrees with numerous witnesses that the primary motivation of using e-liquid products is as a healthier replacement for traditional cigarette smoking; AND further that many traditional cigarette smokers became business people within the e-liquid community specifically because of their desire to help and encourage others to kick the proven dangerous smoking habit.

- The Board finds no evidence the e-liquid industry markets products to children, and all witnesses favored preventing use by children.
- The Board finds that the Food and Drug Administration has conducted itself boldly by ordering manufacturers to label even zero-level nicotine products as "This is a Tobacco Product". That is a false label and use of it violates the false claim and brand statutes. The only link of any e-liquid device or product to tobacco is nicotine. If a product is derived from a non-tobacco source, or is a zero-level nicotine product, there is no tobacco, thus it is not a tobacco product. The FDA is forcing an individual or company to issue a false and misleading label.

Due to the fact that false labeling is widely known and proven to be a criminal offense, and due to the fact that the FDA has demanded that individuals and businesses commit acts of false labeling in order to comply with the Deeming Regulations, the Board finds that the Commissioner should stay, and then rescind the Deeming Regulations.

IX. BIG MONEY HAS SPOKEN TO PROTECT TOBACCO COMPANIES AND PHARMACEUTICAL COMPANIES AT THE EXPENSE OF THE MUCH SAFER E-LIQUID INDUSTRY

The Board was privileged to hear from Aaron Biebert, a Milwaukee-based filmmaker and producer of the multi award winning documentary, A Billion Lives, which tells the story of how tobacco abuse will kill a billion people. (What this refers to is that of all the people currently smoking combustible tobacco, one billion will die if they do not quit.) He told us that he was skeptical when he first heard that tobacco and pharmaceutical money found its way into the coffers of the organizations that oppose smoking. So, he went to the lung and cancer organizations to interview them, but found that they did not want to be interviewed. That made him curious to find the answers. When he did, he found that the Center for Disease Control (CDC) is the source for funding many state health departments and CDC gets money from the big pharmaceutical companies, and many of the departments are lobbying against the much safer e-liquid products. State organizations get money from tobacco through grants for anti-smoking programs; yet provide money for lobbying against the most effective anti smoking program there is in the e-liquid products. Legislatures are beneficiaries of tobacco money and they are imposing harsh taxes and regulations on the anti-smoking e-liquid industry. He has concluded that to follow the money is to find that tobacco companies and big pharmaceutical companies are bankrolling public agencies and anti-smoking organizations in order to get their support for their products as opposed to the e-liquid products.

He has concluded that there is total corruption involved in the anti-smoking campaigns that have turned into campaigns dedicated to destroying the most effective, safest means of escaping the illness and death that comes from tobacco abuse and addiction: the e-liquid products that are available now, but threatened with destruction at the hands of the FDA. He has found that in California, for example, money has been pulled from anti smoking campaigns

and re-directed to anti-vaping campaigns. Further, he has concluded from his extensive research that the main fear of the states and their agencies is that they will lose the big amounts of tobacco money they have been receiving over the years since the big tobacco settlement. That settlement has been used as a staple of funding by state legislatures for so long now that they are addicted to the money and either can't or don't want to do without it. State governments have been funded for years with the proceeds from an industry that sells death.

The Board finds there is a rationale to his statements and finds that the anti smoking efforts to destroy the e-liquid industry are at odds with good public policy because the evidence is clear, and is not disputed by facts or science, that e-liquid products are safer and are the most effective weapon against continued addiction to tobacco and the death that results.

DECISION

The Board has made sufficient Findings to justify its decision that the Deeming Regulations, issued by the FDA, in fact are Ultra Vires, that they harm public policy and health, that they violate the Regulatory Flexibility Act, and that they were issued without coordination with Hartland. Too often, we believe, agencies ignore local governments. President Trump has said that in Executive Orders issued in the past three months.

It is time for local governments to be heard. As it was in the beginning of the nation – when the patriots spoke up at town meetings – it shall now be again in Hartland, Wisconsin. We are told by the most ancient Bible teachings, "To every things there is a season, and a time to every purpose under the heaven." Ecclesiastes 3:1

It is time. It is the season. Hartland, Wisconsin says to the Commissioner of the Food and Drug Administration, "Do you job for, not to, our citizens. Follow the law and coordinate with us and with other local governments that serve the hard working, enterprising American citizens trying to live their American Dream – trying to make a living in peace for themselves and their families in the local communities of their choice. We call on you now to step forward and serve within the parameters of our Constitution and its limitations on government."

"We call on you to shelve the Deeming Regulations, issued with no respect for the Regulatory Flexibility Act, the Data Quality Act, the National Environmental Policy Act, the Small Business Administration Act, local governments like Hartland, and American citizens like those in Hartland who are harmed by the harshness of the Regulations. It is time."

CONCLUSIONS, SIGNATURE PAGE AND ACKNOWLEDGEMENT

The above Statements of Findings are the documentation of the Findings of Fact that we the undersigned have made as our Findings based on the testimony we have heard over the course of the Hearing. They lead to the conclusions we state below. Any narrative statements made in the above document shall be taken as Findings of Fact whether the magic phrase "the Board Finds" is used or not.

CONCLUSIONS:

- 1. The e-liquid industry provides a safe, effective alternative to tobacco use and does not threaten major illness and death as does the use of combustible cigarettes.
- 2. The FDA has overstepped its authority and bounds of decorum and law by issuing regulations that are contrary to what Congress directed it to do; instead of promoting less dangerous alternatives, they have issued a de facto ban on the most effective and safe alternative that exists.
- 3. The Deeming Regulations will destroy the e-liquid industry if left in place and enforced in their current state.
- 4. It is contrary to public policy and against the interests of public health to implement and enforce the Deeming Regulations.
- 5. It is not in the best interests of the people of Hartland to see the Deeming Regulations implemented and enforced.
- 6. It is not in the best interests of the people of Waukesha County or the state of Wisconsin to see the Deeming Regulations implemented and enforced.
- 7. The FDA has violated the National Environmental Policy Act by failing to Coordinate with The Village of Hartland and the County of Waukesha. The FDA has also violated the orders given it by President Barack Obama and by President Donald Trump. President Obama's order to coordinate with local governments was in place when the Deeming Regulations were being developed, and President Trump has ordered that all agencies including, FDA examine all regulations and review them to see whether there is any adverse impact on jobs and business; the Deeming Regulations fall within that mandate from the current President, thus today the FDA stands in violation of his Order.

- 8.The FDA has also violated the Regulatory Flexibility Act and the Data Quality Act by not doing the impact analysis on small entities and businesses and by not verifying its own data as to accuracy, integrity, confidentiality, relevance and utility, all requirements of the Data Quality Act.
- 9. The FDA has violated due process of law procedurally and substantively in violation of the Fourth and Fourteenth Amendments to the Constitution of the United States of America.
- 10. The FDA has acted in derogation of public health and public policy, thus contrary to the duty owed to the people of Hartland and Waukesha County.
- 11. The FDA has violated federal statutes that prohibit false labeling, and has made innocent third parties in the e-liquid industry accomplices to their violation.
- 12. The FDA has violated the freedom of speech provisions of the First Amendment to the Constitution of the United States of America.
- 13. In the exercise of the police powers of the Village of Hartland, it is the duty of the Village Board of Trustees to Oppose and Resist Implementation and enforcement of the Deeming Regulations, and to that end we entreat the Commissioner of FDA to stay the implementation and enforcement of the Regulations until he has the chance to review them in view of our Findings and Conclusions and the evidence upon which we base them, and then to rescind the Regulations as being ultra vires and unlawfully developed, and unconstitutional and unlawful if applied. To that end, we instruct the Village Administrator to assure that copies of these Findings and Conclusions and the record supporting them be delivered to the Commissioner of FDA, to the Secretary of the Department of Health and Human Services, to the Chairman of the Council on Environmental Quality in the White House and to President Donald Trump. Courtesy copies should be delivered to the County Executive of Waukesha County, to the legislators who represent Hartland in the Wisconsin legislature, to Governor Scott Walker, Representative F. James Sensenbrenner, Jr., Speaker Paul Ryan, and to United States Senators Ron Johnson and Tammy Baldwin.
- 14. Implementation of the Deeming Regulations will violate the due process rights of every person to whom they apply, thus will constitute a violation of the Civil Rights Act of 1866 as interpreted and applied by the United States Supreme Court in the case familiarly known as the "Monterey Dunes" Case.

The above Findings of Fact and resulting Conclusions are entered in Hartland, Wisconsin on this $1^{\rm st}$ day of May, 2017 by the following Members of the Hearing Board designated by the Hartland Village Board of Trustees and by the Village Administrator.

Chair of the Hearing Board

Member, Hearing Board

Member, Hearing Board

William & Karch

Member, Hearing Board

Michael Clife

Hearing Officer

Village Administrator

RhJE Fail.

Member, Hearing Board

Member, Hearing Board

Harm Compton

Member, Hearing Board

Electronic Vaping Coalition of America

1629 K Street, NW, Suite 300, Washington, DC 20006 | www.evapingcoalition.org

WHAT IS "COORDINATION" IN FEDERAL LAW?

"COORDINATION" REQUIRES FEDERAL AGENCIES TO REACH CONSISTENCY WITH LOCAL GOVERNMENTS' PLANS, POLICIES AND ACTIONS

- The process of Coordination requires that all levels of government must "coordinate" with the lowest levels (local levels) of government prior to enforcing policies, plans, actions, and regulations to ensure that there will be no negative economic impact on the local community as a result of enforcement.
- It is the federal law of the land that federal regulatory agencies must coordinate their policies, plans, actions, and regulations with local governments. The law requires them to work on an equal footing with the local government for purposes of resolving conflicts in policy or action in order to benefit the "human environment" which is identified as being the primary concern of the national government. The "human environment" is defined as including economic, historic, cultural, social, health, and ecologic interests of man.
- In the Federal Land Policy and Management Act, Congress defined "coordination" to mean that the federal agency must use all practicable means to reach consistency of plan, policy and action with local governments. The Supreme Court has ruled that when Congress defines a term of common usage like coordination, then whenever it uses that word in a like statute, it means the same unless it re-defines the term. So in all cases where the human benefits of economic, social, cultural, historic, and ecological considerations are impacted by regulations, the agencies must work with the local government until they reach a stage of consistency. The federal agency has the burden of finding a position consistent with that of the local government. Federal District Judges have set aside federal plans and actions which were shown to be inconsistent with a policy or plan of the local government affected by the action. The President of the United States ordered coordination by all agencies working with rural America in Executive Order # 13575.
- In late 1960-early 1970s, Congress began passing environmental laws that heavily impacted the social and economic environment of human beings. The very first one passed into law, the National Environmental Policy Act (NEPA) requires federal agencies to cooperate with local governments by using "all practicable means to...coordinate...plans, functions, programs and resources." The Act created the Council on Environmental Quality to oversee implementation and enforcement of the Act. The Council ordered all agencies to accomplish the Congressional policy as early in a relationship with a local government as possible in order to avoid or resolve inconsistencies between the federal and local governments. 40 Code of Federal Regulations, Part 1500, ex. 1501.2
- What is the rationale for Congress to have put this burden on the agencies? From our
 earliest days as a nation, local governments have been the most important level of
 government to the citizens. Government services needed by citizens are most effectively
 delivered at the local community level. To prevent local governments and communities
 from being overwhelmed by an enormous national government, Congress has mandated in
 law that all federal agencies "coordinate" their policies, plans and actions with local
 governments such as the Village of Hartland.

The Food and Drug Administration, in its regulation 21 Code of Federal Regulations 25.1, acknowledges that NEPA's coordination requirement is consistent with its statutory duties and responsibilities, thus it must follow the NEPA requirements

Wisconsin - P.O. Box 510564 - New Berlin, Wisconsin 53151

Attachment 1
Village of Hartland, Wisconsin
FDA Coordination Hearing

Attachment 2
Village of Hartland, Wisconsin
FDA Coordination Hearing

RESUME OF FRED KELLY GRANT SHOWING QUALIFICATIONS TO SERVE AS HEARING OFFICER

Formal Education:

Nampa Idaho Senior High School, Salutatorian, 1954

College of Idaho, Summa Cum Laude, BA,1958

University of Chicago School of Law, JD, 1961

Master's Work, University of Chicago School of Law, Federalism and International and Domestic Commercial and Cultural Law, 1961-2

Associate, Lord, Bissell and Brooke, Chicago law firm serves as American counsel for Lloyds of London

Law Clerk, Chief Judge Frederick W. Brune, Maryland Court of Appeals

Assistant United States Attorney, District of Maryland 1964-5

Assistant States Attorney and Chief of Organized Crime Division, States Attorney of Baltimore City, 1965-69

Private practice, Baltimore 1969-70

Counsel to Governors Cecil Andrus and John Evans, Idaho 1971-74

Hearing Officer---Ada County, Canyon County, Owyhee County, Boise City, Caldwell City, Nampa City, personnel hearings, zoning and land use hearings, administrative law enforcement hearings, disciplinary hearings, annexation hearings 1974-1990

Private Practice and consulting on Tenth Amendment and federalism 1990present

Oversight of appellate cases and capital punishment sentencing processes for Public Defender of Canyon County Idaho, 1990-2000 (19 capital cases)

Author: Articles on Personnel hearings; administrative hearings; book Justice My Ass; articles on land use and land rights; articles on federalism.

Attachment 2 Village of Hartland, Wisconsin FDA Coordination Hearing

Sillage Hartland

ADMINISTRATION

210 Cottonwood Avenue Hartland, WI 53029 Phone (262) 367-2714 Fax (262) 367-2430 www.villageofhartland.com

DESIGNATION OF HEARING OFFICER TO CONDUCT PUBLIC HEARING/MEETING RELATED TO DEEMING REGULATIONS OF THE FOOD AND DRUG ADMINISTRATION

Pursuant to authority granted by the Village Board in Resolution 02/13/2017-01, I, Jeffrey Pfannerstill, hereby designate Fred Kelly Grant to serve as Hearing Officer to conduct the public hearing/meeting scheduled for April 27-29, 2017 in Hartland, Wisconsin, and to work with the Village and Village Board in presenting the Findings from said Hearing to the Village Board for final action. Grant's resume is attached hereto as Exhibit 1.

Name: Jeffrey Pfannerstill

Title: Village President

Signature:

Date: 4-21-2017

VILLAGE OF HARTLAND

RESOLUTION NO. 02/13/2017-01

A RESOLUTION AUTHORIZING THE VILLAGE PRESIDENT AND VILLAGE STAFF TO EXECUTE DOCUMENTS INTERVENING IN FDA REGULATIONS IMPACTING LOCAL INTERESTS

WHEREAS, the Village of Hartland recognizes the importance of a vibrant, positive and healthy business environment and business sector have on the overall social, cultural and economic health of the Village of Hartland; and

WHEREAS, as authorized by the Wisconsin State Constitution and the Wisconsin State Statutes, the Village of Hartland is charged with promoting the general welfare, good order and prosperity of the Village of Hartland and its inhabitants including residents, businesses and visitors; and

WHEREAS, integral to this charge is an obligation to provide as healthy a business climate as possible within acceptable regulations and balancing the interests of businesses and residents to allow existing and new businesses to grow and flourish; and

WHEREAS, the FDA has adopted certain regulations that are expected to have a significant negative impact on a particular business in the Village of Hartland engaged in the electronic cigarette, or vaping, industry; and

WHEREAS, certain State and Federal Laws require that regulators consider the impact of their regulations on small entities such as the Village of Hartland and that these laws require regulators to coordinate with local officials regarding the development and implementation of such regulations; and

WHEREAS, the Village of Hartland desires to coordinate with the FDA and other agencies as necessary regarding the consideration, development and implementation of regulations that will impact Hartland businesses and, by extension, the economic stability and health of the Village of Hartland.

NOW, THEREFORE, BE IT RESOLVED by the Village Board of Trustees for the Village of Hartland in furtherance of this desire that the Village President and Village Staff are hereby authorized to adopt and execute documents, papers, letters or other items on behalf of the Village of Hartland to request coordination with the FDA and other agencies.

BE IT FURTHER RESOLVED that this authorization specifically includes execution as a Resolution of the Village of Hartland Board of Trustees the concept resolution attached hereto

Resolution No. 02/13/2017-01
Page 1 of 2
2932

Exhibit 1
Village of Hartland, Wisconsin
FDA Coordination Hearing

as Exhibit A in a form substantially similar to the version attached hereto, which resolution shall be numbered Resolution No. 02/13/2017-02.

BE IT FURTHER RESOLVED that this authorization specifically does not authorize the execution of any other official Resolutions on behalf of the Village Board the contents of which have not been considered by the Village Board of Trustees in an open session meeting.

Dated this 13 day of Feb., 2017.

David Lamerand, Village President

ATTEST:

Darlene Igl, MMC, WOPC, Village Clerk

Resolution No. 02/13/2017-01 Page 2 of 2

EXHIBIT A

Concept Language for Resolution No. 02-13-2017-02

Hartland, Wisconsin will celebrate its One Hundred Twenty Fifth anniversary as an incorporated Village on January 18, 2017.

Hartland was settled and developed in the early 19th century "go west, go west young man, go west" migration, which implemented the Manifest Destiny of the United States of America.

In the autumn of 1837, Stephen Warren of Ann Arbor, Michigan, decided to seek his future and fortune by going west, even before the westward movement was popularized. He walked to Fort Dearborn (now Chicago), where he worked and saved enough money to continue his journey, which took him through Milwaukee and Waukesha (Prairieville) and to land that he purchased between what is now Maple and Cottonwood Avenues in Hartland.

"Go west and earn your fortune," was a theme that promoted migration by unemployed clerks, mechanics, soldiers, farmers, and settlers and which Wisconsin history professor, Frederick Jackson Turner, argued was directly responsible for the independence and resourcefulness that imbued the settlers with a greater resourcefulness and fiercer love of democracy than any other people in the world.

The westward movement brought other pioneer farmers and settlers to the fertile Bark River Valley, where in 1842 Christian Hershey built the first water-powered grist mill which helped fire an economy that led to development in 1846 of the Watertown Plank Road (literally constructed with 10' log planks), which served as a main highway for transporting grains and hops to Milwaukee breweries.

The healthy economy led to a fast growing community which drew settlers and travelers who chose to enjoy recreation; a race track was built in 1845, in the center of which was a baseball diamond where teams from neighboring towns drew fans up to 10,000, which led to development of inns, hotels, and resorts throughout the area.

The first Post Office was opened in 1846, and in 1854 the railroad arrived, the community took on the name Hartland, and the first newspaper, the Hartland Index, was established.

By 1890 the population was 500, the community was a regular train stop from Milwaukee, and residents began to plan for incorporation as a Village. Incorporation became final and official on January 18, 1892.

The economic stability created by the early settlers has continued through the decades and Hartland continues to grow and thrive with a governmental and community climate favoring business development.

This industrious, early development of a Hartland community well balanced for business, recreational, and community interests helps explain why the Village is a destination of choice for industry, manufacturing, commercial, and service businesses that choose to thrive here, where they have easy accessibility, first class business parks, outstanding municipal services, low tax rates, and a quality work force needed for cutting edge business development and health.

The Village is governed by a Village Board consisting of a President and six trustee members operating and exercising powers under the village form of government established by Wisconsin statutes, Chapter 61, as authorized by the Wisconsin Constitution, Article XI, section 3. The Board works with a City Manager, and other Village officials dedicated to providing a healthy atmosphere for economic development. The Village Board works actively with the Hartland Business Improvement District Board of Directors, and encourages federal, state, and county government agencies to support the activities of the District.

Hartland continues to grow. The population has increased six times over from 1950 to 2000, with a steady growth of economic stability to match population.

Hartland's master plan predicts a population from 10,500 to 11,000 by the year 2020, and predicts the job market to reach from 4400 to 4600 jobs by 2020, which will be a 22 to 28 percent increase over the year 2000.

It is critical to the social, cultural, and economic health of Hartland that the Village Board continues to provide an encouraging, positive business environment.

The Village of Hartland exercises its powers and duties under statutory authorization that promotes "the largest measure of self-government in accordance with the spirit of Article XI, section 3 of the constitution [municipal home rule]" by declaring that the grant of Village powers "shall be liberally construed in favor of the rights, powers and privileges of villages to promote the general welfare, peace, good order and prosperity of such villages and the inhabitants thereof." Wisconsin Statutes 61.34 (5)

Article XI, section 3 of the Wisconsin Constitution provides that Villages can "determine their local affairs and government, subject only to this

constitution and to such enactments of the legislature of statewide concern as with uniformity shall affect every other city or every village." Thus, the Constitution establishes municipal home rule for the Village of Hartland and allows municipal regulation over matters of local concern and protects against conflicting stet law Madison Teachers, Inc. v. Walker, 358 Wis. 2d 1.

The legislature has empowered the Hartland Village Board with the power to manage and control village property, finances, highways, streets, navigable waters, and the public service, and further with the power "to act for the government and good order of the village, for its commercial benefit and for the health, safety, welfare and convenience of the public."

Hartland functions as does the state under the mandate that free government be maintained: "The blessings of a free government can only be maintained by a firm adherence to justice, moderation, temperance, frugality and virtue, and by frequent recurrence to fundamental principles." Art XI, section 22

As in so much of America, state and federal laws and regulations impact local business environments, with no input from local interests.

The Hartland Master Comprehensive Plan identifies sixteen percent of the planned urban service area of Hartland for commercial and industrial business uses, identifies areas in which new commercial and industrial uses can develop, and recommends new business-commercial park areas to accommodate expected growth of economic interests.

Hartland recognizes that the success of the Plan and of the potential for growth as predicted depends upon continued success of the businesses already established in Hartland, the growth of such established businesses, and a climate positive for future growth.

Hartland has recognized the need for its elected local officials to provide as healthy a business climate as possible under the law in order for current businesses to continue success, and in order to attract new businesses that will thrive in the community.

Hartland's entire community health---schools, medical, business, and government---depends upon a healthy business climate.

Recognizing the adverse impact of regulations on small businesses of the type which are community based in Hartland, it is time that the local officials call upon state and federal regulators to recognize the importance of their impact on communities such as Hartland, and to recognize the importance of

involving local officials in the development of and implementation of business restrictive regulations.

State and federal laws require that regulators coordinate with local officials regarding development of and implementation of such regulations, and coordination includes earnest efforts to avert inconsistencies between state and federal policies and local policies, and even more earnest efforts to resolve any such inconsistencies to the benefit of local government and its citizens.

State and federal laws require that regulators consider the impact of their regulations on small entities such as Hartland, under the Regulatory Flexibility Act and the Data Quality Act, and to coordinate such consideration with the local officials.

The Hartland Village Board recognizes the importance of calling upon state and federal regulators to engage the Village in coordination regarding regulations that may have adverse impact on Hartland's business community, and therefore on Hartland itself and its citizens.

WHEREFORE, IT IS HEREBY RESOLVED THAT THE VILLAGE OF HARTLAND, WISCONSIN SHALL ADVISE ALL STATE AND FEDERAL AGENCIES OF ITS INTENT TO EXERCISE LOCAL AUTHORITY IN CALLING FOR SAID AGENCIES TO ENTER INTO COORDINATION WITH THE VILLAGE REGARDING CONSIDERATION OF, DEVELOPMENT OF, AND IMPLEMENTATION OF REGULATIONS THAT WILL IMPACT BUSINESSES OPERATING IN HARTLAND, AND THE ECONOMIC STABILITY AND HEALTH OF THOSE BUSINESSES.

This local authority to call for coordination is based upon federal laws such as the National Environmental Policy Act, the Regulatory Flexibility Act, the Data Quality or Information Quality Act, and sections of the many statutes governing the Department of Health and Human Services and its Food and Drug Administration, all of which mandate the agencies and Food and Drug Administration to coordinate its data-quality, scientific quality, and delivery of program efficiency with local governments.

None of these agencies have engaged Hartland in coordination discussions, and now Hartland calls upon them specifically to commence such discussions regarding any adverse impact that might be felt by Hartland and/or its constituents from implementation of regulations relating to any product manufactured, distributed, marketed, advertised, sold, or purchased by a business operating in Hartland or within Hartland's economic improvement district.

Presidential Executive Order 13575, issued in June, 2011, directs all executive department regulators to coordinate their programs and activities with local governments like the Village of Hartland. In directing the agencies, including the Department of Health and Human Services to coordinate, the Order emphasizes the importance of rural communities such as Hartland:

"The strong, sustainable rural communities are essential to winning the future and ensuring American competitiveness in the years ahead. These communities supply our food, fiber, and energy, safeguard our natural resources, and are essential in the development of science and innovation. Though rural communities face numerous challenges, they also present enormous economic potential. The Federal Government has an important role to play in order to expand access to the capital necessary for economic growth, promote innovation, improve access to health care and education, and expand outdoor recreational activities on public lands." The Order then creates the White House Rural Council to "better coordinate Federal programs and maximize the impact of Federal investment to promote economic prosperity and quality of life in our rural communities."

The Food and Drug Administration operates within the Department of Health and Human Services, which is a member of the Council and is directed to coordinate with Hartland, a direction which to date has not been followed.

No statute or Executive Order that requires coordination with local governments such as the Village of Hartland exempts the Food and Drug Administration, so that agency is obligated by law to coordinate with Hartland.

The Council on Environmental Quality has directed all agencies subject to the National Environmental Policy Act to cooperate with local governments "to the fullest extent possible" to reduce duplication and to avoid inconsistencies between federal and local plans and laws "whether or not federally sanctioned", and to describe the "extent to which [the federal agency] will go in reconciling "its proposed action" with the local government's plan or law. 40 CFR 1500 et seq.

Hartland has adopted a health, safety, and business policy resolution that refutes the lawfulness of Food and Drug regulating manufactured by a company that does business within the boundaries of the Village of Hartland and/or its Economic Development District. Resolution No. points out that marketing of the product has been found to effectively reduce the use of and addiction to cigarette smoking, and as a result, the product has been successfully marketed by its

maker. Expert scientific testimony and other evidence exists which makes it apparent that the Food and Drug regulations will cause production and sale of the product to decrease, forcing the maker to go out of business. The result will be adverse to the company, all its employees, all other employees in and around the Village of Hartland who work inter-dependently with the company, and to the economic health and stability of the tax base of Hartland. The Food and Drug Administration has made no effort to discuss this adverse impact with the Village Board of Hartland, thus has not complied with the law.

The Village of Hartland calls upon the Food and Drug Administration to delay implementation and enforcement of the regulations until it has engaged Hartland in the coordination process as directed by law.

VILLAGE OF HARTLAND

RESOLUTION NO. 02-13-2017-02

A RESOLUTION REQUESTING COORDINATION WITH THE FDA AND OTHER FEDERAL AGENCIES

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"Go west and earn your fortune," was a theme that promoted migration by unemployed clerks, mechanics, soldiers/farmers, and settlers and which Wisconsin history professor, Frederick Jackson Turner, argued was directly responsible for the Independence and resourcefulness that imbued the settlers with a greater resourcefulness and fiercer love of democracy than any other people in the world.

The westward movement brought other pioneer farmers and settlers to the fertile Bark River Valley, where, in 1842, Christian Hershey built the first water-powered grist mill which helped fire an economy that led to development in 1846 of the Watertown Plank Road (literally constructed with 10' log planks), which served as a main highway for transporting grains and hops to Milwaukee breweries.

The healthy economy led to a fast growing community which drew settlers and travelers who chose to enjoy recreation; a race track was built in 1845, in the center of which was a baseball diamond where teams from neighboring towns drew fans up to 10,000, which led to development of inns, hotels, and resorts throughout the area.

The first Post Office was opened in 1846, and, in 1854, the railroad arrived, the community took on the name Hartland, and the first newspaper, the Hartland Index, was established.

By 1890 the population was 500, the community was a regular train stop from Milwaukee, and residents began to plan for incorporation as a Village. Incorporation became final and official on January 18, 1892.

Exhibit 2 Village of Hartland, Wisconsin FDA Coordination Hearing The economic stability created by the early settlers has continued through the decades and Hartland continues to grow and thrive with a governmental and community climate favoring business development.

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Hartland has been advised that vaping products have been found to effectively reduce the use of and addiction to cigarette smoking, and as a result, the products have been successfully marketed by its maker, a local Hartland company. Further, Hartland has been advised that expert scientific testimony and other evidence exists which makes it apparent that the Food and Drug Administration regulations will cause production and sale of the product to decrease, forcing the maker to go out of business. The result will be adverse to the company, all its employees, all other employees in and around the Village of Hartland who work inter-dependently with the company, and to the economic health and stability of the tax base of Hartland. The Food and Drug Administration has made no effort to discuss this adverse impact with the Village Board of Hartland, thus has not complied with the law.

The Village of Hartland calls upon the Food and Drug Administration to delay implementation and enforcement of the regulations until it has engaged Hartland in the coordination process as directed by law.

Dated this 13th day of February, 2017.

ATTEST:

ISI David Lamerand

David Lamerand, Village President

<u> |S| Darlene Igl</u>

Darlene Igl, MMC, WCPC, Village Clerk



ADMINISTRATION

210 Cottonwood Avenue Hartland, WI 53029 Phone (262) 367-2714 Fax (262) 367-2430 www.villageofhartland.com

davidc@villageofhartland.com

April 18, 2017

1892-2017

Department of Health and Human Services Thomas E. Price, M.D., Secretary 200 Independence Avenue, S.W. Washington, DC 20201

Food and Drug Administration—United States Government Stephen Ostroff, M.D., Acting Commissioner 10903 New Hampshire Avenue Silver Spring, MD 20993-0002

Food and Drug Administration – Milwaukee Office 2675 North Mayfair Road Wauwatosa, WI 53226

Ladies and Gentlemen:

This is to advise you that Hartland, Wisconsin has invoked the coordination process afforded it by federal statute, offered it by Presidential Executive Orders, guaranteed it by the Constitutions of the United States and the State of Wisconsin and facilitated by agency rules and regulations including those of the Council on Environmental Quality and the Food and Drug Administration. We expect coordination by your offices regarding the Deeming Regulations issued by Food and Drug and now to be interpreted in light of Presidential Executive Order 13777.

Hartland will hold a public hearing on April 27, 28, and 29, 2017 focused on whether your agency has coordinated as the laws require, and on what course of coordination is needed for compliance with the law. The hearing will be held in the Board Room of the Municipal Building, 210 Cottonwood Avenue, Hartland, Wisconsin 53029.

The Thursday, April 27 session will begin at 5:30 pm (Central Standard) and will recess at approximately 9:00 pm; the hearing will resume Friday morning at 9:30 am and will recess at approximately 9:00 pm; the hearing will resume Saturday morning at 9:30 am and will continue until all witnesses have been heard.

Exhibit 3
Village of Hartland, Wisconsin
FDA Coordination Hearing

Thomas E. Price, M.D., Secretary April 18, 2017 Page 2

If you will provide me with names of persons you want to testify as to whether you believe you are obligated to coordinate with Hartland on these issues or whether you have indeed so coordinated, I will assure that the Hearing Officer includes them on his witness schedule.

Enclosed is a copy of the Notice of Public Hearing, which is being posted by Hartland regarding the Hearing.

Also enclosed is a copy of Hartland's Resolutions 02/13/2017-01 and 02/13/2017-02. The first authorizes me to adopt and execute papers to invite coordination by your agency. Please consider this letter to be my invitation to you, and my request to you, to attend and provide witnesses to testify as to the issues set forth herein and inherent in the language of Resolution 02 as read in light of Presidential Executive Order 13777. Please notify me of names of witnesses by 12:00 noon Central Time on April 25, 2017. You may advise me either by telephone at 262.367.2714 or by email at davidc@villageofhartland.com. Also enclosed is a copy of a letter that the Hearing Officer is sending to witnesses and prospective witnesses.

Witnesses will appear to testify to the following relevant issues:

- (1) whether Food and Drug is obligated to stay within the parameters of presidential and legislative demands that the agencies coordinate with local governments such as Hartland, the County of Waukesha and all local communities within the tri-county area around Hartland,
- (2) whether the coordination required by the National Environmental Policy Act, the rules of the Council on Environmental Quality, your agency's own rules, and required by presidential orders and directives issued in the first 100 days is inapplicable to your agency and if not, why not (with reference to specific legal immunity);
- (3) what sound science and data provide the backdrop consistent with and supportive of the Deeming Regulations and how was it tested by application of the coordination process and/or the Data Quality Act processing;
- (4) what due process of law related standard of conduct and performance was used as a gauge to constitutionality was used in determining lawfulness of the impact of the Deeming Regulations;
- (5) what process was used to test the compliance with the Regulatory Flexibility Act of the Deeming Regulations and what due process standard was used to gauge the constitutionality of the impact of the Regulations;

Thomas E. Price, M.D., Secretary April 18, 2017 Page 3

- (6) what was the originating concept for the Deeming Regulations and who developed that concept and through what process;
- (7) whether the Deeming Regulations are within the statutory and constitutional parameters to which your agency is committed legally;
- (8) any other issue relevant to the issues comprehended within the categories stated hereinabove.

If you have any questions regarding this matter, please do not hesitate to call me. Our thanks go to the President for his issuance of the Orders and directives, which focus on local government's rightful place in the federal structure, a place guaranteed by the Constitution of the United States of America.

Cordially

David E. Cox

Village Administrator

Village of Hartland, Wisconsin

VILLAGE OF HARTLAND, WISCONSIN NOTICE OF PUBLIC HEARING RELATED TO COORDINATION WITH THE FOOD AND DRUG ADMINISTRATION

On April 27-29, 2017 the Village of Hartland will conduct a public hearing/meeting related to coordination and lack of coordination by the federal Food and Drug Administration and other agencies regarding deeming regulations and the review of regulations impacting the economy and culture of Hartland, the County of Waukesha, and their surrounding communities.

The Hearing will commence at 5:30pm on April 27 in the Board Room of the Municipal Building, 210 Cottonwood Avenue, Hartland, Wisconsin, 53029. The hearing will be recessed at 9:00pm and will resume on April 28 at 9:30am; it will recess at 5:30pm, and will resume on April 29 at 9:30am, concluding at a time to be determined.

The Hearing Board will consist of elected and appointed officials representing the Village of Hartland and surrounding areas.

This will be considered and implemented as a public hearing/meeting of Hartland, the results of which may be used as the basis for official business of the Village.

A hearing officer, Fred Kelly Grant, Esq., will conduct the hearing for the Hearing Board. Witnesses will be administered the oath or affirmation before testifying and documents will be verified either by witness testimony of by affidavit as to source and authenticity.

The issues are:

- (1) whether the federal Food and Drug Administration coordinated with the Village of Hartland and other local governments regarding the implementation of the FDA Deeming Regulations
- (2) whether the FDA Deeming Regulations are based on sound science verified under the federal Data Quality Act
- (3) whether the Food and Drug Administration vetted its Deeming Regulations under and within the provisions of the Regulatory Flexibility Act
- (4) whether the Food and Drug Administration established a standard by which its Deeming Regulations were developed and whether within the Regulations there is created a standard by which their impact can be measured for purposes of the due process clause of the United States and

Exhibit 4
Village of Hartland, Wisconsin
FDA Coordination Hearing

State of Wisconsin Constitutions and the provisions of the United States Civil Rights Act of 1866.

- (5) whether Food and Drug or any other agency including but not limited to the Environmental Protection Agency has coordinated with the Village of Hartland regarding the Executive Order 13777 as to review of all regulations from the standpoint of adverse impact.
- (4) whether other issues regarding the regulations may impact the communities and the rights of businesses and individuals affected thereby.

Anyone who desires to testify should contact David Cox, Village Administrator, at 262.367.2714 or by email at davidc@villageofhartland.com no later than thirty minutes prior to the start of the hearing.

David E. Cox Village Administrator

Published on Thursday, April 20, 2017

GUIDELINES FOR HARTLAND, WISCONSIN PUBLIC HEARING

PURSUANT TO RESOLUTION No. 02/13/2017-01 PASSED BY THE HARTLAND, WISCONSIN VILLAGE BOARD, THE FOLLOWING GUIDELINES ARE ESTABLISHED FOR CONDUCT OF THE EVIDENTIARY HEARING TO BE HELD COMMENCING ON APRIL 27, 2017 AT 5:30 PM [Central Time] IN THE BOARD ROOM IN THE MUNICIPAL BUILDING IN Hartland, Wisconsin, to be recessed at 9:00 pm, and to resume at 9:30 am on April 28, 2017, to recess again at 5:30 pm, and to resume at 9:30 am on April 29 to run until witnesses have all been heard:

- 1. Prior to testifying, witnesses shall be sworn by an appropriate and authorized notary or public official, and will file as exhibits any text of their testimony and/or exhibits to which they will refer, with said exhibits being marked into evidence alphabetically, A to Z, beginning again with AA through ZZ and if necessary AAA through ZZZ;
- 2. Testimony may be audio recorded and video recorded, with the audio and video product becoming part of the official record overseen by the Hearing Officer, to be preserved by the Village Manager;
- 3. Witnesses scheduled prior to the Hearing will be assigned a specific time to testify; at the completion of scheduled testimony, or between sessions of scheduled witnesses, members of the public may testify to any issue relevant to coordination and/or the basis for and content of the "deeming regulations" or other Food and Drug Administration action as it relates to Hartland;
- 4. No time limit will be imposed on witnesses prior to the Hearing, and will be imposed by the Hearing Officer only if it appears that all scheduled witnesses would not otherwise have time to complete their testimony;
- 5. Witnesses will submit to questions from members of the Hearing Board asked through the Hearing Officer; members of the public may submit questions to the Hearing Officer and if time permits those questions will be asked of the witnesses;
- 6. Each day there will be a lunch recess at 11:45 am and the afternoon session will begin at 1:00 pm;
- 7. Other guidelines or rules may be imposed at the request of the Hearing Board members or if order requires additional guidance.
- 8. Any Question of relevance shall be decided by the members of the Hearing Board which shall be guided by the following instructions:

Witnesses will present evidence as to the following questions or issues:

I;

Coordination, or lack thereof, between the federal Food and Drug Administration and the Village of Hartland, the County, any other unit of government in the County and/or state of Wisconsin, the County, the State of Wisconsin, or any other unit of local or state government from any other part of the nation by special permission of the Hearing Board;

ii:

Content and meaning of federal statutes relating to coordination and to the duties of Food and Drug;

iii;

Content of the deeming regulations as to:
Science supporting the regulations,
policy within which said regulations were written and adopted
and/or standards by which regulations are to be applied
and compliance of regulations with law, common, natural and statutory

Economic impact of the regulations on the Community and on interstate commerce

V

Compliance of said regulations with statutes, lawful regulations, and executive orders directed to the federal agencies

νi

Considerations of public health and safety

vii:

Other concerns such as special taxes placed on products covered by the regulations and the impact of such taxes on the community

viii;

Other matters upon recommendation of the Hearing Officer and/or request of the Hearing Board

In order to be assured of a time to testify, witnesses should advise the Village Administrator of the intent to testify by 12:00 noon on April 25, 2017. He may be contacted for this purpose at 262.367.2714 or by email at davidc@villageofhartland.com.



FKG

Professional Consulting Co.

Fred Kelly Grant, JD College of Idaho, BA 1958 University of Chicago Law, JD 1961 Senior Fellow Goldwater Institute Public Policy Land Use Federalism Civil Rights

April 18, 2017

To: Prospective Witnesses at Coordination Hearing in Hartland, Wisconsin

From: Fred Kelly Grant, Hearing Officer

The Village of Hartland, Wisconsin has asked me to act as Hearing Officer and conduct a public hearing/meeting in Hartland, commencing on April 27, 2017 at 5:30 pm in the Board Room of the Municipal Building. The time is Central Standard Time.

A Hearing Board of elected officials from the Village of Hartland, and perhaps including a representative of the County and of other surrounding communities will hear evidence relating to the following issues: (1) failure of the Food and Drug Administration to coordinate issuance and development of the deeming regulations with Hartland and the other local jurisdictions represented on the Board; (2) failure of Food and Drug to comply with the Data Quality Act re the deeming regulations; (3) failure of Food and Drug to comply with the Regulatory Flexibility Act re the deeming regulations; (4) failure of Food and Drug to fix standards for issuance of guidelines that satisfy all aspects of due process of law; (5) failure of Food and Drug to stay within the parameters of agency interests; (6) failure to observe constitutional boundaries of the distinct powers of government (7) remedy for violations; and (8)other issues determined prior to beginning of hearing to be relevant.

A list of invited witnesses will be posted on the Village of Hartland website on Monday, April 24, 2017; any other person desiring to offer evidence should contact the Village Administrator at 262.367.2714 prior to April 26, 2017 at 9:00 am with name of witness and issue to be discussed in order to be included on the agenda to testify.

Exhibit 5
Village of Hartland, Wisconsin
FDA Coordination Hearing

The Hearing will commence on April 27 at 5:30 pm and will recess at approximately 9:00 pm; will resume again at 9:30 am on April 28 and will recess at approximately 5:30 pm; and will resume at 9:30 am April 29 and continue until a time to be determined. At the conclusion of the hearing, the Board will adjourn for a brief period and will reconvene to discuss the preliminary Findings of Fact. When those are completed, the Board will recess until Monday evening, May 1, 2017 or a time to be decided. At the resumed session, the final findings and conclusions will be decided and issued.

Only evidence relevant to the issues identified by the Board will be admitted, and information may be offered either in writing or oral format, but with the limited time left available at the end of scheduled witnesses, any last minute added witness should be prepared to offer written evidence.

The Hearing Officer may impose time limits if the list of witnesses grows to the point at which every one cannot otherwise testify.

Questions as to the process I will follow should be directed to the Village Administrator at the above telephone number and he will relay them to me.

I look forward to a very productive and meaningful hearing, and with all your cooperation, we will have a product in which we can all take pride.

Cordially,

Fred Kelly Grant



Testimony on Coordination with the Food and Drug Administration

Coordination hearing in Hartland, Wisconsin April 27, 2017

Thank you to the Village of Hartland, hearing board, and hearing officer for holding this Coordination Hearing and allowing me to submit testimony. The purpose of my testimony is to outline to the board that, as a state elected official, no effort was made by the Food and Drug Administration (FDA) to coordinate with our state government regarding the so called Deeming Regulations. In addition, I will discuss the perspective I would have offered to the FDA regarding the egregious reach of the Deeming Regulations had they coordinated with state governments.

Since first being elected to state office in 2010, representing Hartland and the surrounding area, I have chaired committees that have deal with federal issues. These include committees on the Constitution and State-Federal Relations, through which I have frequently been in touch with federal agencies regarding their policies.

Despite my role as an elected official in state government tasked with overseeing federal issues, I never received any contact from the FDA pertaining to the Deeming Regulations. At no point did anyone from the FDA contact me to coordinate with state government to ensure there would be no negative economic impact on our communities as a result of the Deeming Regulations. Other locally elected officials here to testify this week verify that they also were not contacted for coordination on these rules. Based on the lack of coordination, I believe the FDA failed to comply with the coordination requirement under federal law.

Had the FDA coordinated with local governments, I would have explained the significant negative economic impact the Deeming Regulations will have on Hartland and the surrounding communities. Within my district, there are several small and medium sized businesses that operate within the field the Deeming Regulations seeks to regulate. The increased regulation to bring a product to market and to maintain compliance will cost our economy jobs and income. In addition, many of my constituents utilize the products regulated by the Deeming Regulations as an effective means of tobacco harm reduction. If the FDA regulates these materials as tobacco is regulated, these individuals will likely have limited access to products that are far less harmful than tobacco.

In conclusion, the FDA has violated federal law by not communicating with me or other locally elected officials. Had the agency coordinated with local governments, they would have seen the negative economic impact the Deeming Regulations will have on our community. Thank you for considering my testimony on this important matter.

STATE SENATOR

Leah Vukmir

Wednesday, April 26, 2017

David Cox Village of Hartland Administrator 210 Cottonwood Avenue Hartland, WI 53029

Mr. Cox.

Thank you for the opportunity to submit written testimony for your public hearing about the deeming regulations enacted by the U.S. Food and Drug Administration that will have a detrimental impact to the economy of the village of Hartland.

Since 2011, the state of Wisconsin has been focused on making our state open for business to great success. Our unemployment rate is now at 3.4%, the lowest since 2000, and the labor force participation rate is at 68.4%. This has been due in large part to state government opening up the marketplace and eliminating unnecessary red tape so small businesses can flourish.

As a new administration takes control in Washington, I hope it will consider better, more effective coordination with local governments, like the village of Hartland, to reconsider these rules and study the needs of a local economy before enacting any new regulations. Federal coordination with municipalities on rules is critical to ensure that new proposals don't have unintended consequences and that government is as adaptable to the needs of everyday Americans as possible.

It is clear that the deeming regulations from the FDA that treat vaping products similarly to tobacco products are overly burdensome to the vaping industry. Because of the presence of Johnson Creek Enterprises, these new rules disproportionately affect Hartland — and the state of Wisconsin and may cause many to lose their jobs. Additionally, I struggle to see how overregulating an industry which provides a product many use to gain independence from tobacco is helpful for the public health of our country.

Thank you again for the opportunity to submit testimony on this issue, if I can answer any further questions, please feel free to contact me in the future.

Sincerely,

Leah Vukmir

Assistant Majority Leader

Wisconsin State Senate

WISCONSIN STATE CAPITOL

P.O. Box 7882 Madison, WI 53707

PHONE (608) 266-2512

EMAIL Sen. Vukmir@legis.wi.gov WEBSITE www.SenatorVukmir.com

Exhibit 7 Village of Hartland, Wisconsin FDA Coordination Hearing





The Economic Impact of the FDA's Deeming Regulation on Hartland, Wisconsin and the Wisconsin Economy

4.28.2017

Good afternoon, my name is Brett Healy. I am President of the John K. MacIver Institute for Public Policy based in Madison, Wisconsin.

I am here today to testify on the federal Food and Drug Administration (FDA) so-called "deeming regulation" and the impact this regulation will have on the people of Wisconsin and our economy.

First, I want to thank the Village of Hartland, Village President Pfannerstill, the entire Village Board and Village administrator Cox for calling this public hearing on this very important public policy matter. A new and flourishing industry, an industry that, by one estimate, is an almost \$3 billion dollar a year industry, faces extinction at the hands of the FDA and the impending deeming regulation. This is a very serious matter and a public policy debate of national importance. Village President Pfannerstill, Administrator Cox and the Village Board all deserve recognition for holding this hearing today and the people of Wisconsin owe you a debt of gratitude for bringing much-needed attention to this oppressive regulation, the antics of the FDA and the adverse impact it will have on our economy.

The Food and Drug Administration's new regulation deeming vaping-related products to be tobacco products, which forces these products to undergo a rigorous and costly new approval process, is likely to destroy the budding vapor industry. The FDA, using authority granted to it under the Tobacco Control Act, has seemingly arbitrarily picked February 15, 2007 as the "predicate date" for the new rule. Any products, even products that consumers have been using for years, that entered the market after that date will be subject to the stringent new requirements, including the byzantine approval process and the massive price tag that it costs these small businesses to seek permission from the FDA to sell a product.

The number of lost jobs and businesses that will close because of the deeming regulation is likely to have a devastating impact on Hartland, the surrounding communities of Waukesha County and a forceful ripple effect across every corner of Wisconsin. By one estimate, this regulation will force the vast majority of companies in the e-vapor market out of business within three years.

One of the central questions that you are here today to examine and to seek the public's input on is what will the impact be on the village of Hartland and the state of Wisconsin if this new regulation is adopted in its current form. The MacIver Institute is currently working on an analysis that seeks to demonstrate to the committee and federal regulators the economic impact this rule will have on the Wisconsin e-vape industry and the ancillary impact the rule will have on

44 E. Mifflin Street, Suite 201 Madison, WI 53703 Exhibit 8
Village of Hartland, Wisconsin
FDA Coordination Hearing

Wisconsin businesses that service or benefit from the e-vape industry. Unfortunately, our report is not completed at this time but as soon as it is ready for publication, we will share our findings with the committee.

Even though you cannot review MacIver's economic impact study at this time, fortunately there are other indicators available that give us an idea of what that impact will be if the rule is enacted as drafted.

Johnson Creek Vapor Company is a national leader in the e-vape industry headquartered right here in Hartland, Wisconsin. Founded by Christian Berkey in his garage in 2007, Johnson Creek Vapor is a quintessential example of the American entrepreneur success story and proofpositive that the American dream is still alive and attainable today.

Johnson Creek Vapor was the first e-liquid manufacturer in the country. Today, it has grown into the largest manufacturer of e-liquid in the U.S. and second largest in the world, shipping 50,000 gallons of their product to more than 120 countries each year.

Johnson Creek Vapor employs 47 people full-time in a variety of family-supporting jobs. By all measures, it's a model of success and a good corporate citizen. Unfortunately, this doesn't seem to matter to the bureaucrats in Washington, DC. Berkey told the MacIver Institute earlier this year that the FDA's regulations could cost his company alone up to \$200 million to bring all their products into compliance - a staggering figure that will surely have a negative impact on Johnson Creek Vapor's bottom line and Berkey's ability to provide family-supporting jobs to his hard-working employees. What will become of Johnson Creek Vapor's employees and their families if the FDA is allowed to continue down this current path?

In addition to Johnson Creek Vapor, Wisconsin is also home to many small businesses that will be harmed by the FDA regulation, from vape retail shops to e-liquid and vaping hardware manufacturers. A recent survey of these businesses, organized by the Electronic Vaping Coalition of America (EVCA), gives us another glimpse at the potential impact of the deeming regulation. According to the preliminary EVCA survey of vaping businesses, 70 percent of these businesses reported having between only one and five full-time employees, and 73 percent report having between one and five part-time employees. Ninety-one percent have between one and five locations. Clearly, the survey respondents are generally small mom-and-pop operations, not gigantic corporate enterprises that will be able to easily-absorb the hundreds of thousands of dollars it will cost to seek approval from the FDA to bring a product to market.

The EVCA survey, although just a small sample at this time, gives the public an idea of what this burdensome regulation and the staggering cost to comply with this regulation will do to these small businesses. According to the survey, 74 percent of vaping businesses planned to reduce or eliminate inventory as a result of the regulations. Fifty-one percent said they planned to lay-off employees in order to survive, and 42 percent are considering selling or closing their businesses thanks to this overly-burdensome regulation.

44 E. Mifflin Street, Suite 201 Madison, WI 53703 The exact cost of the FDA regulation to these businesses and the total economic cost to communities like Hartland is hard to measure, but we have an idea from the survey how much money these small business owners have invested - 51 percent reported having invested more than \$100,000 in their business. That lost investment, combined with the potential for lost jobs and closed businesses, will cost Wisconsin communities enormously and rob many entrepreneurs of their piece of the American Dream.

Other estimates paint an even darker picture for the future of the vaping industry. According to the American Vaping Association, the product approval process is so onerous and expensive that up to 99 percent of the products currently available will not even be submitted to the FDA. The cost of the regulation will impose such a barrier on these businesses - in applications fees, legal fees, and many other compliance costs - that many will be forced under and the select few that actually survive will be rendered unprofitable for many years to come. Why would we allow our federal government to do this to our own people?

While we all await the completion of a more formal economic impact analysis, clearly the preliminary indicators discussed here of the harm that this regulation will do to communities like Hartland is substantial and deeply concerning.

I want to thank again the Village Board of Hartland for holding this coordination hearing. I want to thank you for defending the entrepreneurs and small businesses that will be decimated by this regulation. I want to thank you for defending the hard-working Wisconsinites all across our state that will be negatively-impacted by this rule. And, most importantly, I want to thank you again for standing up to the heavy-handed and unbounded federal government before they kill off this promising and rapidly-expanding e-vape industry. Thank you.

Brett Healy

President
The John K. MacIver Institute for Public Policy
44 E. Mifflin Street, Ste. 201
Madison, WI 53703

Tobacco Laws Affecting California

2016

Fully updated, user-friendly guide to laws regulating exposure to secondhand smoke, the sale and marketing of tobacco products, including the federal Family Smoking Prevention and Tobacco Control Act.

ChangeLab Solutions www.changelabsolutions.org

This booklet was developed by ChangeLab Solutions with funds received from the California Department of Public Health, under contract #14-10214.

ChangeLab Solutions is a nonprofit organization that provides legal information on matters relating to public health. The legal information in this document does not constitute legal advice or legal representation. For legal advice, readers should consult a lawyer in their state.

 $@\ 2016\ Change Lab\ Solutions$

Tobacco Laws Affecting California 2016

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⁴ Tobacco Laws Affecting California 2016

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OVERVIEW

This booklet provides summaries of state and federal tobacco laws that affect California. It is designed as a resource for tobacco control advocates, government attorneys, local law enforcement agencies, and anyone who is working on tobacco control issues. The booklet includes information on California state laws and regulations related to tobacco, including the Stop Tobacco Access to Kids Enforcement Act (known as the STAKE Act), as well as federal laws and regulations that apply within California, such as the Family Smoking Prevention and Tobacco Control Act (known as the Tobacco Control Act).¹ It also summarizes portions of the 1998 Master Settlement Agreement (MSA) between the attorneys general of 46 states (including California) and the major tobacco companies, and the 1998 Smokeless Tobacco Master Settlement Agreement (STMSA) between the attorneys general of 45 states (including California) and U.S. Smokeless Tobacco Company.

In some cases, there are multiple laws covering a particular topic. For example, both California and the federal government ban distributing free samples of cigarettes (see entries 76–78 for more information on the distribution of free samples). In other cases, state and federal laws may cover the same topic but have different restrictions. Moreover, California and federal laws often use similar terminology with different definitions. A glossary of terms used in federal and California laws is included below. Readers will need to examine the scope of each law closely to determine what is prohibited.

The information in this booklet includes tobacco-related laws that are effective as of September 1, 2016. However, entry 92 includes Proposition 56's new tobacco products tax, adopted in November 2016.

This booklet does not contain information on the numerous local laws in California that regulate tobacco use, sales, or distribution. Many of these local laws are stricter than state or federal law. For example, local governments in California have passed laws to limit exposure to secondhand smoke in both indoor and outdoor areas where smoking is permitted by state law. Local governments in California also have enacted laws to supplement state laws regarding how tobacco products are sold. For instance, the state tobacco retailer licensing law focuses on protecting state revenue by targeting tax evasion, while numerous communities have local tobacco retailer licensing laws that focus on protecting the public's health.

It is important to review local laws to determine whether a jurisdiction has adopted restrictions to supplement the laws described in this book.

¹This booklet does not include every instance in which the word *tobacco* is mentioned in state or federal law. However, the booklet contains information on the laws that are relevant to tobacco control implementation and enforcement efforts in California. If you note any omissions in the booklet, please contact ChangeLab Solutions.

UPDATED STATE TOBACCO CONTROL LAWS

On June 9, 2016, 5 tobacco bills took effect in California, updating many areas of existing law. These updates are reflected throughout this booklet.

- Senate Bill X2-5 changed the definitions of smoking and tobacco products in major tobacco laws throughout the California code. Updated provisions that formerly regulated the smoking of tobacco products now cover electronic smoking devices with or without nicotine. See https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=201520162SB5.
- Senate Bill X2-7 raised the minimum legal sales age for tobacco products, including electronic smoking devices with or without nicotine, from 18 to 21 years of age, with an exception for active military personnel who are at least 18 years of age, with proper identification. See https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=201520162SB7.
- Assembly Bill X2-7 extended California's smokefree workplace requirements to some previously exempted locations. See https://leginfo.legislature.ca.gov/faces/ billTextClient.xhtml?bill_id=201520162AB7.
- Assembly Bill X2-9 expanded restrictions on the use of tobacco products in schools and related facilities. See https://leginfo.legislature.ca.gov/faces/billTextClient. xhtml?bill_id=201520162AB9.
- Assembly Bill X2-11 modified the state's Tobacco Products Licensing Act of 2003 by increasing the fees for tobacco retail, distribution, and wholesale licenses and renewals. See https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=201520162AB11.

Under most of these state laws, the following changes apply:

- **Smoking** includes the use of an electronic smoking device that creates an aerosol or a vapor, in any manner or in any form, or the use of any oral smoking device for the purpose of circumventing the prohibition of smoking. California Business and Professions Code Section 22950.5(c).
- Tobacco Product means
 - (A) A product containing, made from, or derived from tobacco or nicotine that is intended for human consumption, 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, or snuff.
 - (B) An electronic device that delivers nicotine or other vaporized liquids to the person inhaling from the device, including, but not limited to, an electronic cigarette, cigar, pipe, or hookah.
- Tobacco Laws Affecting California 2016

(C) Any component, part, or accessory of a tobacco product, whether or not sold separately.

Tobacco Products do not include products approved by the U.S. Food and Drug Administration for sale as a tobacco cessation product or for other therapeutic purposes where the product is marketed and sold solely for such an approved purpose.

Local laws that use the words smoking and tobacco product are not affected by these changes, unless a local law specifically refers to a state law definition. None of the 2016 bills alters the authority for local governments to regulate the use of tobacco products. Furthermore, local governments may regulate electronic smoking devices to the same extent they are able to regulate traditional tobacco products.

FEDERAL REGULATION OF ELECTRONIC NICOTINE DELIVERY SYSTEMS, CIGARS, AND OTHER TOBACCO PRODUCTS

As of August 8, 2016, the U.S. Food and Drug Administration's (FDA) authority over the regulation of tobacco products extends to all tobacco products, including cigarettes, smokeless tobacco, cigars, pipe tobacco, hookah tobacco, gels, dissolvables, electronic nicotine delivery systems containing anything made or derived from tobacco, and other newly deemed tobacco products. 81 Federal Registrar 28973 (May 10, 2015), available at www.federalregister.gov/articles/2016/05/10/2016-10685/deeming-tobacco-products-to-be-subject-to-the-federal-food-drug-and-cosmetic-act-as-amended-by-the. The FDA applies varying requirements and limitations to different categories of tobacco products. The following is a non-exhaustive list of terms used in the Tobacco Control Act and FDA regulations (it is possible for a product to fall under more than one category below):

- The deeming rule refers to the final rule issued by the FDA that extends its regulatory
 authority under the Tobacco Control Act to all tobacco products. The rule does not
 apply to accessories of newly deemed tobacco products. The FDA has released a
 chart with the effective and compliance dates applicable to retailers, manufacturers,
 importers, and distributors of newly deemed tobacco products: www.fda.gov/
 TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm500778.htm.
 - Under the Tobacco Control Act, the scope of preemption that applies to state and local regulation of newly deemed tobacco products subject to FDA authority will likely be the same or less than it is for regulation of cigarettes. However, provisions in the Federal Cigarette Labeling and Advertising Act and the Comprehensive Smokeless Tobacco Health Education Act that preempt states from regulating the content of cigarette and smokeless tobacco product advertisements, respectively, still apply only to cigarettes and smokeless tobacco products (see entries 56, 83, and 117 for more information about preemption).
- A **tobacco product** means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product. Tobacco products do not include raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product, nor any article regulated as a drug, device, or combination product under the Food, Drug, and Cosmetics Act (FDCA). 21 United States Code Sections 321(g)(1), 321(h), 353(g).
- An accessory means any item that (1) does not contain tobacco; (2) is not derived from tobacco; (3) is used with or for the human consumption of a tobacco product; and (4) does not affect or alter the performance, composition, constituents, or characteristics of a tobacco product, with the exception of items that only control moisture/ temperature or provide an external heat source to ignite but not maintain combustion. 21 Code of Federal Regulations Section 1140.3.
- A **component or part** means any software or assembly of materials intended or reasonably expected (1) to alter or affect the tobacco product's performance,

- composition, constituents, or characteristics; or (2) to be used with or for the human consumption of a tobacco product. Component or part excludes anything that is an accessory of a tobacco product. 21 Code of Federal Regulations Section 1140.3.
- A **newly deemed tobacco** product means a tobacco product that is not cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. For example, this includes cigars, pipe tobacco, hookah tobacco, gels, dissolvables, and electronic nicotine delivery systems containing anything made or derived from tobacco. Newly deemed tobacco products include any component or part of newly deemed products, but do not include their accessories. On varying effective and compliance dates, different newly deemed tobacco products will be subject to many Tobacco Control Act provisions that apply to cigarettes, roll-your-own tobacco, and smokeless tobacco, including the following:
 - (1) Adulteration and misbranding provisions
 - (2) Required submission of ingredient listing and reporting of harmful and potentially harmful constituents
 - (3) Required registration and product listing
 - (4) Prohibition against the use of modified risk descriptors and claims (eg, "light," "low," and "mild" descriptors), unless the FDA issues an order permitting their use
 - (5) Prohibition on the distribution of free samples
 - (6) Premarket review requirements
- Electronic nicotine delivery systems are tobacco products under the FDA deeming rule, and may include products such as e-cigarettes, e-cigars, e-hookah, vape pens, personal vaporizers, and electronic pipes. These products are all subject to FDA regulation, regardless of what they're called or their heating source. Components or parts of electronic nicotine delivery systems may include, for example, e-liquids, tanks, cartridges, pods, wicks, or atomizers. 81 Federal Registrar 28974, 29028.
- A covered tobacco product means any tobacco product deemed to be subject to the Federal Food, Drug, and Cosmetic Act under 21 Code of Federal Regulations Section 1100.2. However, covered tobacco products exclude any component or part that is not made or derived from tobacco. 21 Code of Federal Regulations Section 1140.3.
 - In addition to the requirements and limitations applicable to all newly deemed tobacco products, the deeming rule applies 3 additional provisions to covered tobacco products:
 - (1) Restricting sales to individuals under 18 years of age
 - (2) Requiring health warnings for product packages and advertisements
 - (3) Prohibiting vending machine sales, unless the vending machine is located in a facility where the retailer ensures that individuals under 18 are prohibited from entering at any time

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Glossary of State and Federal Terms

- A **finished tobacco** product means a tobacco product, including all components and parts, sealed in final packaging intended for consumer use. 81 Federal Registrar 28973, 28995 (May 10, 2016).
- A **new tobacco product** means any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007. A new tobacco product also includes any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product in which the modified product was commercially marketed in the United States after February 15, 2007. 21 United States Code Section 387j(a)(1).

This booklet includes a discussion of these provisions where applicable and provides effective and compliance dates relevant to retailers, manufacturers, importers, and distributors of newly deemed tobacco products. The FDA has reserved the authority to impose additional restrictions and limitations on newly deemed tobacco products.

FINDING THE ACTUAL LAWS

The full text of the laws and regulations described in this booklet can be found on the following websites:

• California Laws

www.leginfo.ca.gov/calaw.html

This website is the easiest place to find the California laws. To locate a particular code section, check the box next to the type of code (eg, Penal Code), type the number of the section in the keyword(s) box, and click on the search button under the keyword(s) box. To browse an entire code (as opposed to a particular section), check the box next to the type of code and click on the search button without typing anything into the keyword(s) box.

• California Regulations

http://ccr.oal.ca.gov

This website provides access to the California Code of Regulations. To find a specific regulation, you can search by key word, by exact citation, or by browsing through the different Titles.

Federal Laws

www.ecfr.gov/cgi-bin/ECFR?SID=829200e2378d1731cf45dfd0e581fe21&mc=true&pag

This website contains the full text of the federal laws (the United States Code). To pinpoint a particular federal law, you can search by several methods, including keyword, title, and section.

Federal Regulations

www.gpoaccess.gov/cfr/index.html

This website provides access to the Code of Federal Regulations (C.F.R.).

U.S. Food and Drug Administration (FDA) Guidance, Compliance and Regulatory Information

www.fda.gov/tobaccoProducts/guidancecomplianceregulatoryInformation/default. htm

This website provides access to FDA guidance and compliance information on the 2009 federal Family Smoking Prevention and Tobacco Control Act.

Master Settlement Agreement (MSA) and Smokeless Tobacco Master Settlement Agreement (STMSA)

http://ag.ca.gov/tobacco/msa.php

This website contains the entire MSA between the attorneys general of 46 states (including California) and the major tobacco companies, as well as the entire STMSA between the attorneys general of 45 states (including California) and the U.S. Smokeless Tobacco Company.

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ADDITIONAL COPIES OF THIS BOOKLET

You may download a copy of this booklet from ChangeLab Solutions' website at www.changelabsolutions.org/publications/tobacco-laws-affecting-california.

SEGONDHAND SMOKE

WORKPLACES

California Labor Code Section 6404.5

Scope: It is against the law to smoke, including the use of electronic smoking devices, in an enclosed space at a place of employment or owner-operated business. No employer or owner-operated business shall knowingly or intentionally permit smoking in an enclosed space. *Enclosed space* includes covered parking lots, lobbies, lounges, waiting areas, elevators, stairwells, and restrooms that are a structural part of the building. A place of employment is any place where employees or owner-operators carry on their work.

An employer or owner-operator who permits any nonemployee access to his or her place of employment on a regular basis must take reasonable steps to prevent smoking by any nonemployee, as specified.

Note: This law applies to places of employment at any time of day or night, regardless of whether any employees are present. Legis. Counsel of Cal. Op. 16332, Question No. 18 (May 12, 1995).

Note: A business constitutes a "place of employment" if employment of any kind is carried on at the business location, whether the employment is carried on by employees, by individuals who are employed by someone other than the business owner, or by the business owner himself or herself.

Note: In many cases, volunteers may be considered employees for the purposes of determining whether a space is a place of employment. For instance, a person who provides unpaid services but who receives some other kind of benefit from these services (such as reduced-price admission) may be considered an employee. Legis. Counsel of Cal. Op. 24807, Question No. 3 (Dec. 20, 1997).

Note: Local governments may impose and enforce their own smoking restrictions if they apply to areas not covered by state law. *City of San Jose v. Dep't of Health Services*, 66 Cal. App. 4th 35, 44 (1998). However, to the extent that state law currently prohibits smoking in an enclosed place of employment, a local government may only enforce the state law (and not a similar local law).

Exception: The following places are exempt from the smoking ban:

1. Up to 20% of hotel and motel guest rooms.

Note: Hotels and motels may choose to be 100% smokefree.

 Retail or wholesale tobacco shops (businesses whose main purpose is the sale of tobacco products, including electronic smoking devices) and private smokers' lounges (any enclosed area, in or attached to a retail or wholesale tobacco shop, dedicated to tobacco use, including the use of electronic smoking devices).

Note: Businesses that serve alcoholic beverages do not qualify for this exception. Cal. Atty. Gen. Op. No. 09-507 (Dec. 21, 2011).

- 3. Cabs of trucks or tractors, if nonsmoking employees are not present.
- 4. Theatrical production sites, if smoking is an integral part of the story.
- 5. Medical research and treatment sites, if smoking is integral to the research and treatment being conducted.
- 6. Private residences except for those licensed as family day care homes (where smoking is prohibited pursuant to Section 1596.795 of the Health and Safety Code).
- 7. Patient smoking areas in long-term health facilities.

Enforcement: This section may be enforced by local law enforcement agencies, including local health departments, as determined by the local governing body. The enforcement agency may refer the violation to the California Occupational Safety and Health Administration (Cal/OSHA) for further enforcement; however, Cal/OSHA is not required to respond to a complaint until after a third conviction under Labor Code Section 6404.5. In addition, under Labor Code Section 2699, an aggrieved employee or former employee may bring a civil action if Cal/OSHA fails to act upon a complaint.

PENALTY: Violators are guilty of an infraction and subject to a fine of up to \$100 for a first violation, \$200 for a second violation within 1 year, and \$500 for a third or subsequent violation within 1 year.

Note: Cal/OSHA's fines are potentially much greater; Cal/OSHA has fined a violator over \$50.000.

2. MULTIUNIT RESIDENCES

California Labor Code Section 6404.5

Scope: The workplace smoking prohibitions in Labor Code Section 6404.5 apply to the indoor common areas of apartment and condominium complexes (including, for example, hallways, stairwells, laundry rooms, and recreation rooms) if these areas are places of employment (see entry 1 for a summary of Labor Code Section 6404.5). Smoking includes the use of electronic smoking devices.

Note: An indoor common area may be a place of employment if *any* employment is carried on at the property, even if the employment is carried on by the property owner or by individuals who are employed by someone other than the property owner. Cal. Atty. Gen. Op. No. 12-901 (Dec. 20, 2013). Thus, this law may apply to common areas if the property has any individual who works on the property at any time (eg, manager, security guard, or maintenance worker), regardless of whether the individual is the property owner, is employed directly by the property owner, or is employed by a separate business that the property owner hires to perform services.

Note: Landlords and condominium associations may adopt policies further restricting where residents smoke. Such policies could prohibit smoking in indoor and outdoor common areas as well as in individual units.

Note: Tenants or condominium owners with certain disabilities relating to smoke sensitivity may have other legal remedies available to address the problem of drifting smoke entering their units (see entries 120–123 for more information on remedies available to people with disabilities).

ENFORCEMENT: See entry 1 for a summary of how the Labor Code may be enforced.

PENALTY: See entry 1 for penalties available under the Labor Code.

California Civil Code Section 1947.5

Scope: A landlord may prohibit the smoking of cigarettes or other tobacco products, including electronic smoking devices, on the property or in any portion of the building.

Note: Landlords who exercise their authority to prohibit smoking remain subject to all federal, state, and local laws regarding changes to the terms of a lease or rental agreement for all leases or rental agreements that were entered into before the smokefree policy was adopted (eg, notice requirements, local rent ordinances, etc.). If a landlord prohibits smoking anywhere on the property, any lease or rental agreement entered into on or after January 1, 2012, must include a provision specifying where smoking is prohibited. For a lease or rental agreement entered into before January 2012, a prohibition against smoking in any portion of the property where smoking was previously allowed constitutes a change of the terms of tenancy, requiring adequate notice in writing.

Note: This law explicitly permits local governments to pass ordinances, regulations, and policies that prohibit smoking or tobacco product use, including the use of electronic smoking devices, in residential dwellings.

Enforcement: Not applicable.

PENALTY: Not applicable.

Proposed Rule, 24 Code of Federal Regulations Parts 965 and 966

Scope: In October 2015, the U.S. Department of Housing and Urban Development (HUD) proposed a rule to require all Public Housing Authorities (PHAs) and Moving-to-Work (MTW) agencies to prohibit lit tobacco products (eg, cigarettes, cigars, and pipes) in all public housing units, indoor common areas and offices, and within a buffer zone of 25 feet of all buildings. The proposed rule also affirms the right of PHAs to go beyond the rule's requirements to make their grounds entirely smokefree. At the time of publication, HUD had only released a proposed rule and solicited comments, and the scope of any final rule was not known. Therefore, a final rule may differ from the proposed rule in scope, exceptions, enforcement, and penalties. The docket for the proposed rule is available at www.regulations.gov/#!d ocumentDetail;D=HUD-2015-0101-0001.

EXCEPTION: The proposed rule does not apply to units in mixed-finance buildings or Section 8 housing. The proposed rule does not apply to smokeless tobacco, electronic smoking devices, hookahs, and marijuana products.

ENFORCEMENT: Because the rule has not been finalized, enforcement is not in effect. The final enforcement measures may differ from those in the proposed version. In the current draft, the smoking prohibition would be implemented through tenants' leases (with an amendment or upon renewal) in order to incorporate existing lease enforcement mechanisms. Additionally, in the current draft, PHAs would be required to include smokefree policies in their PHA plans and planning process.

PENALTY: Penalties would be determined by the enforcement provisions contained in tenants' leases.

STATE, COUNTY, AND CITY BUILDINGS

California Government Code Sections 7596-7598 California Education Code Section 89031

SCOPE: Smoking, including the use of electronic smoking devices, is prohibited:

- Inside a public building, which is a building owned and occupied, or leased and occupied, by the state, a county, a city, or a California community college district
- In an outdoor area within 20 feet of a main exit, entrance, or operable window of a public building
- In a passenger vehicle owned by the state

This law explicitly permits local governments and campuses (eg, a campus of the University of California, the California State University, or the California community college system) to pass more restrictive ordinances, regulations, and policies.

Note: The workplace smoking restrictions in California Labor Code Section 6404.5 also apply (see entry 1).

EXCEPTION: The smoking prohibition does not apply to private living areas of public buildings (such as dormitories) or to the parking areas of covered public parking lots. Smoking may be allowed in any outdoor area of a public building unless otherwise prohibited by state or local law and a sign describing the prohibition is posted by the state, county, or city agency, or other appropriate entity.

ENFORCEMENT: The governing bodies of the University of California, the California State University, and each community college district have the authority to enforce their requirements by citation and fine. If a campus exercises its enforcement and fine authority, it must (and a campus of the University of California may) post signs stating its tobacco use policy and inform employees and students of the policy.

Furthermore, the trustees of the California State University may establish rules and regulations for the governance and maintenance of the university's buildings and grounds.

PENALTY: The governing bodies of the University of California, the California State University, and each community college district may impose a fine for each offense, with the amount to

be determined by the local governing body. Funds shall be allocated to include, but not be limited to, the designated enforcement agency, education and promotion of the policy, and tobacco cessation treatment options. The civil penalty shall not exceed \$100.

Violations or attempted violations of the rules and regulations governing and maintaining the buildings and grounds of California State University constitute misdemeanors.

4. CERTIFIED FARMERS' MARKETS

California Health and Safety Code Section 114371(f)

Scope: Smoking, including the use of electronic smoking devices, is prohibited within 25 feet of the common commerce area of a certified farmers' market. The *common commerce area* is comprised of sales personnel and shopping customers of the certified farmers' market.

ENFORCEMENT: Health enforcement officers are authorized to enforce this law and related regulations under Health and Safety Code Section 114390 *et seq.*

PENALTY: Violators are guilty of a misdemeanor, and each offense is punishable by a fine of \$25 to \$1,000 and/or by imprisonment for no more than 6 months. For violations by employees, or at shared facilities, each owner, manager, or operator may be held responsible.

5. TOT LOTS AND PLAYGROUNDS

California Health and Safety Code Section 104495

Scope: Smoking, including the use of electronic smoking devices, is prohibited within 25 feet of a playground or tot lot sandbox area. The disposal of tobacco-related waste, such as cigar and cigarette butts, in these areas is also prohibited. A *playground* is defined as a park or recreational area specifically designed for use by children that has play equipment installed. This includes facilities located on public or private school grounds or on city, county, or state park grounds. A tot lot sandbox area is a play area within a public park designated for use by children under 5 years of age. The law allows local governments to pass and enforce stricter laws.

EXCEPTION: The law does not apply to public sidewalks within 25 feet of a playground or tot lot sandbox area.

ENFORCEMENT: Local law enforcement agencies have the general authority to enforce this law under California Penal Code Section 830.1.

PENALTY: Violators are guilty of an infraction and subject to a fine of \$250 per violation.

YOUTH SPORTS EVENTS

California Health and Safety Code Section 104495

Scope: The use of tobacco products, including electronic smoking devices, is prohibited within 250 feet of a youth sports event when the user is located in the same park or facility where a youth sports event is taking place. A youth sports event is any practice, game, or related activity, organized by any entity, at which athletes up to 18 years of age are present.

Enforcement: Local law enforcement agencies have the general authority to enforce this law under California Penal Code Section 830.1.

PENALTY: Violators are guilty of an infraction and subject to a fine of \$250 per violation.

7. SCHOOLS

California Health and Safety Code Section 104559

Scope: California law prohibits the use of tobacco and nicotine products, including electronic nicotine delivery devices, at all times in county offices of education, in buildings owned or leased by a charter school or school district, on school or school district property, and in school or school district vehicles. School districts, charter schools, and county offices of education shall prominently display signs stating "Tobacco Use Is Prohibited" at all entrances to school property.

Note: The workplace smoking restrictions in California Labor Code Section 6404.5 also apply (see entry 1). When a school is housed in a government-owned or governmentleased building, the smoking restrictions in California Government Code Sections 7596–7598 also apply (see entry 3).

Note: See entries 17–18 for summaries of tobacco possession and use restrictions relating to schools.

Enforcement: Not applicable.

20 United States Code Section 6083

Scope: It is illegal under federal law to permit smoking within any indoor facility utilized for kindergarten, elementary, or secondary education or library services for children.

Note: The workplace smoking restrictions in California Labor Code Section 6404.5 also apply (see entry 1).

Note: See entries 17–18 for summaries of tobacco possession and use restrictions relating to schools.

Enforcement: The U.S. Department of Education is authorized to enforce this law.

Note: A school or library may use its general power over its property to enforce no-smoking rules against visitors and its general power over its terms of employment to enforce no-smoking rules against employees. A school may use its normal disciplinary powers to enforce no-smoking rules against students.

PENALTY: Violators may be liable for a civil penalty of up to \$1,000 for each violation and/ or may be subject to an administrative compliance order. Each day a violation continues constitutes a separate violation.

8. DAY CARE FACILITIES

California Health and Safety Code Sections 1596.795, 1596.890

Scope: California law prohibits smoking, including the use of electronic smoking devices, on the premises of a licensed day care center and in a licensed family day care home (eg, a day care for children based in the home of the provider) at all times, including non-business hours. The law allows for more stringent local laws.

Note: The workplace smoking restrictions in California Labor Code Section 6404.5 also apply (see entry 1).

Enforcement: This law may be enforced by the California Department of Social Services or by local law enforcement agencies.

PENALTY: Violators are guilty of a misdemeanor punishable by a \$1,000 fine and/or imprisonment for no more than 180 days.

20 United States Code Section 6083

Scope: It is illegal under federal law to permit smoking within any indoor facility that is used for federally funded health care, day care, or Head Start services for children or that is used by the employees of the provider of such services.

Note: The workplace smoking restrictions in California Labor Code Section 6404.5 also apply (see entry 1).

EXCEPTION: This law does not apply to any private residence or to areas used for inpatient hospital treatment for drug or alcohol addiction.

Note: California Health and Safety Code Section 1596.795 prohibits smoking in family day care homes.

Enforcement: The U.S. Department of Education is authorized to enforce this law.

Note: The facilities covered by this law may use their general power over their property to enforce no-smoking rules against visitors and their general power over their terms of employment to enforce no-smoking rules against employees.

PENALTY: Violators may be liable for a civil penalty of up to \$1,000 for each violation and/ or may be subject to an administrative compliance order. Each day a violation continues constitutes a separate violation.

9. FOSTER HOMES

California Health and Safety Code Section 1530.7

Score: Smoking, including the use of electronic smoking devices, is prohibited in group homes, foster family agencies, small family homes, transitional housing placement providers' facilities, and crisis nurseries licensed pursuant to the California Community Care Facilities Act.

Indoor smoking is prohibited in foster family homes and certified family homes. When a child is present, outdoor smoking within these facilities is also prohibited. Moreover, a foster care provider shall not smoke in any vehicle regularly used to transport the child or children in foster care.

Enforcement: The California Department of Social Services is authorized to enforce this law.

PENALTY: Violation may result in the denial or revocation of a certificate of approval for a certified family home or other disciplinary action against the certified or prospective foster parent.

10. SMOKING IN VEHICLES WITH CHILDREN

California Health and Safety Code Sections 118947-118949

Scope: It is illegal to smoke, including the use of electronic smoking devices, in any motor vehicle in which a minor is present, regardless of whether the vehicle is in motion or at rest.

ENFORCEMENT: A law enforcement officer may not stop a vehicle for the sole purpose of determining whether the driver is violating this prohibition.

PENALTY: Violation of this section is an infraction punishable by a fine not exceeding \$100 per violation.

11. PUBLIC TRANSIT SYSTEMS

California Health and Safety Code Sections 118925-118945

Scope: Smoking, including the use of electronic smoking devices, is prohibited on public transportation systems and in any vehicle of an entity receiving transit assistance from the state. A notice prohibiting smoking, displayed as a symbol and in English, must be posted in such vehicles or aircraft, in addition to other sign posting requirements. The law allows for more restrictive local laws.

Note: The workplace smoking restrictions in California Labor Code Section 6404.5 also apply (see entry 1).

ENFORCEMENT: Local law enforcement agencies have the general authority to enforce this law under Penal Code Section 830.1.

PENALTY: Violators are guilty of an infraction and subject to a fine of up to \$100 for a first

violation, up to \$200 for a second violation within 1 year, and up to \$500 for a third and for each subsequent violation within 1 year.

California Public Utilities Code Section 99580(b)(4)

California Penal Code Section 640

Scope: Smoking, including the use of electronic smoking devices, is not allowed on public transportation in areas where it is prohibited by that system.

Note: The workplace smoking restrictions in California Labor Code Section 6404.5 also apply (see entry 1).

Enforcement: Local law enforcement agencies have the general authority to enforce this law under California Penal Code Section 830.1. A public transportation agency may also enact and enforce an ordinance to impose an administrative penalty for smoking in places where smoking has been prohibited.

PENALTY: Violators are guilty of an infraction and subject to a fine of up to \$250 and 48 hours of community service.

12. AIRPLANES AND TRAINS

California Health and Safety Code Sections 118925–118945 California Public Utilities Code Section 561

Score: Smoking, including the use of electronic smoking devices, is prohibited on any aircraft or Amtrak train, except to the extent permitted by federal law. The law contains sign posting requirements.

Note: Under the Public Utilities Code, any railroad corporation, passenger stage corporation, passenger air carrier, and street railroad corporation providing departures originating in this state shall prohibit smoking, including the use of electronic smoking devices, in passenger seating areas. They must also post readily visible signs advising passengers of these no smoking requirements.

Note: The workplace smoking restrictions in California Labor Code Section 6404.5 also apply (see entry 1).

ENFORCEMENT: Local law enforcement agencies have the general authority to enforce this law under California Penal Code Section 830.1.

PENALTY: Violators are guilty of an infraction and subject to a fine of up to \$100 for a first violation, up to \$200 for a second violation within 1 year, and up to \$500 for a third or subsequent violation within 1 year.

49 United States Code Section 41706

14 Code of Federal Regulations Section 252.3

49 Code of Federal Regulations Section 175

Scope: Smoking is prohibited on domestic U.S. airline flights. Smoking also is prohibited in foreign air travel arriving in or departing from the United States.

Note: In February 2016, the U.S. Department of Transportation updated its definition of smoking to explicitly include the use of electronic smoking devices in the prohibition of smoking on aircraft. Products (other than electronic cigarettes) that meet the definition of a medical device in section 201(h) of the Federal Food, Drug, and Cosmetic Act are exempted from this definition.

Note: In October 2015, the U.S. Pipeline and Hazardous Materials Safety Administration issued an interim final rule, effective November 2015, that disallows several actions: carrying electronic smoking devices in checked baggage, carrying on board any associated batteries exceeding certain capacity limits, and charging electronic smoking devices or their batteries on board an aircraft. The rule applies to all battery-powered portable electronic smoking devices, such as e-cigarettes, e-cigs, e-cigars, e-pipes, e-hookahs, personal vaporizers, and electronic nicotine delivery systems.

EXCEPTION: If a foreign government objects to the prohibition of smoking during foreign air travel, the Secretary of Transportation shall negotiate an alternative.

Enforcement: The Secretary of Transportation shall prescribe regulations necessary to carry out this section.

PENALTY: Not specified.

13. YOUTH BUSES AND PUBLIC PARATRANSIT VEHICLES

California Vehicle Code Sections 336, 680, 12523(d)(2), 12523.5(d)(2), 13369(c)(3)

Scope: Drivers of a *youth bus* (a bus that is not a school bus but is used to transport children) may not smoke, including the use of electronic smoking devices, while operating the bus. Operators of *general public paratransit vehicles* (motor vehicles designed to carry no more than 24 persons that provide local transportation to the public, including transporting students who are at or below the 12th grade level to or from a public or private school or school activity) shall refrain from smoking.

Note: The workplace smoking restrictions in California Labor Code Section 6404.5 also apply (see entry 1).

Enforcement: The California Department of Motor Vehicles is authorized to enforce this law.

PENALTY: A violator may be subject to the denial, suspension, or revocation of a certificate to drive a youth bus or general paratransit vehicle.

14. ADOPTION OF LOCAL SECONDHAND SMOKE LAWS

California Health and Safety Code Section 118910

Scope: A local governing body may regulate or completely ban smoking, including the use of electronic smoking devices, in any manner not inconsistent with state law.

Note: Several state laws explicitly permit cities and counties to pass secondhand smoke laws that have stricter restrictions than those imposed by the state (see entries 1–3, 5–6, 8, and 11 for summaries of those state laws). Some cities and counties have passed local laws banning smoking in areas not covered by state law, including parks, beaches, outdoor dining areas, bus stops, and areas within 20 feet of commercial building entryways. These local laws are enforced by various local agencies and impose various penalties.

Enforcement: Not applicable.

PENALTY: Not applicable.

POSSESSION AND USE

15. STATE MENTAL HEALTH HOSPITALS

California Welfare and Institutions Code Sections 4138, 4139

Scope: Upon receiving a request from the director of a state mental hospital, the state Director of Mental Health may prohibit the possession and use of tobacco products on the grounds of the requesting facility following a phase-in period. The Director must provide an implementation plan to effectuate the prohibition, and must provide any requesting patient with smoking cessation information and assistance. At hospitals where possession and use of tobacco products are prohibited, the facility's store or canteen may not sell tobacco products. This law applies to California's 5 state mental hospitals: Atascadero State Hospital, Coalinga State Hospital, Metropolitan State Hospital, Napa State Hospital, and Patton State Hospital.

EXCEPTION: The prohibition shall not apply on the premises of residential staff housing where patients are not present. Also, departmentally approved religious ceremonies are exempt.

ENFORCEMENT: Not specified, but the state mental hospitals are under the jurisdiction of the Department of Mental Health.

PENALTY: In a state hospital where the possession of tobacco products by a patient has been prohibited by law or regulation, delivery of tobacco products to a patient or possession of tobacco with the intent to deliver to a patient is a misdemeanor, punishable by a fine not to exceed \$1,000 for each item. If a person visiting a patient in a state hospital is found with an item prohibited for patient possession, the item is subject to confiscation but must be returned on the same day unless the item is held as evidence.

16. YOUTH PURCHASE AND POSSESSION NO LONGER ILLEGAL

As of June 9, 2016, under California law it is no longer illegal for individuals of any age to purchase, receive, or possess any tobacco products or paraphernalia. However, California law prohibits **selling**, **giving**, **or in any way furnishing** tobacco products or paraphernalia, including electronic smoking devices, to any individual under the age of 21, or under the age of 18 for active military personnel with valid identification (for more information, see entries 25–26). See California Senate Bill X2-7, which enacted these changes, available at https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=201520162SB7.

Note: See entries 17–18 for summaries of tobacco possession and use restrictions relating to schools.

17. STUDENT POSSESSION AND USE

California Education Code Section 48901

Scope: No elementary or secondary school shall permit its students to smoke, including the use of electronic smoking devices, while the students are on campus, attending school-sponsored activities, or under the supervision and control of school district employees.

EXCEPTION: This provision does not prohibit students' use or possession of cessation or therapeutic products approved by the U.S. Food and Drug Administration.

Note: The workplace smoking restrictions in California Labor Code Section 6404.5 also apply to the enclosed areas of schools (see entry 1).

Note: See entry 7 for a summary of the laws prohibiting smoking that apply to schools.

Enforcement: Not specified except to say that the governing board of any school district maintaining a high school shall take all steps it deems practical to discourage high school students from smoking.

Note: A school may use its normal disciplinary powers to enforce no-tobacco-use rules against students.

PENALTY: Not specified.

California Education Code Sections 48900(h), 48900(s)

Scope: A student who possesses or uses tobacco products, or products containing tobacco or nicotine, may be suspended or expelled if the act is related to school activity or attendance (for instance, while on school grounds, while going to or returning from school or a school-sponsored activity, or during the on- or off-campus lunch period).

EXCEPTION: This provision does not prohibit students' use or possession of their own prescription products.

Enforcement: The superintendent or principal of the school is authorized to enforce this law.

PENALTY: The student may be suspended or expelled.

18. TOBACCO-FREE CAMPUS POLICIES

California Health and Safety Code Section 104420(n)(2)

Scope: Each school district, charter school, and county office of education that receives Proposition 99 tobacco control funding from the State of California must adopt and enforce a tobacco-free campus policy. The policy shall prohibit the use of tobacco products at all times in buildings owned or leased by a charter school or school district, on school or school district property, and in school or school district vehicles. Tobacco products may include, but are not limited to, smokeless tobacco, snuff, chew, clove cigarettes, and electronic cigarettes that can deliver nicotine and non-nicotine vaporized solutions. Under

the policy, signs stating Tobacco Use Is Prohibited shall be prominently displayed at all entrances to school property.

Note: See entry 7 for a summary of the laws prohibiting smoking that apply to schools.

Note: See entry 17 for a summary of the tobacco use and possession prohibitions that apply to students.

ENFORCEMENT: The California Department of Education monitors the school districts and county offices of education that receive Proposition 99 funding.

Note: A school may use its normal disciplinary powers to enforce no-tobacco-use rules against students, its general power over its property to enforce no-tobacco-use rules against visitors, and its general power over its terms of employment to enforce no-tobacco-use rules against employees.

PENALTY: Any school district, charter school, or county office of education that does not have a tobacco-free policy on July 1 of any given year is not eligible to apply for Proposition 99 funds for that fiscal year (see entry 92 for a summary of Proposition 99).

19. BASEBALL STADIUMS

California Health and Safety Code Section 118916

Scope: As of December 1, 2016, the use and possession of smokeless tobacco products are prohibited on a baseball stadium's playing field, including the dugout, bullpen, and team bench areas. A baseball stadium is any physical area in which a professional baseball game or practice is occurring in connection with Major League Baseball or minor league baseball. Local ordinances with more restrictive bans are allowed, and in the event that a local law conflicts with state law, the more restrictive ban shall control.

Enforcement: Not specified.

PENALTY: Not specified.

20. POSSESSION AND USE IN PRISONS

California Penal Code Section 5030.1 California Code of Regulations, Title 15, Sections 3006(c)(18), 3187–3189

Scope: The possession or use of any product that contains tobacco is prohibited by inmates under the jurisdiction of the California Department of Corrections and Rehabilitation. The possession or use of tobacco products is prohibited by anyone on the grounds of any facility under the jurisdiction of the California Department of Corrections and Rehabilitation. Tobacco products are considered to be contraband when possessed or used by inmates or by anyone in facilities where inmates are housed or detained.

Exception: Inmates may use tobacco products in departmentally approved religious ceremonies. A non-inmate may use tobacco products in certain residential staff housing

where inmates are not present. A non-inmate may possess tobacco products in a locked private vehicle for personal use off facility grounds. Tobacco cessation products such as a patch, inhaler, or lozenges are permitted for immediate personal use by staff.

Enforcement: California Department of Corrections and Rehabilitation officials are authorized to enforce this law.

PENALTY: Possession of tobacco products by inmates may result in disciplinary action and the confiscation of the tobacco products.

Note: A prison may use its general power over its property to enforce no-tobacco rules against visitors and its general power over its terms of employment to enforce no-tobacco rules against employees.

21. POSSESSION AND USE IN YOUTH CORRECTIONAL FACILITIES

California Welfare and Institutions Code Section 1712.5

Scope: The possession or use of tobacco products by wards and inmates in all institutions and camps under the jurisdiction of the Department of the Youth Authority is prohibited. The use of tobacco products by anyone on the grounds of any institution or facility under the jurisdiction of the Department of the Youth Authority is prohibited.

EXCEPTION: Inmates and wards may use tobacco products in departmentally approved religious ceremonies. Tobacco products may be used in residential staff housing where inmates or wards are not present.

Enforcement: Division of Juvenile Facilities officials are authorized to enforce this law.

PENALTY: Not specified.

Note: A facility may use its normal disciplinary powers to enforce no-tobacco rules against inmates and wards, its general power over its property to enforce no-tobacco rules against visitors, and its general power over its terms of employment to enforce no-tobacco rules against employees.

22. POSSESSION IN LOCAL CORRECTIONAL FACILITIES

California Penal Code Section 4575

Scope: The possession of any tobacco products in any form, or any device intended to be used for ingesting or consuming tobacco, by a person housed in a local correctional facility is prohibited if the local board of supervisors has adopted an ordinance or resolution banning tobacco products in its correctional institutions.

Note: See entry 20 for prohibitions and restrictions on tobacco use and possession in state prisons under the jurisdiction of the California Department of Corrections and Rehabilitation.

EXCEPTION: Possession of tobacco products is not prohibited in local correctional institutions in counties where the board of supervisors has not adopted an ordinance banning tobacco products in those facilities.

PENALTY: Violation of this section is an infraction, punishable by a fine not to exceed \$250.

23. USE IN FOOD SERVICE FACILITIES AND NONPROFIT TEMPORARY FOOD FACILITIES

California Health and Safety Code Sections 113953.3(a)(5), 113977, 113978, 114390, 114395, 114405

Scope: Food service employees may use any form of tobacco only in designated areas where contamination of food and equipment cannot result. Food service employees shall wash their hands after using tobacco. Owners, managers, and operators are responsible for violations by employees. Food facilities shall have a No Smoking sign posted in the food preparation, food storage, and dishwashing areas.

Note: The workplace smoking restrictions in California Labor Code Section 6404.5 also apply (see entry 1).

Enforcement: State and local environmental health services officials are authorized to enforce this law. Local law enforcement agencies have the general authority to enforce the misdemeanor penalty under California Penal Code Section 830.1.

PENALTY: Violators are guilty of a misdemeanor punishable by a fine of \$25 to \$1,000 and/or imprisonment for up to 6 months. A violator may be subject to the suspension or revocation of a permit to operate a food facility.

California Health and Safety Code Sections 113842, 114332.1, 114332.3(f), 114332.7, 114390, 114395, 114405

Scope: Smoking, including the use of electronic smoking devices, is prohibited in nonprofit charitable temporary food facilities. A nonprofit charitable temporary food facility is (1) a temporary food facility that is conducted by a nonprofit charitable organization, or (2) an established club or organization of students that operates under the authorization of a school or another type of educational facility.

Note: The workplace smoking restrictions in California Labor Code Section 6404.5 also apply to enclosed temporary food facilities that constitute places of employment (see entry 1).

Enforcement: Enforcement officers from the departments or local health agencies that have jurisdiction over these food facilities are authorized to enforce this law by performing inspections of, or requiring permits for, any nonprofit charitable temporary food facility to ensure compliance with this provision and the other food safety provisions in this chapter.

PENALTY: Violators are guilty of a misdemeanor punishable by a fine of \$25 to \$1,000 and/or imprisonment for up to 6 months. A violator may be subject to the suspension or revocation of any applicable permit to operate.

24. EMPLOYMENT AND OFF-DUTY USE

California Labor Code Sections 98.6, 98.7

Scope: It is illegal for an employer to discriminate against an employee or applicant on the basis of off-duty lawful conduct.

Note: This law could apply to legal, off-duty tobacco use.

EXCEPTION: An employer may discriminate against an applicant on the basis of off-duty lawful conduct if the conduct is actually in direct conflict with the essential enterprise-related interest of the employer and if the conduct is prohibited in an employment contract or collective bargaining agreement. An employer may discriminate on the basis of off-duty tobacco use against an applicant for a position as a firefighter. Local and state law enforcement agencies, certain media organizations, and religious associations may discriminate against employees and applicants on the basis of off-duty lawful conduct.

Enforcement: Anyone who believes that he or she has suffered discrimination in violation of the law may file a complaint with the Division of Labor Standards Enforcement of the California Department of Industrial Relations within 6 months of the alleged occurrence. In addition, under Labor Code Section 2699, an aggrieved individual may bring a civil action if the California Labor and Workforce Development Agency declines to act upon a complaint.

PENALTY: The Division of Labor Standards Enforcement shall order a violator to cease and desist from the violation and may order the violator to take any action deemed necessary to remedy the violation.

TOBACCO SALES

25. AGE-BASED SALES RESTRICTIONS: PENAL CODE 308

California Penal Code Section 308(a)-(d)

Scope: It is illegal for any person, firm, or corporation to sell, give, or in any way furnish to an individual under the age of 21 any tobacco products or paraphernalia, including electronic smoking devices, if that person, firm, or corporation knows or should otherwise have grounds to know that the recipient is under 21 years of age. This law may be enforced against a business owner or an employee who sold the tobacco product or paraphernalia. Penal Code Section 308(d) states that cities and counties may not adopt any ordinance or regulation that is inconsistent with this law.

EXCEPTION: It is legal for any person, firm, or corporation to sell, give, or furnish tobacco products or paraphernalia to active-duty military personnel who are 18 years of age or older. An identification card issued by the U.S. Armed Forces shall be used as proof of age for this purpose.

EXCEPTION: These restrictions do not include the sale of products approved by the U.S. Food and Drug Administration for sale as tobacco cessation products or as products that have other therapeutic purposes where the products are marketed and sold solely for such approved purposes.

EXCEPTION: A valid defense to an action under this law is proof that the person who sold or furnished the tobacco products or paraphernalia demanded, was shown, and reasonably relied upon evidence of legal age (such as a driver's license).

Enforcement: A city attorney, county counsel, or district attorney may bring a civil action to enforce the law. Local law enforcement agencies have the general authority to enforce this law under Penal Code Section 830.1.

Note: A local licensing law that suspends or revokes a license based on a violation of Penal Code Section 308 is not legally inconsistent with this law, and such local licensing laws are expressly permitted under California Business and Professions Code Section 22971.3 (see entry 98).

Note: Local law enforcement agencies do not need to use the STAKE Act protocol described in entry 26 when enforcing this law.

PENALTY: Violators are subject to a criminal action for misdemeanor or a civil action punishable by a fine of \$200 for a first offense, \$500 for a second offense, and \$1,000 for a third offense. Each individual franchise or location of a business is treated as a separate entity for purposes of determining liability for the second and subsequent violations of the law. The prosecuting agency receives 25% of penalties collected.

Note: A business may not be penalized for the same incident under both Penal Code Section 308 and the STAKE Act (see entry 26 for a summary of the STAKE Act age-based sales restrictions; see entry 100 for license-related penalties that attach to Section 308 violations).

Note: If an employee sells tobacco to an underage individual, the business owner can be penalized under the STAKE Act and the employee can be penalized under Penal Code Section 308. This is because the owner and employee are not legally the same violator (see entry 100 for license-related penalties that attach to STAKE Act violations).

Note: Underage individuals are no longer legally responsible for purchasing, receiving, or possessing tobacco products or paraphernalia (see entry 16).

26. AGE-BASED SALES RESTRICTIONS: THE STAKE ACT

California Business and Professions Code Sections 22952, 22957, 22958 (STAKE Act) California Code of Regulations, Title 17, Section 6903

Scope: It is illegal for any person, firm, or corporation to sell, give, or in any way furnish any tobacco products or paraphernalia, including electronic smoking devices, to an individual under the age of 21. This law may be enforced only against a business owner and not against an employee who sold the tobacco product or paraphernalia.

EXCEPTION: It is legal for any person, firm, or corporation to sell, give, or furnish tobacco products or paraphernalia to active-duty military personnel who are 18 years of age or older. An identification card issued by the U.S. Armed Forces shall be used as proof of age for this purpose.

EXCEPTION: These restrictions do not include the sale of products approved by the U.S. Food and Drug Administration for sale as tobacco cessation products or as products that have other therapeutic purposes where the products are marketed and sold solely for such approved purposes.

EXCEPTION: A valid defense to an action under this law is that a youth decoy's appearance was not that which could be generally expected of a person under 21 years of age, or that the undercover operation was not carried out in reasonable compliance with the detailed protocol specified in the law. Any failure on the part of the person under 21 years of age to provide true and correct identification, if verbally asked for it, is also a valid defense.

Enforcement: The STAKE Act may be enforced by any defined "enforcing agency," including the California Department of Public Health, Office of the Attorney General, and local law enforcement agencies. The law instructs enforcing agencies to use youth decoys in on-site inspections to determine whether retailers are making illegal sales of tobacco products. The law authorizes enforcing agencies to use youth decoys to investigate illegal sales to underage individuals by telephone, mail, or the internet.

An enforcing agency may conduct such inspections at random, in response to public complaints (eg, on the 1-800-5ASK-4-ID phone line), or at retail sites where violations have previously occurred. The law contains a detailed protocol for an enforcing agency to follow in its undercover operations (the STAKE Act protocol).

PENALTY: Violators are subject to a civil penalty of \$400 to \$600 for a first violation; \$900 to \$1,000 for a second violation within a 5-year period; \$1,200 to \$1,800 for a third violation

within a 5-year period; \$3,000 to \$4,000 for a fourth violation within a 5-year period; and \$5,000 to \$6,000 for a fifth or subsequent violation within a 5-year period.

Additional civil penalties in the amount of \$250 each for the third, fourth, and fifth violations are assessed by the State Board of Equalization (BOE) and deposited into the Cigarette and Tobacco Products Compliance Fund for the administration of these provisions. The BOE may also suspend or revoke the retailer's license with 10 days' notice (see entry 100 for license-related penalties that attach to STAKE Act violations).

A business owner may not be penalized for the same incident under both the STAKE Act and California Penal Code Section 308 (see entry 25 for a summary of Penal Code Section 308 prohibitions on sales to underage individuals).

Note: If an employee sells tobacco to an underage individual, the business owner can be penalized under the STAKE Act and the employee can be penalized under Penal Code Section 308. This is because the owner and employee are not legally the same violator (see entry 100 for license-related penalties that attach to STAKE Act violations).

27. SALES TO MINORS: THE TOBACCO CONTROL ACT

21 United States Code Sections 333, 372, 387a-1, 387f(d)

21 Code of Federal Regulations Sections 1100.3, 1140.14(a), (b)

Scope: It is illegal for any tobacco retailer to sell covered tobacco products to any person under the age of 18. As of August 8, 2016, this restriction includes cigarettes, smokeless tobacco, cigars, pipe tobacco, hookah tobacco, gels, dissolvables, and electronic nicotine delivery systems containing anything made or derived from tobacco (see the overview on page 7 for more information about recent updates to this definition under the deeming rule).

EXCEPTION: Tobacco products do not include articles that are drugs, devices, or combination products under the U.S. Food, Drug, and Cosmetic Act. 21 United States Code Sections 321(g) (1), 321(h), 353(g).

Enforcement: The U.S. Department of Health and Human Services (HHS) is authorized to enforce this provision with the help of other federal agencies and state governments. In California, HHS has contracted with the California Department of Public Health's Food and Drug Branch to enforce this provision.

PENALTY: Any person who violates this provision shall be subject to a civil penalty of up to \$15,000 for each violation and up to \$1 million for multiple violations ruled on in a single proceeding.

Retailers who violate this provision and have a training program in place that complies with standards developed by the FDA shall be subject to the following penalties, not to exceed:

- A warning letter for a first violation;
- \$250 for a second violation within a 12-month period;
- \$500 for a third violation within a 24-month period;

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- \$2,000 for a fourth violation within a 24-month period;
- \$5,000 for a fifth violation within a 36-month period; and
- \$10,000 for a sixth or subsequent violation within a 48-month period.

Retailers who violate this provision and do not have an approved training program in place shall be subject to civil penalties not to exceed:

- \$250 for a first violation;
- \$500 for a second violation within a 12-month period;
- \$1,000 for a third violation within a 24-month period;
- \$2,000 for a fourth violation within a 24-month period;
- \$5,000 for a fifth violation within a 36-month period; and
- \$10,000 for a sixth or subsequent violation within a 48-month period.

Note: In June 2014, the FDA updated its guidance regarding Tobacco Control Act penalties. The guidance discusses the procedures that apply if the FDA seeks civil money penalties and describes the amount of the penalties that the FDA may assess. If a retailer has "repeated violations" of the Tobacco Control Act, the FDA may impose a "no-tobacco-sale order" prohibiting the retailer from selling tobacco products for a specified period. The FDA interprets "repeated violation" to mean the following: a retailer incurs at least 5 violations of the Tobacco Control Act, each of the retailer's 5 violations represents the second or subsequent violation of a particular requirement, and each of the retailer's 5 violations occurs within a 36-month period. The FDA states that it generally does not intend to seek a civil money penalty or no-tobacco-sale order the first time an inspection identifies violations by a retailer; the FDA instead intends to send the retailer a warning letter after the first violation. *Guidance for FDA and Tobacco Retailers: Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers* (Revised) (June 2014), www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM252955.pdf.

At the time of publication, the FDA had not yet established standards for retailer training programs. Until the FDA establishes standards for retailer training programs, all retailers who violate this provision are treated as though they have an approved retailer training program in place. However, until the FDA establishes these standards, having a training program in place can nevertheless lead the FDA to further reduce the penalty for violations of the Tobacco Control Act. *Guidance for Industry: Tobacco Retailer Training Programs* (Revised) (June 2014), www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM218906.pdf.

28. SALES TO MINORS: THE SYNAR AMENDMENT

42 United States Code Section 300x-26 45 Code of Federal Regulations Section 96.130

Scope: In order to receive the annual Substance Abuse Prevention and Treatment federal block grant, a state must have and enforce a law prohibiting the sale of tobacco products to individuals under the age of 18. The state must conduct annual youth purchase surveys to ensure compliance with the law and must report the results of these inspections to the U.S. Department of Health and Human Services (HHS).

Note: California enacted the STAKE Act to comply with the Synar Amendment.

Enforcement: HHS is authorized to monitor states' compliance and to reduce the amount of the block grant upon noncompliance.

PENALTY: For a state that reports more than a 20% rate of illegal sales to youth, the annual Substance Abuse Prevention and Treatment federal block grant will be reduced by up to 40% of the amount originally allocated to the state, if the Secretary determines that the state is not in substantial compliance with the law.

29. ID CHECK REQUIREMENT: THE STAKE ACT

California Business and Professions Code Sections 22956, 22957 (STAKE Act)

Scope: Retailers must check the identification of purchasers of tobacco products, including electronic smoking devices, who reasonably appear to be under 21 years of age.

Enforcement: This requirement may be enforced by any "enforcing agency" authorized to enforce the STAKE Act, including the California Department of Public Health, California Attorney General's office, and local law enforcement agencies.

PENALTY: Not specified.

30. ID CHECK REQUIREMENT: THE TOBACCO CONTROL ACT

21 United States Code Sections 333, 372, 387a-1, 387f(d)

21 Code of Federal Regulations Sections 1100.3, 1140.14(a), (b)

Scope: Tobacco retailers must verify that a purchaser of any covered tobacco product is 18 years of age or older through a photo identification card containing the individual's date of birth. As of August 8, 2016, this requirement applies to sales of cigarettes, smokeless tobacco, cigars, pipe tobacco, hookah tobacco, gels, dissolvables, and electronic nicotine delivery systems containing anything made or derived from tobacco (for more information about products covered by the deeming rule, see the overview on page 7.

Note: See entry 29 for information about California's requirement to check the identification of purchasers who reasonably appear to be under 21 years of age.

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Exception: Verification is not required for any person over the age of 26.

Enforcement: The U.S. Department of Health and Human Services (HHS) is authorized to enforce this provision with the help of other federal agencies and state governments. In California, HHS has contracted with the California Department of Public Health's Food and Drug Branch to enforce this provision.

PENALTY: Any person who violates this provision shall be subject to a civil penalty of up to \$15,000 for each violation and up to \$1 million for multiple violations ruled on in a single proceeding.

Retailers who violate this provision and have a training program in place that complies with standards developed by the U.S. Food and Drug Administration (FDA) shall be subject to the following penalties, not to exceed:

- A warning letter for a first violation;
- \$250 for a second violation within a 12-month period;
- \$500 for a third violation within a 24-month period;
- \$2,000 for a fourth violation within a 24-month period;
- \$5,000 for a fifth violation within a 36-month period; and
- \$10,000 for a sixth or subsequent violation within a 48-month period.

Retailers who violate this provision and do not have an approved training program in place shall be subject to civil penalties not to exceed:

- \$250 for a first violation;
- \$500 for a second violation within a 12-month period;
- \$1,000 for a third violation within a 24-month period;
- \$2,000 for a fourth violation within a 24-month period;
- \$5,000 for a fifth violation within a 36-month period; and
- \$10,000 for a sixth or subsequent violation within a 48-month period.

Note: In June 2014, the FDA updated its guidance regarding Tobacco Control Act penalties. The guidance discusses the procedures that apply if the FDA seeks civil money penalties and describes the amount of the penalties that the FDA may assess. If a retailer has "repeated violations" of the Tobacco Control Act, the FDA may impose a "no-tobacco-sale order" prohibiting the retailer from selling tobacco products for a specified period. The FDA interprets "repeated violation" to mean the following: a retailer incurs at least 5 violations of the Tobacco Control Act, each of the retailer's 5 violations represents the second or subsequent violation of a particular requirement, and each of the retailer's 5 violations occurs within a 36-month period. The FDA states that it generally does not intend to seek a civil money penalty or no-tobacco-sale order the first time an inspection identifies violations by a retailer; the FDA instead intends to send the retailer a warning letter after the first violation. *Guidance*

for FDA and Tobacco Retailers: Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers (Revised) (June 2014), www.fda.gov/downloads/TobaccoProducts/ GuidanceComplianceRegulatoryInformation/UCM252955.pdf.

At the time of publication, the FDA had not yet established standards for retailer training programs. Until the FDA establishes standards for retailer training programs, all retailers who violate this provision are treated as though they have an approved retailer training program in place. However, until the FDA establishes these standards, having a training program in place can nevertheless lead the FDA to further reduce the penalty for violations of the Tobacco Control Act. Guidance for Industry: Tobacco Retailer Training Programs (Revised) (June 2014), www.fda.gov/downloads/TobaccoProducts/ GuidanceComplianceRegulatoryInformation/UCM218906.pdf.

31. SIGN POSTING REQUIREMENT: THE STAKE ACT

California Business and Professions Code Sections 22952(b), 22957, 22958(e) (STAKE Act) California Code of Regulations, Title 17, Section 6902(a) California Penal Code Section 308(b)

Scope: Every store that sells tobacco products, including electronic smoking devices, must post a boldly printed, contrasting-color sign in a conspicuous place at each point of purchase saying that tobacco products may not be sold to underage individuals.

The sign must contain the following words with initial letters capitalized in the following manner: "The Sale of Tobacco Products to Persons Under 21 Years of Age Is Prohibited by Law and Subject to Penalties. To Report an Unlawful Tobacco Sale Call 1-800-5 ASK-4-ID. U.S. Armed Forces active duty personnel with military ID must be at least 18 years of age. Valid Identification May Be Required. Business and Professions Code Section 22952." The sign must be square (at least 5.5 inches by 5.5 inches) or rectangular (at least 3.66 inches by 8.5 inches), and the required words must meet specified font sizes and typefaces.

Enforcement: This requirement may be enforced by any "enforcing agency" authorized to enforce the STAKE Act, including the California Department of Public Health, California Attorney General's office, and local law enforcement agencies.

PENALTY: The STAKE Act authorizes a \$200 civil fine for the first violation for failure to post the required signage, and a \$500 civil fine for each subsequent violation.

Under Penal Code Section 308(b), violators who fail to post the sign are subject to a fine of \$50 for a first offense, \$100 for a second offense, \$250 for a third offense, and \$500 for a fourth or subsequent offense, or by imprisonment for not more than 30 days.

A business owner may not be penalized for the same incident under both the STAKE Act and Penal Code Section 308 (see entry 100 for license-related penalties that attach to STAKE Act violations).

32. VENDING MACHINES: THE STAKE ACT

California Business and Professions Code Sections 22960, 22958, 22957 (STAKE Act)

Scope: Tobacco products, including electronic smoking devices, shall not be sold, offered for sale, or distributed from vending machines. This law may be enforced against a business owner only and not against an employee. A local government may also restrict or completely ban tobacco vending machines.

EXCEPTION: Vending machines may be located where an on-sale public premises license to sell alcoholic beverages (usually a bar) has been issued, provided that the machine is inside the premises and at least 15 feet away from the entrance.

Enforcement: This requirement may be enforced by any "enforcing agency" authorized to enforce the STAKE Act, including the California Department of Public Health, Attorney General's office, and local law enforcement agencies.

PENALTY: Violators are subject to a civil penalty of \$400 to \$600 for a first violation; \$900 to \$1,000 for a second violation within a 5-year period; \$1,200 to \$1,800 for a third violation within a 5-year period; \$3,000 to \$4,000 for a fourth violation within a 5-year period; and \$5,000 to \$6,000 for a fifth or subsequent violation within a 5-year period (see entry 25 for possible related penalties under Penal Code Section 308, and entry 100 for license-related penalties that attach to STAKE Act violations).

33. SELF-SERVICE DISPLAYS: THE STAKE ACT

California Business and Professions Code Sections 22958, 22960, 22962 (STAKE Act)

Scope: It is illegal to sell, offer for sale, or display any tobacco products or paraphernalia, including electronic smoking devices, through a self-service display, which is an open display of tobacco products or paraphernalia that is accessible to the public without the assistance of the clerk. This law may be enforced against a business owner only and not against an employee. The law allows local governments to pass and enforce laws that are stricter than state law.

EXCEPTION: Tobacco stores may make available by self-service display pipe tobacco, snuff, chewing tobacco, and dipping tobacco. However, only the following cigars are permitted for self-service display in tobacco stores:

- Single, unwrapped cigars;
- Single, individually wrapped cigars **only if** they are sold from the manufacturer's original box, bundle, or other container;
- Multiple cigars only if they are not in a sealed box, bundle, tin, or multiple-pack container; and
- Multiple cigars in sealed boxes, bundles, tins, or multiple-pack containers **only if** they contain at least 6 cigars.
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Aside from these exceptions, self-service displays of tobacco products and paraphernalia are not permitted in a tobacco store. A *tobacco store* is defined as a business that (1) primarily sells tobacco products; (2) generates more than 60% of its gross revenue annually from the sale of tobacco products and paraphernalia; (3) prohibits individuals under 18 years of age on the premises unless they are accompanied by a parent or guardian; and (4) does not sell alcohol or food for consumption on the premises.

Note: This law does not affect the state law allowing tobacco to be sold through vending machines in limited circumstances (see entry 32).

Enforcement: The state Attorney General, a city attorney, a county counsel, or a district attorney may bring a civil action to enforce this law.

PENALTY: Violators are subject to a civil penalty of \$400 to \$600 for a first violation; \$900 to \$1,000 for a second violation within a 5-year period; \$1,200 to \$1,800 for a third violation within a 5-year period; \$3,000 to \$4,000 for a fourth violation within a 5-year period; and \$5,000 to \$6,000 for a fifth or subsequent violation within a 5-year period (see entry 100 for license-related penalties that attach to STAKE Act violations).

34. SELF-SERVICE DISPLAYS: THE TOBACCO CONTROL ACT

21 United States Code Sections 333, 372, 387a-1, 387f(d) 21 Code of Federal Regulations Sections 1140.14(a), (b), 1140.16(c)

Scope: Cigarettes and smokeless tobacco may be sold only via a direct, face-to-face exchange. The use of vending machines and self-service displays is not permitted. As of August 8, 2016, the prohibition of sales from vending machines also includes cigars, pipe tobacco, hookah tobacco, gels, dissolvables, and electronic nicotine delivery systems containing anything made or derived from tobacco (for more information about these and other tobacco products newly covered by the deeming rule, see the overview on page 7.

EXCEPTION: Mail-order sales are permitted. (Mail-order redemption of coupons and distribution of free samples through the mail do not fall within the exception and are prohibited.) Vending machines and self-service displays are permitted in facilities where the retailer ensures that no person under the age of 18 is present or allowed to enter at any time.

Enforcement: The U.S. Department of Health and Human Services (HHS) is authorized to enforce this provision with the help of other federal agencies and state governments. In California, HHS has contracted with the California Department of Public Health's Food and Drug Branch to enforce this provision.

PENALTY: Any person who violates this provision shall be subject to a civil penalty of up to \$15,000 for each violation and up to \$1 million for multiple violations ruled on in a single proceeding.

Retailers who violate this provision and have a training program in place that complies with standards developed by the U.S. Food and Drug Administration (FDA) shall be subject to the following penalties, not to exceed:

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- A warning letter for a first violation;
- \$250 for a second violation within a 12-month period;
- \$500 for a third violation within a 24-month period;
- \$2,000 for a fourth violation within a 24-month period;
- \$5,000 for a fifth violation within a 36-month period; and
- \$10,000 for a sixth or subsequent violation within a 48-month period.

Retailers who violate this provision and do not have an approved training program in place shall be subject to civil penalties not to exceed:

- \$250 for a first violation:
- \$500 for a second violation within a 12-month period;
- \$1,000 for a third violation within a 24-month period;
- \$2,000 for a fourth violation within a 24-month period;
- \$5,000 for a fifth violation within a 36-month period; and
- \$10,000 for a sixth or subsequent violation within a 48-month period.

Note: In June 2014, the FDA updated its guidance regarding Tobacco Control Act penalties. The guidance discusses the procedures that apply if the FDA seeks civil money penalties and describes the amount of the penalties that the FDA may assess. If a retailer has "repeated violations" of the Tobacco Control Act, the FDA may impose a "no-tobacco-sale order" prohibiting the retailer from selling tobacco products for a specified period. The FDA interprets "repeated violation" to mean the following: a retailer incurs at least 5 violations of the Tobacco Control Act, each of the retailer's 5 violations represents the second or subsequent violation of a particular requirement, and each of the retailer's 5 violations occurs within a 36-month period. The FDA states that it generally does not intend to seek a civil money penalty or no-tobacco-sale order the first time an inspection identifies violations by a retailer; the FDA instead intends to send the retailer a warning letter after the first violation. *Guidance for FDA and Tobacco Retailers: Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers* (Revised) (June 2014), www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM252955.pdf.

At the time of publication, the FDA had not yet established standards for retailer training programs. Until the FDA establishes standards for retailer training programs, all retailers who violate this provision are treated as though they have an approved retailer training program in place. However, until the FDA establishes these standards, having a training program in place can nevertheless lead the FDA to further reduce the penalty for violations of the Tobacco Control Act. *Guidance for Industry: Tobacco Retailer Training Programs* (Revised) (June 2014), www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM218906.pdf.

35. BIDIS

California Penal Code Section 308.1

Scope: It is illegal to sell, offer to sell, distribute, or import bidis (also known as beedies), which are defined as products containing tobacco wrapped in temburni leaf or tendu leaf, or products that are marketed and sold as "bidis" or "beedies."

Note: Bidis are hand-rolled filterless cigarettes that are imported primarily from India and some Southeast Asian countries. They are available in a variety of candy-like flavors and often are sold in packs of fewer than 20, which makes them more affordable.

EXCEPTION: The law does not apply to businesses that legally prohibit individuals under 18 years of age on the premises.

Enforcement: The state Attorney General, a city attorney, a county counsel, or a district attorney may bring a civil action to enforce this law. Local law enforcement agencies have the general authority to enforce this law under Penal Code Section 830.1.

36. SINGLE CIGARETTES

California Penal Code Section 308.2

Scope: No person may sell 1 or more cigarettes, other than in a sealed and properly labeled package. A sealed and properly labeled package means the original packaging of the manufacturer or importer that meets federal labeling requirements.

Enforcement: Local law enforcement agencies have the general authority to enforce this law under Penal Code Section 830.1.

PENALTY: Violators are guilty of an infraction.

37. MINIMUM PACKAGE SIZE

California Penal Code Section 308.3

Scope: Cigarettes may not be manufactured, distributed, sold, or offered for sale in packages of fewer than 20 cigarettes. Roll-your-own tobacco may not be manufactured, distributed, sold, or offered for sale in a package containing less than 0.60 ounces of tobacco.

Enforcement: A civil action to enforce the law may be brought by the state Attorney General, a district attorney, a county counsel, or a city attorney. Local law enforcement agencies have the general authority to enforce this law under Penal Code Section 830.1.

PENALTY: Violators are liable for a civil penalty of \$200 for a first violation, \$500 for a second violation, and \$1,000 for each subsequent violation or are guilty of an infraction.

38. SINGLE ITEMS AND MINIMUM PACKAGE SIZE: THE TOBACCO CONTROL ACT

21 United States Code Sections 333, 372, 387a-1, 387f(d) 21 Code of Federal Regulations Sections 1100.3, 1140.14(a)(4), 1140.16(b)

Scope: Cigarettes may not be manufactured, sold, or distributed in packages containing fewer than 20 cigarettes. A tobacco retailer may not sell or distribute any quantity of cigarettes or smokeless tobacco that is smaller than the smallest package distributed by the manufacturer for individual consumer use.

Enforcement: The U.S. Department of Health and Human Services (HHS) is authorized to enforce this provision with the help of other federal agencies and state governments. In California, HHS has contracted with the California Department of Public Health's Food and Drug Branch to enforce the provisions that create obligations for tobacco retailers.

PENALTY: Any person who violates this provision shall be subject to a civil penalty of up to \$15,000 for each violation and up to \$1 million for multiple violations ruled on in a single proceeding.

Retailers who violate this provision and have a training program in place that complies with standards developed by the FDA shall be subject to the following penalties, not to exceed:

• A warning letter for a first violation;

\$250 for a second violation within a 12-month period;

- \$500 for a third violation within a 24-month period;
- \$2,000 for a fourth violation within a 24-month period;
- \$5,000 for a fifth violation within a 36-month period; and
- \$10,000 for a sixth or subsequent violation within a 48-month period.

Retailers who violate this provision and do not have an approved training program in place shall be subject to civil penalties not to exceed:

- \$250 for a first violation;
- \$500 for a second violation within a 12-month period;
- \$1,000 for a third violation within a 24-month period;
- \$2,000 for a fourth violation within a 24-month period;
- \$5,000 for a fifth violation within a 36-month period; and
- \$10,000 for a sixth or subsequent violation within a 48-month period.

Note: In June 2014, the FDA updated its guidance regarding Tobacco Control Act penalties. The guidance discusses the procedures that apply if the FDA seeks civil money penalties and describes the amount of the penalties that the FDA may assess. If a retailer has "repeated violations" of the Tobacco Control Act, the FDA may impose

a "no-tobacco-sale order" prohibiting the retailer from selling tobacco products for a specified period. The FDA interprets "repeated violation" to mean the following: a retailer incurs at least 5 violations of the Tobacco Control Act, each of the retailer's 5 violations represents the second or subsequent violation of a particular requirement, and each of the retailer's 5 violations occurs within a 36-month period. The FDA states that it generally does not intend to seek a civil money penalty or no-tobaccosale order the first time an inspection identifies violations by a retailer; the FDA instead intends to send the retailer a warning letter after the first violation. Guidance for FDA and Tobacco Retailers: Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers (Revised) (June 2014), www.fda.gov/downloads/TobaccoProducts/ GuidanceComplianceRegulatoryInformation/UCM252955.pdf.

At the time of publication, the FDA had not yet established standards for retailer training programs. Until the FDA establishes standards for retailer training programs, all retailers who violate this provision are treated as though they have an approved retailer training program in place. However, until the FDA establishes these standards, having a training program in place can nevertheless lead the FDA to further reduce the penalty for violations of the Tobacco Control Act. Guidance for Industry: Tobacco Retailer Training Programs (Revised) (June 2014), www.fda.gov/downloads/TobaccoProducts/ GuidanceComplianceRegulatoryInformation/UCM218906.pdf.

39. MAIL ORDER/INTERNET SALES: THE STAKE ACT

California Business and Professions Code Section 22963 (STAKE Act)

Scope: No person may sell, distribute, or engage in the *non-sale distribution* of tobacco products, including electronic smoking devices, to persons under 21 years of age via public or private postal services. The law includes directives designed to ensure that people who order tobacco products by mail, fax, phone, or the internet are 21 years of age or older. For example, distributors or sellers must either (1) match the name, address, and date of birth provided by the customer to information contained in a database of individuals verified to be 21 or older, or (2) require the customer to submit verification of age, including a copy of a valid form of government identification. The law establishes a 2-carton minimum on each order of cigarettes. It also mandates that all applicable purchases be made by personal check or credit card and that the distributor or seller call purchasers to confirm their orders.

Non-sale distribution is defined as giving smokeless to bacco or cigarettes to the general public at no cost, or at nominal cost, or to give coupons, coupon offers, gift certificates, gift cards, or other similar offers, or rebate offers for smokeless tobacco or cigarettes to the general public at no cost or at nominal cost. Distribution of tobacco products, coupons, coupon offers, gift certificates, gift cards, or other similar offers, or rebate offers in connection with the sale of another item, including tobacco products, cigarette lighters, magazines, or newspapers shall not constitute non-sale distribution.

EXCEPTION: The U.S. Postal Service and other common carriers are exempt from penalties when they deliver a package without any reason to know the package's contents.

ENFORCEMENT: A district attorney, city attorney, or the state Attorney General may assess civil penalties against any person or entity that violates this law.

PENALTY: Violators who make prohibited sales or distributions are liable for a civil penalty of \$1,000 to \$2,000 for a first violation; \$2,500 to \$3,500 for a second violation; \$4,000 to \$5,000 for a third violation within a 5-year period; \$5,500 to \$6,500 for a fourth violation within a 5-year period; and \$10,000 for a fifth or subsequent violation within a 5-year period.

40. MAIL ORDER/INTERNET SALES: THE PACT ACT

15 United States Code Sections 375, 376, 377 18 United States Code Section 1716E

Scope: The Prevent All Cigarette Trafficking Act (the PACT Act) prohibits the delivery of sales of cigarettes (including roll-your-own tobacco) and smokeless tobacco via the U.S. Postal Service. Other common carriers (eg, UPS, FedEx) may deliver a package containing cigarettes or smokeless tobacco if the package weighs less than 10 pounds and bears stamps and signs verifying that all appropriate local, state, and federal taxes have been paid. Upon delivery, the age and identity of the buyer must be confirmed, and the recipient must be of minimum legal age to purchase tobacco products.

EXCEPTION: The U.S. Postal Service restrictions do not apply to sales shipments that begin and end entirely within Alaska or Hawaii and to certain APO/FPO military addresses. Infrequent, lightweight shipments can still be sent via U.S. mail by age-verified adults as long as certain restrictions are met. Additional exceptions apply for authorized business/regulatory purposes, as well as for consumer testing and public health purposes.

Enforcement: The U.S. Postal Service provision is enforced by the Postmaster General with the cooperation of any other federal agency or agency of any state, local, or tribal government, whenever appropriate. The common carrier provisions are enforced by the U.S. Attorney General, state attorneys general, and state tobacco tax administrators.

PENALTY: Violators are subject to criminal penalties of up to 3 years imprisonment. Retailers who violate the law are also subject to civil penalties in an amount not to exceed the greater of \$5,000 for a first violation and \$10,000 for a subsequent violation, or 2% of their gross sales of cigarettes or smokeless tobacco during the 1-year period ending on the date of the violation. Common carriers or other delivery services that knowingly violate the new law are subject to civil penalties in an amount not to exceed \$2,500 for a first violation and \$5,000 for any violation within 1 year of a prior violation.

Any person found delivering cigarettes or smokeless tobacco through the U.S. Postal Service is subject to an additional civil penalty in the amount equal to 10 times the retail value of the non-mailable cigarettes or smokeless tobacco, including all federal, state, and local taxes. Any cigarette or smokeless tobacco that is deposited in the mail shall be subject to seizure

and forfeiture. Any tobacco products seized and forfeited under this subsection shall be destroyed or retained by the federal government for the detection or prosecution of crimes or related investigations and then destroyed.

41. MAIL ORDER/INTERNET SALES: THE TOBACCO CONTROL ACT

21 United States Code Sections 333, 372, 387f(d)

21 Code of Federal Regulations Section 1100.3

Scope: The Tobacco Control Act directed the U.S. Department of Health and Human Services (HHS) to issue regulations regarding the remote sale and distribution of tobacco products, such as via the internet or mail order, by December 22, 2010. The Tobacco Control Act also directed HHS to issue regulations regarding the promotion and marketing of tobacco products sold or distributed remotely by June 22, 2011.

Note: In March 2010, Congress enacted the Prevent All Cigarette Trafficking (PACT) Act of 2009, which regulates the remote sale and distribution of cigarettes (including roll-your-own tobacco) and smokeless tobacco via the internet or mail order, and made a new HHS regulation largely unnecessary. Specifically, the PACT Act largely prohibits the U.S. Postal Service from shipping cigarettes (including roll-your-own tobacco) and smokeless tobacco (see entry 40 for additional information on the PACT Act).

In September 2011, the FDA issued an advance notice of proposed rulemaking and requested comments, data, research, or other information related to non–face-to-face sale and distribution of tobacco products; the advertising, promotion, and marketing of such products; and the advertising of tobacco products via the internet, email, direct mail, telephone, smart phones, and other communication technologies that can be directed to specific recipients. 76 Fed. Reg. 55,835 (Sept. 9, 2011).

Enforcement: HHS is authorized to enforce the regulations it issues under this provision with the help of other federal agencies and state governments.

PENALTY: At the time of publication, regulations had not yet been issued by the FDA. Once regulations go into effect, the following penalties will apply:

Any person who violates this provision shall be subject to a civil penalty of up to \$15,000 for each violation and up to \$1 million for multiple violations ruled on in a single proceeding.

Retailers who violate this provision and have a training program in place that complies with standards developed by the FDA shall be subject to the following penalties, not to exceed:

- A warning letter for a first violation;
- \$250 for a second violation within a 12-month period;
- \$500 for a third violation within a 24-month period;
- \$2,000 for a fourth violation within a 24-month period;
- \$5,000 for a fifth violation within a 36-month period; and

• \$10,000 for a sixth or subsequent violation within a 48-month period.

Retailers who violate this provision and do not have an approved training program in place shall be subject to civil penalties not to exceed:

- \$250 for a first violation;
- \$500 for a second violation within a 12-month period;
- \$1,000 for a third violation within a 24-month period;
- \$2,000 for a fourth violation within a 24-month period;
- \$5,000 for a fifth violation within a 36-month period; and
- \$10,000 for a sixth or subsequent violation within a 48-month period.

Note: In June 2014, the FDA updated its guidance regarding Tobacco Control Act penalties. The guidance discusses the procedures that apply if the FDA seeks civil money penalties and describes the amount of the penalties that the FDA may assess. If a retailer has "repeated violations" of the Tobacco Control Act, the FDA may impose a "no-tobacco-sale order" prohibiting the retailer from selling tobacco products for a specified period. The FDA interprets "repeated violation" to mean the following: a retailer incurs at least 5 violations of the Tobacco Control Act, each of the retailer's 5 violations represents the second or subsequent violation of a particular requirement, and each of the retailer's 5 violations occurs within a 36-month period. The FDA states that it generally does not intend to seek a civil money penalty or no-tobacco-sale order the first time an inspection identifies violations by a retailer; the FDA instead intends to send the retailer a warning letter after the first violation. *Guidance for FDA and Tobacco Retailers: Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers* (Revised) (June 2014), www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM252955.pdf.

At the time of publication, the FDA had not yet established standards for retailer training programs. Until the FDA establishes standards for retailer training programs, all retailers who violate this provision are treated as though they have an approved retailer training program in place. However, until the FDA establishes these standards, having a training program in place can nevertheless lead the FDA to further reduce the penalty for violations of the Tobacco Control Act. *Guidance for Industry: Tobacco Retailer Training Programs* (Revised) (June 2014), www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM218906.pdf.

42. HOME DELIVERY OF UNSOLICITED TOBACCO PRODUCTS

California Penal Code Section 308b

Scope: It is illegal for a person to knowingly deliver or cause to be delivered any unsolicited tobacco products to any residence in California (see entry 76 for more information on mailing unsolicited samples of smokeless tobacco products).

EXCEPTION: It is a defense to a violation of this section that the sender personally knows the recipient of the tobacco products at the time of the delivery. The law does not impose liability on any U.S. Postal Service employee for actions performed in the scope of his or her employment.

ENFORCEMENT: Local law enforcement agencies have the general authority to enforce this law under Penal Code Section 830.1.

PENALTY: Violators are guilty of a misdemeanor, and violations constitute a nuisance within the meaning of California Civil Code Section 3479.

43. FIRE SAFE CIGARETTES

California Health and Safety Code Sections 14950-14960

Scope: It is illegal to sell, offer to sell, or possess for sale cigarettes unless they meet fire safety standards modeled on standards currently in place in New York. Specifically, manufacturers must certify to the state Fire Marshal that their cigarettes have been tested in accordance with standards established by the American Society of Testing and Materials, and that no more than 25% of the cigarettes tested in a test trial exhibited full-length burns. Manufacturers shall mark the packaging and case of cigarettes in compliance with this law.

EXCEPTION: Distributors, wholesalers, or retailers may sell their existing inventory of cigarettes after January 1, 2007, if certain conditions are met.

Enforcement: The state Attorney General may bring a civil action to enforce the law. Any law enforcement agency may seize cigarettes sold, offered for sale, or possessed for sale in violation of the law.

PENALTY: Manufacturers or others who knowingly sell or offer cigarettes in violation of these provisions other than through retail sale are subject to a civil penalty of up to \$10,000 for each sale. Retailers, distributors and wholesalers who knowingly sell cigarettes in violation of these provisions are subject to a civil penalty of up to \$500 for each sale of up to 50 packages of cigarettes and a civil penalty of up to \$1,000 for each sale of more than 50 packages of cigarettes. Cigarettes that are sold in violation of these provisions are subject to seizure.

44. LIQUID NICOTINE PACKAGING REQUIREMENTS

California Health and Safety Code Section 119406 16 Code of Federal Regulations Sections 1700.20

Scope: As of October 1, 2016, all cartridges for electronic cigarettes and solutions for filling or refilling an electronic cigarette shall be in child-resistant packaging, according to federal child-resistant packaging standards and testing procedures.

Enforcement: Not specified.

PENALTY: Not specified.

15 United States Code Section 1472a

16 Code of Federal Regulations Sections 1700.15 et seq.

Scope: As of July 26, 2016, the Child Nicotine Poisoning Prevention Act of 2015 subjects liquid nicotine to existing packaging and testing requirements found in the federal Poison Prevention Packaging Standards. These standards apply to liquid nicotine of any type that is sold, offered for sale, manufactured for sale, distributed in commerce, or imported into the United States. Requirements include child-resistant packaging and restricted flow rates for containers.

EXCEPTION: The Act does not include sealed, prefilled, and disposable liquid nicotine containers that are inserted directly into electronic cigarettes, electronic nicotine delivery systems, or similar products, so long as the nicotine in the container is inaccessible through customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion or other contact by children.

Note: The Child Nicotine Poisoning Prevention Act is not intended to limit or otherwise affect the authority of the Secretary of Health and Human Services to regulate, issue guidance on, or take action regarding any nicotine-related products. The Act is not intended to limit or affect the U.S. Food and Drug Administration's (FDA) advance notice of proposed rulemaking concerning packaging requirements for liquid nicotine, nicotine-containing e-liquid(s), and other tobacco products (see entry 88 for information about the notice). The Act also specifically states that the FDA's deeming rule is not affected by the Act (see the overview on page 7 for information). The Child Nicotine Poisoning Prevention Act makes it clear that the FDA can move forward with these and other regulations regarding the manufacture, marketing, sale, distribution, importation, or packaging of nicotine-related products.

ENFORCEMENT: The U.S. Consumer Product Safety Commission is authorized to enforce this provision with the help of other federal agencies.

Penalty: Not specified.

45. NON-NICOTINE PRODUCT IN A VAPOR STATE

California Health and Safety Code Section 24600

Scope: It is illegal to sell anyone under 18 years of age any device intended to deliver by inhalation a non-nicotine product in a vapor state.

EXCEPTION: This provision exempts drug or medical devices approved by the U.S. Food and Drug Administration.

Enforcement: Local law enforcement agencies have the general authority to enforce this law under California Penal Code Section 830.1.

PENALTY: Violators are guilty of an infraction and subject to a fine of up to \$500 for a first violation; up to \$1,000 for a second violation; and up to \$1,500 for a third or subsequent violation.

46. TOBACCO PRODUCT STANDARDS: THE TOBACCO CONTROL ACT

21 United States Code Sections 333, 372, 387g

21 Code of Federal Regulations Section 1100.3

Scope: The U.S. Department of Health and Human Services (HHS) may establish tobacco product standards for the protection of public health. Tobacco manufacturers may no longer use tobacco that contains an unsafe level of pesticide chemical residue, as determined by federal law.

Enforcement: HHS is authorized to enforce this provision with the help of other federal agencies and state governments.

PENALTY: Any person who violates this provision shall be subject to a civil penalty of up to \$15,000 for each violation and up to \$1 million for multiple violations ruled on in a single proceeding.

Manufacturers who intentionally misrepresent that they meet tobacco product standards may be subject to civil penalties of up to \$250,000 for each violation and up to \$1 million for multiple violations ruled on in a single proceeding. If violations continue after HHS provides written notice of violation, the violator is subject to a penalty of \$250,000 for the first 30-day period, which doubles every 30 days thereafter that the violation continues, up to \$1 million in any 30 day period or \$10 million for all such violations ruled on in a single proceeding.

47. PREMARKET REVIEW OF NEW TOBACCO PRODUCTS: THE TOBACCO CONTROL ACT

21 United States Code Sections 333, 372, 387e, 387j

21 Code of Federal Regulations Sections 25.35, 25.50, 25.52

21 Code of Federal Regulations Section 1100.3

Scope: Tobacco products or modified tobacco products not commercially marketed in the United States as of February 15, 2007, must be approved by the U.S. Food and Drug Administration (FDA) prior to commercial release. Manufacturers and importers of newly-deemed finished tobacco products—such as electronic nicotine delivery systems and cigars—that entered the market between February 15, 2007, and August 8, 2016, must submit an application for premarket review by August 8, 2018. Newly-deemed finished tobacco products that enter the market after August 8, 2016, must obtain premarket review and authorization prior to commercial release (see the overview on page 7 for more information about the FDA's deeming rule).

Applications for new products shall be made available to the public. Approval may be withdrawn as information changes and new findings are made.

For all products on the market as of August 8, 2016, products will be given a compliance extension of 1 year if their applications have been submitted by the required deadlines but they have not been refused for submission or denied approval by the FDA. After this

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extension period, any products that have not been authorized will be subject to enforcement measures. Products entering the market after August 8, 2016, do not receive this extension and may be subject to enforcement measures if they are marketed without authorization.

Note: The FDA has released guidance on the procedures and the types of evidence necessary to establish that a product was commercially marketed in the United States before February 15, 2007. *Guidance for Industry: Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007* (Sept. 2014), www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM416498.pdf.

EXCEPTION: A new or modified tobacco product may be exempted from this requirement if the U.S. Department of Health and Human Services (HHS) Secretary issues an order stating that the

- 1. Substantially equivalent to a tobacco product commercially marketed in the United States as of February 15, 2007 ("substantially equivalent"); and
- 2. Otherwise in compliance with the law.

A modified tobacco product may be exempted from this requirement if the Secretary determines that:

- 1. The modification would be a minor modification of a tobacco product that can be legally sold; and
- 2. A report is not necessary to ensure that allowing the tobacco product to be marketed would be appropriate for protection of public health.

A tobacco product that was first introduced into the commercial market between February 15, 2007, and March 22, 2011, may be exempted from this requirement if the manufacturer submitted a report during that period claiming that the product was substantially equivalent to a tobacco product commercially marketed before February 15, 2007, and if the Secretary did not issue an order to the contrary. Manufacturers and importers of newly-deemed finished tobacco products—such as electronic nicotine delivery systems and cigars—that entered the market between February 15, 2007, and August 8, 2016, must submit any request for a substantial equivalence exemption by August 8, 2017, and any application for a substantial equivalence finding by February 8, 2018 (see the overview on page 7 for more information about the FDA's deeming rule).

If an order is issued finding that a product is not substantially equivalent to another, the product is considered adulterated and misbranded. The FDA has indicated that it will take no enforcement action for at least the first 30 days after it issues such an order for products that are in a retailer's current inventory at a specific retail location on the date the order is issued. *Guidance for Industry and Tobacco Retailers: Enforcement Policy for Certain (Provisional) Tobacco Products that FDA Finds Not Substantially Equivalent* (Sept. 2015), www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM386629.pdf.

Note: At the time of publication, this guidance has been challenged in federal court and partially vacated. *Philip Morris USA, Inc., et al. v. United States Food & Drug Admin.*, No.

15-CV-1590 (APM), 2016 WL 4378970 (D.D.C. Aug. 16, 2016). The guidance states that modifying a tobacco product's label or changing the quantity of products in each package could constitute a new tobacco product, necessitating substantial equivalence review. The court held that changes to a product label do not create a new tobacco product, and vacated that portion of the guidance.

Note: Many of the government actions described in this section are subject to an October 2015 FDA regulation exempting them from certain requirements under the National Environmental Policy Act (NEPA) and the Council on Environmental Quality regulations. Issuance of orders for the following actions are "categorically excluded," and therefore normally do not require preparation of an Environmental Assessment or an Environmental Impact Statement (reports required by NEPA before the government undertakes certain activities):

- Finding a tobacco product "substantially equivalent" or not;
- Denying a request for exemption, or rescinding an order granting exemption, from the requirement to demonstrate substantial equivalence;
- Prohibiting a new tobacco product or a modified risk tobacco product from being introduced into interstate commerce; and
- Rescinding or suspending an order "authorizing the marketing of a new tobacco product" or a modified risk tobacco product.

Enforcement: HHS is authorized to enforce this provision with the help of other federal agencies and state governments.

PENALTY: Civil penalty of up to \$250,000 for each violation and up to \$1 million for multiple violations ruled on in a single proceeding. If violations continue after HHS provides written notice, the violator is subject to a penalty of \$250,000 for the first 30-day period, which doubles every 30 days thereafter that the violation continues, up to \$1 million in any 30-day period or \$10 million for all such violations ruled on in a single proceeding.

48. ADULTERATED AND MISBRANDED TOBACCO PRODUCTS: THE TOBACCO CONTROL ACT

21 United States Code Sections 333, 372, 387b, 387c, 387e, 387f 21 Code of Federal Regulations Sections 1100.3, 1143.3, 1143.5

Scope: A tobacco product is deemed to be adulterated if (1) it is subject to a tobacco product standard but is in any respect out of compliance with such standard, (2) it fails to obtain any required premarket review order, or (3) it violates any modified risk provisions. A tobacco product is deemed to be misbranded if it is manufactured or prepared in an unregistered establishment, or if it is sold in violation of any other federal regulations governing the sale and distribution of tobacco products. A tobacco product is also misbranded if its labeling is false or misleading, or if the package label does not contain all of the following:

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- 1. The name and address of the manufacturer, packer, or distributor;
- 2. An accurate net quantity statement;
- 3. The percentage of tobacco that is foreign versus domestic; and
- 4. The statement "sale only allowed in the United States."

The U.S. Department of Health and Human Services (HHS) may issue regulations requiring prior approval of statements made on the label of a tobacco product.

These provisions also apply to newly deemed tobacco products, such as cigars, pipe tobacco, hookah tobacco, gels, dissolvables, and electronic nicotine delivery systems containing anything made or derived from tobacco (for more information about these and other tobacco products newly covered by the deeming rule, see the overview on page 7).

Note: As of May 10, 2018, it is also illegal to sell tobacco products whose packaging and advertisements do not contain applicable warning labels under the FDA's deeming rule (see entries 84 and 87–88 for required warnings for tobacco products newly covered by the deeming rule).

EXCEPTION: Under this provision, HHS shall establish regulations to permit "reasonable variations" and exemptions for "small packages." For example, the required warning label provisions of the deeming rule include certain exceptions for small packages (see the overview on page 7 for more information about the deeming rule; see entries 84 and 87–88 for required warnings for tobacco products covered by the deeming rule).

Enforcement: HHS is authorized to enforce this provision with the help of other federal agencies and state governments.

PENALTY: Any person who violates this provision shall be subject to a civil penalty of up to \$15,000 for each violation and up to \$1 million for multiple violations ruled on in a single proceeding. Intentional violations of certain provisions may result in higher or compounded penalties.

49. MODIFIED RISK TOBACCO PRODUCTS: THE TOBACCO CONTROL ACT

21 United States Code Sections 333, 372, 387k 21 Code of Federal Regulations Section 1100.3

Scope: No person may introduce a "modified risk" tobacco product into interstate commerce or commercially market such a product without approval from the U.S. Department of Health and Human Services (HHS). As of August 8, 2016, this requirement applies to cigars, "modified risk" electronic nicotine delivery systems containing anything made or derived from tobacco, and other newly deemed tobacco products (see the overview on page 7 for more information about the deeming rule). Approval is limited to a 5-year term but may be renewed. The agency shall approve a modified risk tobacco product only after determining that the product, as it is actually used by consumers, (1) significantly reduces harm and the

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risk of tobacco-related disease to individual tobacco users, and (2) benefits the health of the population as a whole.

Approval is conditioned on the applicant's agreement to conduct post-market surveillance and studies and to submit the results to HHS annually so that the agency may determine the impact of such marketing on consumer perception, behavior, and health. HHS may also impose additional marketing and label restrictions. Approval may be withdrawn if requirements are not met.

Note: This provision in the Tobacco Control Act, among others, was challenged in federal court and upheld. *Discount Tobacco City & Lottery v. United States*, 674 F.3d 509 (6th Cir. 2012), *cert. denied*, 133 S.Ct. 1996 (2013). The lawsuit alleged that the modified risk provision improperly regulated speech and violated the First Amendment.

Note: In September 2015, the FDA proposed a rule to clarify when products are regulated as drugs, devices, or combination products under the Federal Food, Drug, and Cosmetic Act, versus when products are regulated as modified risk tobacco products (MRTPs). The proposed rule clarifies that drugs, devices, or combination products are intended to be used to actively combat or treat disease or other health conditions, whereas MRTPs are products that present relatively less risk of harm than other product. The proposed rule also includes the FDA's regulation of products under its drugs and devices jurisdiction when manufacturers intend products made or derived from tobacco to be used to affect the structure or function of the body in some manner that is not related to the effects of nicotine commonly and legally claimed prior to March 21, 2000. Examples of claims requiring a product to be regulated as a drug or device include products marketed to "relieve tension" or "promote weight loss." The proposed rule is available at www. federalregister.gov/articles/2015/09/25/2015-24313/clarification-of-when-products-made-or-derived-from-tobacco-are-regulated-as-drugs-devices-or#h-19.

EXCEPTION: In some cases a modified risk tobacco product can be introduced into interstate commerce and yet may not be commercially marketed.

Enforcement: HHS is authorized to enforce this provision with the help of other federal agencies and state governments.

PENALTY: Civil penalty for intentionally purporting to meet tobacco product standards of up to \$250,000 for each violation and up to \$1 million for multiple violations ruled on in a single proceeding. If violations continue after the agency provides written notice, the violator is subject to a penalty of \$250,000 for the first 30-day period, which doubles every 30 days thereafter that the violation continues, up to \$1 million in any 30-day period or \$10 million for all such violations ruled on in a single proceeding.

50. "LIGHT," "LOW," AND "MILD" TOBACCO PRODUCTS: THE TOBACCO CONTROL ACT

21 United States Code Sections 333, 372, 387k 21 Code of Federal Regulations Section 1100.3

Scope: Descriptors similar to and including "light," "low," and "mild" are prohibited in all advertising, labeling, and marketing of cigarettes and smokeless tobacco products manufactured on or later than June 22, 2010. As of August 8, 2017, this prohibition applies to the manufacture of all newly deemed tobacco products, including cigars, pipe tobacco, hookah tobacco, gels, dissolvables, and electronic nicotine delivery systems containing anything made or derived from tobacco. Newly deemed tobacco products with these prohibited descriptors can no longer be distributed into interstate commerce beginning September 8, 2017 (see the overview on page 7 for more information about the deeming rule).

Note: This provision in the Tobacco Control Act, among others, was challenged in federal court and upheld. *Discount Tobacco City & Lottery v. United States*, 674 F.3d 509 (6th Cir. 2012), *cert. denied*, 133 S.Ct. 1996 (2013). The lawsuit alleged that the prohibition on the use of the terms, "low," "light," and "mild," improperly regulated speech and violated the First Amendment.

Enforcement: The U.S. Department of Health and Human Services is authorized to enforce this provision with the help of other federal agencies and state governments.

PENALTY: Civil penalty for intentionally purporting to meet tobacco product standards of up to \$250,000 for each violation and up to \$1 million for multiple violations ruled on in a single proceeding. If violations continue after the agency provides written notice, the violator is subject to a penalty of \$250,000 for the first 30-day period, which doubles every 30 days thereafter that the violation continues, up to \$1 million in any 30-day period or \$10 million for all such violations ruled on in a single proceeding.

51. BAN ON FLAVORED CIGARETTES OR CIGARETTE COMPONENTS: THE TOBACCO CONTROL ACT

21 United States Code Sections 333, 372, 387g

Scope: Cigarettes and their component parts (including the tobacco, filter, or paper) must not contain any artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke. The Secretary of the U.S. Department of Health and Human Services (HHS) has the authority to ban menthol or any artificial or natural flavor, herb, or spice not specified in this list.

EXCEPTION: Tobacco flavor and menthol are excluded from this provision. This provision does not apply to tobacco products other than cigarettes.

Note: Two federal circuit courts of appeal have held that local governments may enact laws restricting the sale of flavored non-cigarette tobacco products, such as cigars and chewing tobacco. *See United States Smokeless Tobacco Mfr. Co. v. City of New York*, 708 F.3d 428 (2d Cir. 2013); *Nat'l Ass'n of Tobacco Outlets, Inc. v. City of Providence*, 731 F.3d 71 (1st Cir. 2013). A federal district court similarly dismissed a challenge to Chicago's flavored tobacco sales restriction (which prohibits the sale of flavored tobacco, including menthol cigarettes, within 500 feet of any elementary, middle, or secondary school). *Indeps. Gas & Serv. Stations Associations, Inc. v. City of Chicago*, 112 F. Supp. 3d 749, 753 (N.D. Ill. 2015). These courts found that local laws were not preempted by the federal Tobacco Control Act. These decisions are not binding in California but can be influential, and they signal that courts may be more likely to uphold similar laws in other jurisdictions.

Note: The Tobacco Control Act required the U.S. Food and Drug Administration (FDA) Tobacco Products Scientific Advisory Committee (TPSAC) (see entry 119) to submit a report and recommendation to the Secretary on the public health impacts of the use of menthol in cigarettes, including use among children, African Americans, Hispanics, and other racial and ethnic minorities. The TPSAC submitted its report and recommendations to the FDA in March 2011. On July 24, 2013, the FDA issued an advance notice of proposed rulemaking (ANPR) to solicit public input on menthol in cigarettes. The docket for the ANPR is available at www.regulations.gov/#!documentDetail;D=FDA-2013-N-0521-0001.

Enforcement: HHS is authorized to enforce this provision with the help of other federal agencies and state governments.

PENALTY: Any person who violates this provision shall be subject to a civil penalty of up to \$15,000 for each violation and up to \$1 million for multiple violations ruled on in a single proceeding.

52. ORIGIN LABELING: THE TOBACCO CONTROL ACT

21 United States Code Sections 333, 372, 387t 21 Code of Federal Regulations Section 1100.3

Scope: All tobacco products must bear the statement "sale only allowed in the United States" on all labels, packaging, and shipping containers. This requirement went into effect on July 22, 2010, for non-cigarette tobacco products (or tobacco products other than cigarettes). The Tobacco Control Act stipulated that this requirement will become effective for cigarettes 15 months after the U.S. Department of Health and Human Services (HHS) issues cigarette label and advertising regulations.

As of May 10, 2018, the U.S. Food and Drug Administration (FDA) requires this statement for all newly deemed tobacco products in package form, including cigars, pipe tobacco, hookah tobacco, gels, dissolvables, and electronic nicotine delivery systems containing anything made or derived from tobacco (see the overview on page 7 for more information about the FDA's deeming rule).

Note: The graphic warning labels proposed by the FDA were ruled unconstitutional and were not in effect at the time of publication. *RJ Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205 (D.C. Cir. 2012). In March 2013, the FDA decided not to appeal the D.C. Circuit Court of Appeals ruling to the U.S. Supreme Court. Instead, it decided to redesign the warning labels—a process that is currently underway. At the time of publication, the FDA was not enforcing the new warning label requirements and related provisions, including the origin labeling requirement. The FDA had not indicated its timeline for proposing new warning labels.

Enforcement: HHS is authorized to enforce this provision with the help of other federal agencies and state governments.

PENALTY: Any person who violates this provision shall be subject to a civil penalty of up to \$15,000 for each violation and up to \$1 million for multiple violations ruled on in a single proceeding.

ADVERTISING

53. OUTDOOR ADVERTISING: THE MSA

Master Settlement Agreement (MSA) Sections II(ii), II(xx), III(c), III(d), VII(c) Smokeless Tobacco Master Settlement Agreement (STMSA) Sections II(dd), II(rr), III(c), III(d), VII(c)

Scope: Under the MSA and STMSA, the settling tobacco companies are prohibited from engaging in *outdoor advertising* of tobacco products, defined as (1) billboards; (2) signs and placards in arenas, stadiums, shopping malls, and video game arcades; and (3) any other tobacco advertisements that are outdoors, or on the inside surface of a window but facing outward.

EXCEPTION: The MSA and STMSA do not restrict:

- Advertisements that are 14 square feet or smaller, and are either outside a tobacco retail store but on store property, or on the window of a tobacco retail store facing outward;
- Advertisements inside a tobacco retail store that are not placed on a window facing outward;
- Advertisements located inside an adult-only facility (where the operator ensures that no minors are present);
- Outside Advertisements at the site of an adult-only facility advertising the event with a brand name for the duration of the event, and no more than 14 days before the event;
- Billboards advertising a tobacco brand-sponsored event at the site of the event for 90 days before the initial sponsored event and 10 days after the last sponsored event; or
- Advertisements outside a tobacco manufacturing facility.

Enforcement: The state Attorney General (AG) is authorized to enforce these provisions. Suspected violations can be reported to the AG by calling (916) 565-6486 or by completing an online complaint form at http://caag.state.ca.us/tobacco/contact.htm.

PENALTY: The AG may seek a court order to enforce these provisions or stop a violation of the provisions. If such an order is violated, the AG may pursue monetary compensation, civil contempt charges, or criminal sanctions. The parties must first attempt to resolve alleged violations through discussion.

54. OUTDOOR ADVERTISING: THE STAKE ACT

California Business and Professions Code Sections 22957, 22958, 22961 (STAKE Act)

Scope: No advertising of tobacco products, including electronic smoking devices, on any outdoor billboard located within 1,000 feet of any public or private elementary, junior high, or high school, or public playground.

Note: This law currently is not being enforced and partially overlaps with the limits on outdoor advertising in the Master Settlement Agreement and Smokeless Tobacco Master Settlement Agreement. Moreover, inasmuch as the law applies to cigarettes, it may be preempted by federal law in light of the U.S. Supreme Court decision in *Lorillard Tobacco Co. v. Reilly* (see entry 56 for more information about this decision). *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001).

EXCEPTION: This law does not prohibit a message or advertisement opposing the use of tobacco products.

Enforcement: The Attorney General, a city attorney, a county counsel, or a district attorney may bring a civil action to enforce this section.

PENALTY: Violators are subject civil penalties according to Section 22958(d).

55. OUTDOOR ADVERTISING: THE TOBACCO CONTROL ACT

21 United States Code Sections 333, 372, 387a-1, 387f(d)

21 Code of Federal Regulations Section 1100.3

Scope: The Tobacco Control Act directed the U.S. Food and Drug Administration (FDA) to issue a rule regulating outdoor advertising for tobacco products by June 22, 2010. The FDA was instructed to consider any necessary modifications to its proposed 1996 rule prohibiting advertising (ie, billboards, posters, placards) within 1,000 feet of any public playground or playground areas on public property (eg, swings, seesaws, baseball diamonds, basketball courts, public schools).

Note: In March 2010, the FDA issued an advance notice of proposed rulemaking and request for comments. 75 Fed. Reg. 13,241 (Mar. 19, 2010). At the time of publication, the FDA had not yet issued rules about outdoor advertising.

Note: This provision in the Tobacco Control Act, among others, was challenged in federal court. The federal district court neither upheld nor struck down the provision, instead ruling that the issue was not properly before the court (ie, the issue was not ripe because the FDA had not yet issued an outdoor advertising rule). *Commonwealth Brands, Inc. v. United States*, 678 F.Supp.2d 512 (W.D.Ky. 2010), *overruled in part on other grounds by Discount Tobacco City & Lottery v. United States*, 674 F.3d 509 (6th Cir. 2012), *cert. denied*, 133 S.Ct. 1996 (2013).

Enforcement: The U.S. Department of Health and Human Services is authorized to enforce this provision with the help of other federal agencies and state governments.

PENALTY: Any person who violates this provision shall be subject to a civil penalty of up to \$15,000 for each violation and up to \$1 million for multiple violations ruled on in a single proceeding.

56. FEDERAL PREEMPTION OF STATE AND LOCAL REGULATION OF CIGARETTE AND SMOKELESS TOBACCO ADVERTISING AND PROMOTION

15 United States Code Sections 1331-1341, 4401-4408

Scope: The Federal Cigarette Labeling and Advertising Act (FCLAA) establishes a comprehensive federal program governing cigarette labeling and advertising (for a summary of the FCLAA's warning label requirements and its ban on television advertising, see entries 83 and 65, respectively). In sections 1334(b) and (c), the FCLAA also contains a preemption clause that prohibits most state and local laws and regulations from imposing any requirements or prohibitions based on smoking and health with respect to the advertising or promotion of cigarettes. Permissible state and local laws and regulations must constitute "specific bans or restrictions on the time, place, and manner, but not content, of the advertising or promotion of any cigarettes." Similarly, the Comprehensive Smokeless Tobacco Health Education Act (CSTHEA) establishes a federal program governing smokeless tobacco labeling and advertising. In section 4406, the CSTHEA also contains a preemption clause that prohibits state and local laws and regulations from requiring any statements relating to the use of smokeless tobacco products and health on any package or advertisement of a smokeless tobacco product (unless the advertisement is an outdoor billboard advertisement).

Note: In the 1990s, tobacco companies sued various state and local governments for passing laws that allegedly imposed requirements or prohibitions based on smoking and health with respect to the advertising or promotion of cigarettes. In *Lorillard Tobacco Co. v. Reilly,* 533 U.S. 525 (2001), the U.S. Supreme Court struck down a Massachusetts regulation banning cigarette advertising within 1,000 feet of schools because it found that the state regulation was preempted by the FCLAA. Note that this case preceded the FCLAA provision allowing state and local governments to implement time, place, and manner restrictions on cigarette advertising and promotion.

Note: The FCLAA applies only to cigarettes. It does not preempt state and local governments from passing laws on the basis of smoking and health that regulate the advertising or promotion of other tobacco products (eg, cigars, etc.). However, the First Amendment of the U.S. Constitution remains an important consideration regarding the legality of any such law.

Note: The preemption provision of the FCLAA does not apply to the Master Settlement Agreement (MSA) because the MSA is not a state law but instead is a contract to which the tobacco companies have voluntarily agreed to be bound.

Note: In 2012, a federal court of appeals held that the FCLAA preempted a New York City law requiring tobacco retailers to display signs bearing graphic images showing the adverse health effects of smoking. *23-34 9th St. Grocery Corp. v. N.Y.C. Bd. of Health*, 685 F.3d 174 (2d Cir. 2012). The court concluded that requiring graphic warnings to be placed

adjacent to product displays impermissibly affected cigarette makers' promotions at retail sites. Although this decision is not binding in California, the case may serve as guidance for California courts examining similar issues. By contrast, a different federal court of appeals held that the FCLAA did not preempt a Providence, RI law that prohibits tobacco retailers from accepting or redeeming coupons and multipack discounts for any tobacco products or cigarettes. *Nat'l Ass'n of Tobacco Outlets, Inc. v. City of Providence,* 731 F.3d 71 (1st Cir. 2013). The court also held that the law did not conflict with the First Amendment rights of tobacco manufacturers or distributors because it did not prohibit these parties from disseminating coupons or multipack offers.

Following the ruling upholding Providence's law, in November 2013 New York City adopted a similar law that prohibits tobacco retailers from accepting or redeeming coupons and multipack discounts for any tobacco products or cigarettes. This law also withstood a challenge in federal court, on similar preemption and First Amendment grounds as the First Circuit case. *Nat'l Ass'n of Tobacco Outlets, Inc. v. City of New York*, 27 F.Supp.3d 415 (S.D.N.Y. 2014). New York City's law also set minimum retail prices for the sale of cigarettes, cigars, and little cigars, but this action was not at issue in the case.

Note: The CSTHEA applies only to smokeless tobacco products that contain cut, ground, powdered, or leaf tobacco and are intended to be placed in the oral or nasal cavity. It does not preempt state and local governments from passing laws on the basis of smoking and health that regulate the advertising or promotion of other tobacco products (eg, cigars, etc.). However, the First Amendment of the U.S. Constitution remains an important consideration regarding the legality of any such law.

Enforcement: Aggrieved private parties (eg, tobacco companies or retailers) may bring a civil action against state or local governments in court.

PENALTY: A court will invalidate a law that it finds to be preempted by the FCLAA or CSTHEA.

57. STOREFRONT ADVERTISING

California Business and Professions Code Sections 25612.5(c)(7), 25617, 25619 (Known informally as the Lee Law)

Scope: No more than 33% of the square footage of windows and clear (eg, glass) doors of an alcohol retailer may have advertising signs of any sort, including tobacco.

Note: This law is not preempted by the Federal Cigarette Labeling and Advertising Act or the Comprehensive Smokeless Tobacco Health Education Act (see entry 56) because it applies generally to advertising of all types, not specifically to advertising of cigarettes or smokeless tobacco.

EXCEPTION: The law applies only to retailers with an off-sale premises license to sell alcoholic beverages.

Enforcement: This law may be enforced by the California Department of Alcoholic Beverage Control and by local law enforcement agencies.

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PENALTY: Violators are guilty of a misdemeanor punishable by a fine of up to \$1,000 and/or imprisonment for up to 6 months.

Note: An officer who refuses or neglects to diligently prosecute persons whom they have reasonable cause to believe have violated this provision is guilty of a misdemeanor under Section 25619.

58. BLUNT WRAPS ADVERTISING

California Business and Professions Code Sections 22958(a), 22962 (STAKE Act) California Penal Code Section 308

Scope: No person or business may place advertising for blunt wraps lower than 4 feet above the floor. No person or business offering blunt wraps for sale may place blunt wrap advertising within 2 feet of a candy, snack, or nonalcoholic beverage display. This law may be enforced against a business owner only and not against an employee.

Note: *Blunt wraps* are defined as cigar papers or cigar wrappers that are designed for smoking or ingestion of tobacco products and contain less than 50% tobacco.

Enforcement: The state Attorney General, a city attorney, a county counsel, or a district attorney may bring a civil action to enforce this law.

PENALTY: Violators are subject to a civil penalty of \$400 to \$600 for a first violation; \$900 to \$1,000 for a second violation within a 5-year period; \$1,200 to \$1,800 for a third violation within a 5-year period; \$3,000 to \$4,000 for a fourth violation within a 5-year period; and \$5,000 to \$6,000 for a fifth or subsequent violation within a 5-year period.

Violations by one retail location are not counted against other retail locations of the same corporation or business. Violations against a prior owner of a single franchise location are not counted against a new owner of the same single franchise location (see entry 100 for license-related penalties that attach to STAKE Act violations).

59. STATE BUILDING ADVERTISING

California Government Code Section 19994.35

Scope: No advertising for any product containing tobacco shall be allowed in any building owned and occupied by the state.

EXCEPTION: This law does not apply to tobacco advertising contained in a program, leaflet, newspaper, magazine, or other written material lawfully sold, brought, or distributed within a state building.

Enforcement: Not specified.

PENALTY: Not specified.

60. TRANSIT ADVERTISING

Master Settlement Agreement Sections II(xx), III(c)(3)(E), III(d), VII(c)Smokeless Tobacco Master Settlement Agreement Sections II(rr), III(c)(3)(E), III(d), VII(c)

Scope: The settling tobacco companies are prohibited from placing tobacco *transit* advertisements, defined as advertisements on or within private or public vehicles, and placed at, on, or within a bus stop, taxi stand, transportation waiting area, train station, airport, or similar location.

EXCEPTION: This prohibition does not apply to advertisements inside an adult-only facility (where the operator ensures that no minors are present and that the advertisements are not visible to persons outside the facility) or to outside advertisements on the site of an adult-only facility advertising a brand-sponsored event, no more than 14 days before the event, or to vehicles bearing a tobacco brand name used in a brand-sponsored event.

Enforcement: The state Attorney General (AG) is authorized to enforce these provisions. Suspected violations can be reported to the AG by calling (916) 565-6486 or by completing an online complaint form at http://caag.state.ca.us/tobacco/contact.htm.

PENALTY: The AG may seek a court order to enforce these provisions or stop a violation of the provisions. If such an order is violated, the AG may pursue monetary compensation, civil contempt charges, or criminal sanctions. The parties must first attempt to resolve alleged violations through discussion.

61. CARTOON CHARACTERS

Master Settlement Agreement Sections II(I), III(b), VII(c) Smokeless Tobacco Master Settlement Agreement Sections II(j), III(b), VII(c)

Scope: The settling tobacco companies are prohibited from using cartoons in tobacco advertising, promoting, labeling, and packaging.

Enforcement: The state Attorney General (AG) is authorized to enforce these provisions. Suspected violations can be reported to the AG by calling (916) 565-6486 or by completing an online complaint form at http://caag.state.ca.us/tobacco/contact.htm.

PENALTY: The AG may seek a court order to enforce these provisions or stop a violation of the provisions. If such an order is violated, the AG may pursue monetary compensation, civil contempt charges, or criminal sanctions. The parties must first attempt to resolve alleged violations through discussion.

62. YOUTH TARGETING

Master Settlement Agreement Sections III(a), VII(c) Smokeless Tobacco Master Settlement Agreement Sections III(a), VII(c)

Scope: The settling tobacco companies are prohibited from directly or indirectly targeting youth in tobacco advertising, promotion, and marketing, and from taking any action the primary purpose of which is to initiate, maintain, or increase the incidence of youth smoking.

Enforcement: The state Attorney General (AG) is authorized to enforce these provisions. Suspected violations can be reported to the AG by calling (916) 565-6486 or by completing an online complaint form at http://caag.state.ca.us/tobacco/contact.htm.

PENALTY: The AG may seek a court order to enforce these provisions or stop a violation of the provisions. If such an order is violated, the AG may pursue monetary compensation, civil contempt charges, or criminal sanctions. The parties must first attempt to resolve alleged violations through discussion.

63. VIDEO GAMES

California Penal Code Section 308.5

Scope: This law prohibits paid commercial advertising for alcohol and tobacco products in video games intended for either private use or use in a public establishment, and intended primarily for use by any person under the age of 18 years. Paid commercial advertising includes, for example, containers or packaging, product brand names, trademarks, or copyrighted slogans.

ENFORCEMENT: Local law enforcement agencies have the general authority to enforce this law under Penal Code Section 830.1.

PENALTY: Violators are guilty of a misdemeanor.

64. TELEVISION/RADIO CIGARETTE ADVERTISING

15 United States Code Sections 1335, 1338, 1339

Scope: This law prohibits advertising cigarettes or little cigars (defined by weight) on any medium of electronic communication subject to the jurisdiction of the U.S. Federal Communications Commission (FCC) (such as television and radio).

EXCEPTION: This law does not apply to regular size cigars.

ENFORCEMENT: The U.S. Attorney General may seek an injunction in federal court against violators to prevent future violations of this law.

Note: Information on filing complaints to the FCC is located on the FCC's website: www.fcc.gov/complaints.

PENALTY: Violators are guilty of a misdemeanor punishable by a fine of not more than \$10.000.

65. TELEVISION/RADIO SMOKELESS TOBACCO ADVERTISING

15 United States Code Sections 4402, 4404, 4405

Scope: This law prohibits advertising smokeless tobacco on any medium of electronic communication subject to the jurisdiction of the U.S. Federal Communications Commission (FCC) (such as television and radio).

ENFORCEMENT: The U.S. Attorney General may seek an injunction in federal court against violators to prevent future violations of this law.

Note: Information on filing complaints to the FCC is located on the FCC's website: www.fcc.gov/complaints.

PENALTY: Violators are guilty of a misdemeanor punishable by a fine of not more than \$10,000.

66. BAN ON MISLEADING CONSUMERS ABOUT U.S. FOOD AND DRUG ADMINISTRATION (FDA) ENDORSEMENTS: THE TOBACCO CONTROL ACT

21 United States Code Sections 331(tt), 333, 372

Scope: It is illegal to make any express or implied statement to consumers in tobacco product labeling or through the media or advertising that would mislead consumers into believing that a tobacco product is:

- 1. Approved by the FDA;
- 2. Endorsed by the FDA;
- 3. Deemed safe by the FDA; or
- 4. Less harmful due to FDA regulation.

Note: This provision in the Tobacco Control Act, among others, was challenged in federal court and upheld. *Discount Tobacco City & Lottery v. United States*, 674 F.3d 509 (6th Cir. 2012), *cert. denied*, 133 S.Ct. 1996 (2013). The lawsuit alleged that the ban on misleading consumers about FDA endorsements improperly regulated speech and violated the First Amendment.

Enforcement: The U.S. Department of Health and Human Services (HHS) is authorized to enforce this provision with the help of other federal agencies and state governments.

PENALTY: Any person who violates this provision shall be subject to a civil penalty of up to \$15,000 for each violation and up to \$1 million for multiple violations ruled on in a single proceeding.

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67. CONTENT DISCLOSURES TO THE PUBLIC: THE TOBACCO CONTROL ACT

21 United States Code Sections 387d, 387n 15 United States Code Sections 1333, 1336, 1338, 1339

Scope: The U.S. Department of Health and Human Services (HHS) will determine whether tar and nicotine yields of cigarette and tobacco products must be disclosed on all product packages and advertisements. If HHS decides that the levels of any other cigarette or tobacco constituents should be disclosed to benefit the public health, the disclosure may be required through a product package or advertisement insert, or by another approved means.

EXCEPTION: Mandatory disclosures of yields of cigarette or tobacco constituents, other than tar or nicotine, cannot appear directly on the face of any cigarette package or advertisement.

Enforcement: The U.S. Attorney General is authorized to enforce this provision, acting through several U.S. attorneys. A violation is also considered an unfair or deceptive act or practice and subject to enforcement under the Federal Trade Commission Act.

Note: In April 2012, the FDA issued a notice establishing a list of tobacco product constituents that the agency believes are harmful or potentially harmful to health. The notice includes the criteria the FDA used to develop the list and the reasons the FDA may add or remove constituents from the list. 77 Fed. Reg. 20,034 (Apr. 3, 2012). The FDA has also issued guidance on the meaning of "harmful and potentially harmful constituents" in the context of the list requirements. "Harmful and Potentially Harmful Constituents" in Tobacco Products as Used in Section 904(e) of the Federal Food, Drug, and Cosmetic Act: Guidance for Industry and FDA Staff (revised) (August 2016), www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM241352.pdf.

PENALTY: A violation is considered a misdemeanor, and a conviction will subject the violator to a fine of \$10,000 or less.

68. PERMISSIBLE FORMS OF LABELING AND ADVERTISING: THE TOBACCO CONTROL ACT

21 United States Code Sections 333, 372, 387a-1, 387f(d)

21 Code of Federal Regulations Section 1140.30(a)

Scope: A manufacturer, distributor, or retailer must notify the U.S. Food and Drug Administration (FDA) 30 days in advance if it seeks to advertise cigarettes or smokeless tobacco in a medium other than: in periodicals or other publications; on billboards, posters, and placards; or in promotional material such as direct mail or point-of-sale material, including audio or video presented at the point of sale. The notice to the FDA must discuss the extent to which the advertising or labeling may be seen by people under the age of 18.

Enforcement: The U.S. Department of Health and Human Services is authorized to enforce this provision with the help of other federal agencies and state governments.

PENALTY: Any person who violates this provision shall be subject to a civil penalty of up to \$15,000 for each violation and up to \$1 million for multiple violations ruled on in a single proceeding.

Retailers who violate this provision and have a training program in place that complies with standards developed by the FDA shall be subject to the following penalties, not to exceed:

- A warning letter for a first violation;
- \$250 for a second violation within a 12-month period;
- \$500 for a third violation within a 24-month period;
- \$2,000 for a fourth violation within a 24-month period;
- \$5,000 for a fifth violation within a 36-month period; and
- \$10,000 for a sixth or subsequent violation within a 48-month period.

Retailers who violate this provision and do not have an approved training program in place shall be subject to civil penalties not to exceed:

- \$250 for a first violation;
- \$500 for a second violation within a 12-month period;
- \$1,000 for a third violation within a 24-month period;
- \$2,000 for a fourth violation within a 24-month period;
- \$5,000 for a fifth violation within a 36-month period; and
- \$10,000 for a sixth or subsequent violation within a 48-month period.

Note: In June 2014, the FDA updated its guidance regarding Tobacco Control Act penalties. The guidance discusses the procedures that apply if the FDA seeks civil money penalties and describes the amount of the penalties that the FDA may assess. If a retailer has "repeated violations" of the Tobacco Control Act, the FDA may impose a "no-tobacco-sale order" prohibiting the retailer from selling tobacco products for a specified period. The FDA interprets "repeated violation" to mean the following: a retailer incurs at least 5 violations of the Tobacco Control Act, each of the retailer's 5 violations represents the second or subsequent violation of a particular requirement, and each of the retailer's 5 violations occurs within a 36-month period. The FDA states that it generally does not intend to seek a civil money penalty or no-tobacco-sale order the first time an inspection identifies violations by a retailer; the FDA instead intends to send the retailer a warning letter after the first violation. *Guidance for FDA and Tobacco Retailers: Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers* (Revised) (June 2014), www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM252955.pdf.

At the time of publication, the FDA had not yet established standards for retailer training programs. Until the FDA establishes standards for retailer training programs, all retailers who violate this provision are treated as though they have an approved retailer training program in place. However, until the FDA establishes these standards,

having a training program in place can nevertheless lead the FDA to further reduce the penalty for violations of the Tobacco Control Act. *Guidance for Industry: Tobacco Retailer Training Programs* (Revised) (June 2014), www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM218906.pdf.

69. EQUAL TREATMENT OF RETAIL OUTLETS: THE TOBACCO CONTROL ACT

21 United States Code Sections 333, 372, 387m

Scope: The U.S. Department of Health and Human Services (HHS) must issue rules requiring that retail establishments whose primary business is the sale of tobacco products must comply with all advertising restrictions that apply to retail establishments accessible to people under 18 years of age.

Note: This provision ensures that tobacco stores are subject to the same advertising restrictions as other retailers, such as supermarkets and convenience stores.

Enforcement: HHS is authorized to enforce this provision with the help of other federal agencies and state governments.

PENALTY: Any person who violates this provision shall be subject to a civil penalty of up to \$15,000 for each violation and up to \$1 million for multiple violations ruled on in a single proceeding.

SPONSORSHIP, BRANDING, AND SAMPLING

70. SPONSORSHIP: THE MSA

Master Settlement Agreement (MSA) Sections II(j), III(c), VII(c)
Smokeless Tobacco Master Settlement Agreement (STMSA) Sections II(h), III(c), VII(c)

Scope: Under the MSA and STMSA, each settling tobacco company may engage in only 1 brand name sponsorship in any 12-month period. A national or multistate series or tour (eg, Skoal Racing) will count as 1 brand name sponsorship. The MSA and STMSA prohibit brand name sponsorship of events in which the intended audience is comprised of a significant percentage of youth (*significant percentage* is not defined); events in which paid contestants are under the age of 18; concerts; and football, basketball, soccer, baseball, or hockey games.

The MSA and STMSA prohibit naming a stadium or arena with a brand name and prohibit tobacco companies from paying football, basketball, baseball, soccer, or hockey leagues in exchange for use of a brand name.

EXCEPTION: The MSA and STMSA exempt the following sponsorship activities:

- Events at adult-only facilities (where minors are not present and cannot see inside);
- Vehicles bearing a brand name used in a brand-sponsored event;
- Billboards for the brand-sponsored event at the site of the event for 90 days before and 10 days after the event; and
- Corporate name sponsorship.

Note: The corporate name sponsorship exception allows sponsorship in the name of the parent company (eg, Altria) but not in the name of the brand (eg, Marlboro).

Enforcement: The state Attorney General (AG) is authorized to enforce these provisions. Suspected violations can be reported to the AG by calling (916) 565-6486 or by completing an online complaint form at http://ag.ca.gov/tobacco/contact.php.

PENALTY: The AG may seek a court order to enforce these provisions or stop a violation of the provisions. If such an order is violated, the AG may pursue monetary compensation, civil contempt charges, or criminal sanctions. The parties must first attempt to resolve alleged violations through discussion.

71. SPONSORSHIP: THE TOBACCO CONTROL ACT

21 United States Code Sections 333, 372, 387a-1, 387f(d) 21 Code of Federal Regulations Section 1140.34(c)

SCOPE: Manufacturers, distributors, or retailers may not directly or indirectly sponsor any athletic, social, or cultural event, or any entry or team in any event, in the brand name, logo, symbol, motto, selling message, recognizable color or pattern of colors, or anything identifiable with any brand of cigarettes or smokeless tobacco.

Note: This provision in the Tobacco Control Act, among others, was challenged in federal court and upheld. *Discount Tobacco City & Lottery v. United States*, 674 F.3d 509 (6th Cir. 2012), *cert. denied*, 133 S.Ct. 1996 (2013). The lawsuit alleged that the prohibition on tobacco sponsorships improperly regulated speech and violated the First Amendment.

EXCEPTION: Manufacturers, distributors, or retailers are allowed to sponsor events in the name of the corporation that manufactures the tobacco product if: (1) both the corporate name and the corporation were registered and in use in the United States prior to January 1, 1995; and (2) the corporate name does not include anything identifiable with any brand of cigarettes or smokeless tobacco.

ENFORCEMENT: The U.S. Department of Health and Human Services is authorized to enforce this provision with the help of other federal agencies and state governments.

PENALTY: Any person who violates this provision shall be subject to a civil penalty of up to \$15,000 for each violation and up to \$1 million for multiple violations ruled on in a single proceeding.

Retailers who violate this provision and have a training program in place that complies with standards developed by the U.S. Food and Drug Administration (FDA) shall be subject to the following penalties, not to exceed:

- A warning letter for a first violation;
- \$250 for a second violation within a 12-month period;
- \$500 for a third violation within a 24-month period;
- \$2,000 for a fourth violation within a 24-month period;
- \$5,000 for a fifth violation within a 36-month period; and
- \$10,000 for a sixth or subsequent violation within a 48-month period.

Retailers who violate this provision and do not have an approved training program in place shall be subject to civil penalties not to exceed:

- \$250 for a first violation.
- \$500 for a second violation within a 12-month period;
- \$1,000 for a third violation within a 24-month period;
- \$2,000 for a fourth violation within a 24-month period;
- \$5,000 for a fifth violation within a 36-month period; and
- \$10,000 for a sixth or subsequent violation within a 48-month period.

Note: In June 2014, the FDA updated its guidance regarding Tobacco Control Act penalties. The guidance discusses the procedures that apply if the FDA seeks civil money penalties and describes the amount of the penalties that the FDA may assess. If a retailer has "repeated violations" of the Tobacco Control Act, the FDA may impose a "no-tobacco-sale order" prohibiting the retailer from selling tobacco products for a specified period. The FDA interprets "repeated violation" to mean the following: a

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retailer incurs at least 5 violations of the Tobacco Control Act, each of the retailer's 5 violations represents the second or subsequent violation of a particular requirement, and each of the retailer's 5 violations occurs within a 36-month period. The FDA states that it generally does not intend to seek a civil money penalty or no-tobaccosale order the first time an inspection identifies violations by a retailer; the FDA instead intends to send the retailer a warning letter after the first violation. *Guidance for FDA and Tobacco Retailers: Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers* (Revised) (June 2014), www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM252955.pdf.

At the time of publication, the FDA had not yet established standards for retailer training programs. Until the FDA establishes standards for retailer training programs, all retailers who violate this provision are treated as though they have an approved retailer training program in place. However, until the FDA establishes these standards, having a training program in place can nevertheless lead the FDA to further reduce the penalty for violations of the Tobacco Control Act. *Guidance for Industry: Tobacco Retailer Training Programs* (Revised) (June 2014), www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM218906.pdf.

72. BRAND NAME MERCHANDISE

Master Settlement Agreement Sections III(f), III(c)(3)(C), VII(c)
Smokeless Tobacco Master Settlement Agreement Sections III(f), III(c)(3)(D), VII(c)

Scope: The settling tobacco companies are prohibited from selling or distributing apparel (eg, hats, T-shirts) or other merchandise that bears a tobacco product brand name.

EXCEPTION: These provisions do not apply to apparel or other merchandise distributed or sold by a third party at the site of a brand name sponsorship, under limited circumstances. These provisions do not apply to coupons or other items used by adults solely in connection with the purchase of tobacco products; and do not apply to apparel or other merchandise used within an adult-only facility that is not distributed (by sale or otherwise) to any member of the general public.

Enforcement: The state Attorney General (AG) is authorized to enforce these provisions. Suspected violations can be reported to the AG by calling (916) 565-6486 or by completing an online complaint form at http://caag.state.ca.us/tobacco/contact.htm.

PENALTY: The AG may seek a court order to enforce these provisions or stop a violation of the provisions. If such an order is violated, the AG may pursue monetary compensation, civil contempt charges, or criminal sanctions. The parties must first attempt to resolve alleged violations through discussion.

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73. BRAND NAME LIMITATIONS

Master Settlement Agreement Sections III(j), VII(c)
Smokeless Tobacco Master Settlement Agreement Sections III(j), VII(c)

Scope: Brands of the settling tobacco companies may not be named after any nationally recognized brand or trade name of a non-tobacco product or any nationally recognized sports team, entertainment group, or celebrity.

Enforcement: The state Attorney General (AG) is authorized to enforce these provisions. Suspected violations can be reported to the AG by calling (916) 565-6486 or by completing an online complaint form at http://caag.state.ca.us/tobacco/contact.htm.

PENALTY: The AG may seek a court order to enforce these provisions or stop a violation of the provisions. If such an order is violated, the AG may pursue monetary compensation, civil contempt charges, or criminal sanctions. The parties must first attempt to resolve alleged violations through discussion.

74. BRAND NAME LIMITATIONS: THE TOBACCO CONTROL ACT

21 United States Code Sections 333, 372, 387a-1

21 Code of Federal Regulations Section 1140.16(a)

Scope: Brands of cigarettes or smokeless tobacco may not include a trade or brand name of a non-tobacco product.

EXCEPTION: This provision does not apply to a tobacco product whose trade or brand name was both a tobacco product and a non-tobacco product that were sold in the United States on January 1, 1995.

Enforcement: The U.S. Department of Health and Human Services is authorized to enforce this provision with the help of other federal agencies and state governments.

PENALTY: Any person who violates this provision shall be subject to a civil penalty of up to \$15,000 for each violation and up to \$1 million for multiple violations ruled on in a single proceeding.

Note: In May 2010, after the U.S. Food and Drug Administration (FDA) became aware of concerns regarding the constitutionality of this provision, the FDA announced how it would exercise its enforcement discretion with respect to 21 Code of Federal Regulations Section 1140.16(a). Guidance for Industry and FDA Staff: Enforcement Policy Concerning Certain Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco (May 2010), www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM210766.pdf. The FDA voluntarily suspended enforcement of this provision while the rule is under consideration as long as (1) the trade or brand name of the cigarettes or smokeless tobacco product was registered, or the product was marketed, in the United States on or before June 22, 2009; or (2) the first marketing or registration in the United States of the tobacco product

occurs before the first marketing or registration in the United States of the non-tobacco product bearing the same name, as long as the tobacco and non-tobacco product are not owned, manufactured, or distributed by the same, related, or affiliated entities. On November 17, 2011, the FDA published a proposed rule to amend Section 1140.16(a). 76 Fed. Reg. 71,281 (Nov. 17, 2011). The FDA noted that it was aware of concerns raised by the current rule, including its constitutionality, and that, after considering those concerns, it was proposing to narrow the scope of the rule. At the time of publication, the proposal was pending and the FDA's enforcement discretion policy in its 2010 guidance was still in effect. *Guidance for Industry: Compliance With Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents* (Aug. 2013), www.fda.gov/downloads/TobaccoProducts/ GuidanceComplianceRegulatoryInformation/UCM248241.pdf.

75. PRODUCT PLACEMENT

Master Settlement Agreement Sections III(e), VII(c) Smokeless Tobacco Master Settlement Agreement Sections III(e), VII(c)

Scope: The settling tobacco companies may not pay for product placement in movies, television, theater, video games, music videos, concerts, or other performances.

EXCEPTION: These provisions do not apply to media shown in an adult-only facility (where the operator ensures that no minors are present), media not intended for distribution to the public, or instructional media concerning non-conventional cigarettes if viewed only by adult smokers.

Enforcement: The state Attorney General (AG) is authorized to enforce these provisions. Suspected violations can be reported to the AG by calling (916) 565-6486 or by completing an online complaint form at http://caag.state.ca.us/tobacco/contact.htm.

PENALTY: The AG may seek a court order to enforce these provisions or stop a violation of the provisions. If such an order is violated, the AG may pursue monetary compensation, civil contempt charges, or criminal sanctions. The parties must first attempt to resolve alleged violations through discussion.

76. SAMPLES, COUPONS, AND PROMOTIONAL OFFERS: CALIFORNIA LAW

California Health and Safety Code Section 118950 California Code of Regulations Title 18, Section 4081

Scope: Free or nominal-cost cigarettes or smokeless tobacco products (or coupons, coupon offers, rebate offers, gift certificates, gift cards, or "other similar offers" for such products) may not be distributed on public grounds or on private grounds that are open to the public.

Note: An example of *public grounds* is a state-owned or county-owned fairground. Examples of *private grounds that are open to the public* are most racetracks or retail outlets.

Note: Every package of legally issued samples must be clearly marked as a sample and must contain the wording "Not for sale. Applicable state tax has been paid." Local governments may pass local laws that are stricter than the state law.

Note: Many local jurisdictions in California have adopted ordinances prohibiting tobacco product sampling. In addition, at the time of publication, at least 2 local jurisdictions outside of California—Providence, RI, and New York City—had adopted a prohibition on redeeming tobacco product coupons and multipack discounts. The Providence, RI, ordinance was challenged in federal court and upheld in *Nat'l Ass'n of Tobacco Outlets, Inc. v. City of Providence, 731 F.3d 71 (1st Cir. 2013)*, and the New York City ordinance was similarly challenged in federal court and upheld. *Nat'l Ass'n of Tobacco Outlets, Inc. v. City of New York, 27 F.Supp.3d 415 (S.D.N.Y. 2014)*.

EXCEPTION: This law applies only to cigarettes and smokeless tobacco products (eg, it does not apply to cigars). The law exempts product samples, coupons, coupon offers, rebate offers, gift certificates and gift cards in connection with the sale of another item, including tobacco products, lighters, magazines, or newspapers.

The law does not apply to locations where minors are prohibited by law or to public grounds leased for a private function where minors are denied access to the private function by a peace officer or licensed security guard. Nor does the law apply to a separate distribution area on private property that is open to the public where minors are denied access by a peace officer or licensed security guard. However, the area must be enclosed so as to prevent persons outside the area from seeing the distribution unless they undertake unreasonable efforts to see inside the area.

Enforcement: The state Attorney General may enforce this law.

PENALTY: Violators are liable for a civil penalty of not less than \$200 for a first item distributed, \$500 for a second item, and \$1,000 for each item after that. Each distribution of a single package, coupon, coupon offer, gift certificates, gift cards, or other similar offers, or rebate offer to an individual member of the general public in violation of this section shall be considered a separate violation.

California Business and Professions Code Sections 17534, 17535, 17537.3

Scope: Free samples of smokeless tobacco products may not be distributed within a 2-block radius of any premises or facility whose primary purpose is directed toward persons under the age of 21, including schools, clubhouses, and youth centers, when those premises are being used for their primary purposes.

Promotional offers of smokeless tobacco that require proof of purchase are prohibited unless the offer states that it is not available to individuals under 21 years of age. Mail-in and telephone requests for promotional offers must include appropriate efforts to ensure that the person is at least 21 years old, such as asking for the purchaser's birth date.

Mailing unsolicited samples of smokeless tobacco as part of an advertising program is prohibited (see entry 42 for more information on home delivery of unsolicited tobacco products).

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Enforcement: Local law enforcement agencies have the general authority to enforce this law under California Penal Code Section 830.1. Actions for injunction may be brought by the state Attorney General, district attorney, county counsel, city attorney, city prosecutor, or a private individual.

PENALTY: Violators (which can be a person, firm, corporation, partnership or association or any employee or agent thereof) are guilty of a misdemeanor.

77. SAMPLES, COUPONS, AND PROMOTIONAL OFFERS: MSA/STMSA

Master Settlement Agreement Sections III(g), VII(c) Smokeless Tobacco Master Settlement Agreement Sections III(g), VII(c)

Scope: The settling tobacco companies are prohibited from distributing free samples of cigarettes and smokeless tobacco products.

EXCEPTION: This prohibition does not apply to the distribution of tobacco products in an adult-only facility (where the operator ensures that no minors are present). Nor does this prohibition apply to tobacco products provided to adults in exchange for proof of purchase or through special promotions such as "2-for-1" offers, or for consumer testing.

Enforcement: The state Attorney General (AG) is authorized to enforce these provisions. Suspected violations can be reported to the AG by calling (916) 565-6486 or by completing an online complaint form at http://caag.state.ca.us/tobacco/contact.htm.

PENALTY: The AG may seek a court order to enforce these provisions or stop a violation of the provisions. If such an order is violated, the AG may pursue monetary compensation, civil contempt charges, or criminal sanctions. The parties must first attempt to resolve alleged violations through discussion.

78. SAMPLES: THE TOBACCO CONTROL ACT

21 United States Code Sections 333, 372, 387a-1, 387f(d) 21 Code of Federal Regulations Sections 1100.3, 1140.16(d)

Scope: Manufacturers, distributors, and retailers may not distribute (or cause to be distributed) free samples of tobacco products (for more information about products newly covered by the deeming rule, see the overview on page 7).

Note: This provision in the Tobacco Control Act, among others, was challenged in federal court and upheld. *Discount Tobacco City & Lottery v. United States*, 674 F.3d 509 (6th Cir. 2012), *cert. denied*, 133 S.Ct. 1996 (2013). The lawsuit alleged that the prohibition on tobacco sponsorships improperly regulated speech and violated the First Amendment.

EXCEPTION: This prohibition does not apply to the distribution of free samples of smokeless tobacco in a qualified adult-only facility (QAF), but an adult consumer may only leave with 1 package (15 grams) of smokeless tobacco. A QAF must:

- 1. Have a law enforcement officer present to check photo ID and ensure that access is limited only to adults;
- 2. Be a temporary structure created for the purpose of distributing free samples of smokeless tobacco:
- 3. Be enclosed by a barrier that prevents people from outside the facility from seeing inside the facility unless they make an unreasonable effort to do so;
- 4. Not sell, serve, or distribute alcohol;
- 5. Not be located adjacent to or immediately across from an area used primarily for youth-oriented marketing, promotional, or other activities; and
- 6. Not have exterior advertising other than brand names in conjunction with a word to identify the QAF.

QAFs are not permitted at any football, basketball, baseball, soccer, or hockey event. The Secretary of Health and Human Services has the authority to add additional types of events to this list in the future.

Note: The QAF exception is limited to smokeless tobacco products that contain cut, ground, powdered, or leaf tobacco and that are intended to be placed in the oral or nasal cavity.

Note: This provision does not affect the authority of a state or local government to prohibit or otherwise restrict the distribution of free samples of smokeless tobacco.

Enforcement: The U.S. Department of Health and Human Services is authorized to enforce this provision with the help of other federal agencies and state governments.

PENALTY: Any person who violates this provision shall be subject to a civil penalty of up to \$15,000 for each violation and up to \$1 million for multiple violations ruled on in a single proceeding.

Retailers who violate this provision and have a training program in place that complies with standards developed by the U.S. Food and Drug Administration (FDA) shall be subject to the following penalties, not to exceed:

- A warning letter for a first violation;
- \$250 for a second violation within a 12-month period;
- \$500 for a third violation within a 24-month period;
- \$2,000 for a fourth violation within a 24-month period;
- \$5,000 for a fifth violation within a 36-month period; and
- \$10,000 for a sixth or subsequent violation within a 48-month period.

Retailers who violate this provision and do not have an approved training program in place shall be subject to civil penalties not to exceed:

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- \$250 for a first violation;
- \$500 for a second violation within a 12-month period;
- \$1,000 for a third violation within a 24-month period;
- \$2,000 for a fourth violation within a 24-month period;
- \$5,000 for a fifth violation within a 36-month period; and
- \$10,000 for a sixth or subsequent violation within a 48-month period.

Note: In June 2014, the FDA updated its guidance regarding Tobacco Control Act penalties. The guidance discusses the procedures that apply if the FDA seeks civil money penalties and describes the amount of the penalties that the FDA may assess. If a retailer has "repeated violations" of the Tobacco Control Act, the FDA may impose a "no-tobacco-sale order" prohibiting the retailer from selling tobacco products for a specified period. The FDA interprets "repeated violation" to mean the following: a retailer incurs at least 5 violations of the Tobacco Control Act, each of the retailer's 5 violations represents the second or subsequent violation of a particular requirement, and each of the retailer's 5 violations occurs within a 36-month period. The FDA states that it generally does not intend to seek a civil money penalty or no-tobacco-sale order the first time an inspection identifies violations by a retailer; the FDA instead intends to send the retailer a warning letter after the first violation. *Guidance for FDA and Tobacco Retailers: Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers* (Revised) (June 2014), www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM252955.pdf.

At the time of publication, the FDA had not yet established standards for retailer training programs. Until the FDA establishes standards for retailer training programs, all retailers who violate this provision are treated as though they have an approved retailer training program in place. However, until the FDA establishes these standards, having a training program in place can nevertheless lead the FDA to further reduce the penalty for violations of the Tobacco Control Act. *Guidance for Industry: Tobacco Retailer Training Programs* (Revised) (June 2014), www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM218906.pdf.

79. PROOF-OF-PURCHASE GIFTS

Master Settlement Agreement Sections III(h), VII(c) Smokeless Tobacco Master Settlement Agreement Sections III(h), VII(c)

Scope: The settling tobacco companies are prohibited from giving gifts in exchange for the purchase of a tobacco product (including coupons or credits for a purchase) unless the recipient provides sufficient proof that he or she is an adult (eg, a photocopy of a driver's license or other government-issued ID card).

Enforcement: The state Attorney General (AG) is authorized to enforce these provisions. Suspected violations can be reported to the AG by calling (916) 565-6486 or by completing an online complaint form at http://caag.state.ca.us/tobacco/contact.htm.

PENALTY: The AG may seek a court order to enforce these provisions or stop a violation of the provisions. If such an order is violated, the AG may pursue monetary compensation, civil contempt charges, or criminal sanctions. The parties must first attempt to resolve alleged violations through discussion.

80. LOTTERY

26 United States Code Sections 5723(c), 5762(b)

Scope: Nothing that is or represents a ticket, chance, share, or an interest in a lottery shall be placed in or on any package of tobacco products, processed tobacco, or cigarette papers or tubes.

Enforcement: Not specified.

PENALTY: For each offense, violators are subject to a fine of up to \$1,000 and/or imprisonment for up to 1 year.

81. SALE AND DISTRIBUTION OF NON-TOBACCO ITEMS OR SERVICES: THE TOBACCO CONTROL ACT

21 United States Code Sections 333, 372, 387a-1 21 Code of Federal Regulations Sections 1100.3, 1140.34(a)

SCOPE: Manufacturers and distributors of imported cigarettes or smokeless tobacco may not directly or indirectly market, license, distribute, or sell any item or service bearing anything identifiable with any brand of cigarettes or smokeless tobacco, such as the brand name, logo, symbol, motto, or recognizable color or pattern of colors.

Note: This provision in the Tobacco Control Act, among others, was challenged in federal court and upheld. *Discount Tobacco City & Lottery v. United States*, 674 F.3d 509 (6th Cir. 2012), *cert. denied*, 133 S.Ct. 1996 (2013). The lawsuit alleged that the prohibition on the use of cigarette and smokeless tobacco branding improperly regulated speech and violated the First Amendment.

EXCEPTION: This provision does not apply to the marketing of cigarettes, smokeless tobacco, or roll-your-own tobacco. This provision does not apply to manufacturers of domestic cigarettes or smokeless tobacco.

Enforcement: The U.S. Department of Health and Human Services is authorized to enforce this provision with the help of other federal agencies and state governments.

PENALTY: Any person who violates this provision shall be subject to a civil penalty of up to \$15,000 for each violation and up to \$1 million for multiple violations ruled on in a single proceeding.

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82. JOINT MARKETING: THE TOBACCO CONTROL ACT

21 United States Code Sections 321(rr), 333, 372

Scope: A tobacco product may not be marketed with any other product regulated by the U.S. Food and Drug Administration (FDA), including a drug, food, cosmetic, medical device, or dietary supplement.

Note: This provision in the Tobacco Control Act, among others, was challenged in federal court and upheld. *Commonwealth Brands, Inc. v. United States*, 678 F.Supp.2d 512 (W.D.Ky. 2010), overruled in part on other grounds by *Discount Tobacco City & Lottery v. United States*, 674 F.3d 509 (6th Cir. 2012), *cert. denied*, 133 S.Ct. 1996 (2013). The lawsuit alleged that the prohibition on joint marketing improperly regulated speech and violated the First Amendment.

ENFORCEMENT: The U.S. Department of Health and Human Services is authorized to enforce this provision with the help of other federal agencies and state governments.

PENALTY: Any person who violates this provision shall be subject to a civil penalty of up to \$15,000 for each violation and up to \$1 million for multiple violations ruled on in a single proceeding.



83. CIGARETTE WARNING LABELS

15 United States Code Sections 1333, 1334, 1338, 1339

Scope: Under the Federal Cigarette Labeling and Advertising Act, cigarettes may not be manufactured, packaged, or imported for sale or distribution unless they bear one of the Surgeon General's warning labels. It is also illegal for manufacturers or importers to advertise cigarettes without one of the warning labels.

Note: State and local governments may not create additional cigarette label warning requirements beyond those required by federal law.

Enforcement: The U.S. Federal Trade Commission is responsible for approving labeling plans. The U.S. Attorney General may seek an injunction in federal court against violators to prevent future violations of this law or restrain current violations.

PENALTY: Violators are guilty of a misdemeanor punishable by a fine of not more than \$10,000.

21 United States Code Section 387n

15 United States Code Sections 1333, 1336, 1338, 1339

Scope: All cigarette packages made, sold, or distributed within the United States, and all related advertising and marketing, shall be required to bear 1 of 9 specified warnings regarding associated health risks. The warning labels must adhere to placement and typography restrictions. (For example, the warnings must cover the top 50% of front and rear panels of cigarette packages, and must cover at least 20% of a newspaper, magazine, or poster advertisement and be in the predominant language of the publication.) The U.S. Department of Health and Human Services (HHS) can make changes to the warning label requirements upon a finding that such a change would promote greater public understanding of the risks associated with the use of tobacco products.

Note: HHS issued regulations on June 22, 2011, specifying that the warning labels would include 9 specific graphic images and 9 printed warnings depicting the negative consequences of smoking. The graphic warning label requirements were scheduled to go into effect in September 2012; however, the warning label requirement was the subject of 2 separate lawsuits. Two federal appellate courts issued conflicting rulings regarding the constitutionality of the graphic warning label requirement. The Court of Appeals for the Sixth Circuit held that the label requirement did not violate tobacco companies' First Amendment rights, finding that the graphic warnings were reasonably related to the government's interest in preventing consumer deception. *Discount Tobacco City & Lottery v. United States*, 674 F.3d 509 (6th Cir. 2012), *cert. denied*, 133 S.Ct. 1996 (2013). By contrast, the Court of Appeals for the District of Columbia held that the warning labels proposed by the U.S. Food and Drug Administration (FDA) violated tobacco companies' First Amendment rights, finding that the government failed to show that the labels would lower smoking rates. *RJ Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205 (D.C. Cir. 2012). On March 14, 2013, the U.S. Department of Justice declined to appeal the D.C. Circuit ruling. The FDA

indicated that it will develop a second set of labels that will address the issues identified by the court. As a result, the agency indefinitely postponed implementation of the graphic warning labels.

EXCEPTION: This provision does not apply to tobacco products other than cigarettes or to foreign distribution of cigarettes. A retailer of cigarettes will not be in violation if the packaging contains a warning label, was supplied by a licensed manufacturer or distributor, and was not materially altered by the retailer.

Enforcement: The U.S. Attorney General is authorized to enforce this provision, acting through several U.S. attorneys. A violation is also considered an unfair or deceptive act or practice and subject to enforcement under the Federal Trade Commission Act.

PENALTY: A violation is considered a misdemeanor, and a conviction will subject the violator to a fine of \$10.000 or less.

Note: In another ruling involving the First Amendment, a federal court of appeals affirmed the text of several corrective statements that tobacco companies are required to publish in various media outlets. *United States v. Philip Morris USA Inc.*, 801 F.3d 250, 254 (D.C. Cir. 2015). After years of litigation, the companies were ordered to publish the corrective statements once the court found that the companies deceived the public regarding the addictiveness and health effects of smoking. Finding that these corrective statements were factual and uncontroversial, the appeals court rejected the companies' arguments that the statements violated their First Amendment rights. Examples of the statements that were finally approved on remand include "Smoking is highly addictive" and "There is no safe cigarette." *United States v. Philip Morris USA Inc.*, No. CA 99-2496 (D.D.C. Feb. 8, 2016). The statements must be published on the date when all possible appeals are exhausted. At the time of publication, the parties were still submitting changes to the statements at the district court; further appeals are unknown.

84. TOBACCO PRODUCT LABELS AND ADVERTISING WARNINGS: THE TOBACCO CONTROL ACT

21 United States Code Section 387a(b), 387c, 387n, 387f(d)

21 Code of Federal Regulations Sections 1143.3(a), (b)

Scope: As of May 10, 2018, the U.S. Food and Drug Administration's (FDA) deeming rule requires a nicotine addictiveness warning on all packages and advertisements for cigarette tobacco, roll-your-own tobacco, and covered tobacco products (other than cigars), such as pipe tobacco, hookah tobacco, gels, dissolvables, electronic nicotine delivery systems containing anything made or derived from tobacco (see the overview on page 7 for more information about the FDA's deeming rule). For covered tobacco products that do not contain nicotine, manufacturers must submit a self-certification to the FDA and their products must bear a warning label that reads as follows: "This product is made from tobacco." These warnings must adhere to placement and typography restrictions. As of June 11, 2018, all distribution of products without such warnings must stop.

Note: As of May 10, 2018, all packaged tobacco products are also subject to origin labeling requirements (see entry 52 for more information).

EXCEPTIONS: If a product package is too small or otherwise unable to accommodate a label, it is exempt from these requirements only if the required information or label appears on the carton or other outer container or wrapper. If the carton, outer container, or wrapper does not have sufficient space to display the information, the required information may be located on a tag permanently affixed to the package.

These provisions do not apply to cigars or tobacco products sold outside the United States. A retailer of tobacco products will not be in violation of this provision if the packaging contains a warning label; was supplied by a licensed manufacturer, importer, or distributor; and was not materially altered by the retailer.

Enforcement: The U.S. Department of Health and Human Services is authorized to enforce this provision with the help of other federal agencies and state governments.

PENALTY: Any person who violates this provision shall be subject to a civil penalty of up to \$15,000 for each violation and up to \$1 million for multiple violations ruled on in a single proceeding.

85. SMOKELESS TOBACCO WARNING LABELS

15 United States Code Sections 4402, 4404, 4405

Scope: Smokeless tobacco products may not be manufactured, packaged, or imported for sale or distribution unless they bear one of the warning labels listed in the law. It is also illegal for manufacturers, packagers, or importers to advertise smokeless tobacco products without one of the warning labels.

Enforcement: The U.S. Federal Trade Commission (FTC) is responsible for approving labeling plans. The U.S. Attorney General or the FTC may seek an injunction in federal court against violators to prevent future violations of this law.

PENALTY: Violators are guilty of a misdemeanor punishable by a fine of not more than \$10,000.

86. SMOKELESS TOBACCO LABEL AND ADVERTISING WARNINGS: THE TOBACCO CONTROL ACT

21 United States Code Section 387n

15 United States Code Sections 4402, 4404, 4405

21 Code of Federal Regulations Section 1143.3(a)

Scope: All smokeless tobacco product packages made, sold, or distributed within the United States must bear 1 of 4 specified warnings regarding associated health risks:

- WARNING: This product can cause mouth cancer.
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- WARNING: This product can cause gum disease and tooth loss.
- WARNING: This product is not a safe alternative to cigarettes.
- WARNING: Smokeless tobacco is addictive.

The warning labels must adhere to placement and typography restrictions. The U.S. Department of Health and Human Services can make changes to the warning label requirements upon a finding that such a change would promote greater public understanding of the risks associated with the use of smokeless tobacco products.

Note: As of May 10, 2018, the U.S. Food and Drug Administration's (FDA's) deeming rule also requires nicotine warning labels for covered smokeless tobacco products (see entry 85 for more information about these labels; see the overview on page 7 for more information about the FDA's deeming rule).

Note: As of May 10, 2018, all packaged tobacco products are also subject to origin labeling requirements (see entry 52 for more information).

Note: This provision in the Tobacco Control Act, among others, was challenged in federal court and upheld. *Discount Tobacco City & Lottery v. United States*, 674 F.3d 509 (6th Cir. 2012), *cert. denied*, 133 S.Ct. 1996 (2013). The lawsuit alleged that the required tobacco label and advertising warnings improperly regulated speech and violated the First Amendment.

EXCEPTION: This provision does not apply to tobacco products other than smokeless tobacco or to foreign distribution of smokeless tobacco products. A retailer of smokeless tobacco will not be in violation if the packaging contains a warning label, was supplied by a licensed manufacturer or distributor, and was not materially altered by the retailer.

Enforcement: The U.S. Attorney General is authorized to enforce this provision, acting through several U.S. attorneys. A violation is also considered an unfair or deceptive act or practice and subject to enforcement under the Federal Trade Commission Act.

PENALTY: A violation is considered a misdemeanor, and a conviction will subject the violator to a fine of \$10,000 or less.

87. CIGAR WARNING LABELS

FTC Agreements, File Numbers 0023199-00023205

Scope: Pursuant to agreements between the U.S. Federal Trade Commission (FTC) and the 7 largest cigar companies (comprising approximately 95% of the U.S. cigar market), every signing company's cigar packages and advertisements in the United States must clearly and prominently display 1 of 5 Surgeon General's health warnings listed in the agreement.

Note: For more information about this agreement, see the FTC's website at www.ftc.gov/news-events/press-releases/2000/06/ftc-announces-settlements-requiring-disclosurecigar-health-risks.

Enforcement: The FTC is charged with enforcing this agreement.

PENALTY: Not specified.

California Health and Safety Code Sections 104550-104552

Scope: Cigar manufacturers or importers must label each retail package of cigars with one of the warnings listed in the law. Display boxes or containers used to sell individual cigars must be clearly labeled.

Note: The state Attorney General (AG) has agreed that any cigar company that signed an agreement with the FTC regarding warning labels and that remains in compliance with terms of that agreement is deemed to be in compliance with Health and Safety Code Sections 104550–104552.

Exception: Warning labels are not required on the cellophane wrappers, tubes, or similar wrappings in which individual cigars are sold.

Enforcement: Actions to enforce this section may be brought by the AG, any district attorney, any city attorney of a city with a population greater than 750,000, or, with permission of the district attorney, by a city prosecutor in any city having a full-time city prosecutor.

PENALTY: Violators are subject to a civil penalty up to \$2,500 per day for each violation.

21 United States Code Sections 387a(b), 387c, 387f(d)

21 Code of Federal Regulations Sections 1143.5(a), (b)

Scope: As of May 10, 2018, the U.S. Food and Drug Administration's (FDA) deeming rule requires warning labels on all cigar packaging and advertisements (see the overview on page 7 for more information about the FDA's deeming rule). As of June 11, 2018, all distribution of products without the requisite warnings must stop. For cigars sold individually without packaging, the warning statements must be displayed at all points of sale as of May 10, 2018. All package warnings and signs must adhere to placement and typography restrictions. Packages must bear 1 of these 6 warnings:

- WARNING: Cigar smoking can cause cancers of the mouth and throat, even if you do not inhale.
- WARNING: Cigar smoking can cause lung cancer and heart disease.
- WARNING: Cigars are not a safe alternative to cigarettes.
- WARNING: Tobacco smoke increases the risk of lung cancer and heart disease, even in nonsmokers.
- WARNING: Cigar use while pregnant can harm you and your baby; or SURGEON GENERAL WARNING: Tobacco Use Increases the Risk of Infertility, Stillbirth and Low Birth Weight.
- WARNING: This product contains nicotine. Nicotine is an addictive chemical.

By May 10, 2017, or 12 months before advertising or commercially marketing cigars (whichever is later), retailers, manufacturers, importers, and distributors must submit plans to the FDA for the rotation and distribution of these warnings.

Note: As of May 10, 2018, all packaged tobacco products are also subject to origin labeling requirements (see entry 52 for more information).

Exceptions: A retailer of tobacco products will not be in violation of this provision if the product packaging was supplied by a licensed manufacturer, importer, or distributor; contains a warning label; and was not materially altered by the retailer.

ENFORCEMENT: The U.S. Department of Health and Human Services is authorized to enforce this provision with the help of other federal agencies and state governments.

PENALTY: Any person who violates this provision shall be subject to a civil penalty of up to \$15,000 for each violation and up to \$1 million for multiple violations ruled on in a single proceeding.

88. E-CIGARETTE AND OTHER LIQUID NICOTINE EXPOSURE WARNINGS

Advance Notice of Proposed Rulemaking, 21 Code of Federal Regulations Parts 1100, 1140, and 1143

21 Code of Federal Regulations Sections 1100.3, 1140.14(b)

Scope: In July 2015, the U.S. Food and Drug Administration (FDA) issued an advance notice of proposed rulemaking about new packaging requirements for liquid nicotine, nicotine-containing e-liquid(s), and other tobacco products. The agency requested information about possible nicotine exposure warnings and child-resistant packaging for these products, and potentially for novel tobacco products like dissolvables, lotions, gels, and drinks. At the time of publication, the FDA had issued only an advance notice of proposed rulemaking. The docket for the advance notice and request for comments is available at www.regulations.gov/document?D=FDA-2015-N-1514-0090.

As of May 10, 2018, the FDA's deeming rule requires nicotine warning labels for parts of electronic nicotine delivery systems containing anything made or derived from tobacco (see entry 84 for more information about these labels; see the overview on page 7 for more information about the FDA's deeming rule).

Note: As of July 26, 2016, the Child Nicotine Poisoning Prevention Act regulates the packaging of liquid nicotine, but it is not intended to limit or otherwise affect the authority of the Secretary of Health and Human Services to regulate, issue guidance on, or take action regarding any nicotine-related products (see entry 45 for more information). The Act makes it clear that the FDA can move forward with this advance notice of proposed rulemaking and with any other regulations

Warning Labels

regarding the manufacture, marketing, sale, distribution, importation, or packaging of nicotine-related products.

Enforcement: Not specified.

PENALTY: Not specified.

TAXATION, LICENSING, AND REPORTING

89. FEDERAL TOBACCO TAX

26 United States Code Sections 5701-5704, 5761-5763

Scope: The manufacturer or importer of tobacco products shall pay taxes in the amount specified for each type of tobacco product, including cigars, cigarettes, smokeless tobacco, pipe tobacco, and roll-your-own tobacco. The taxes on all tobacco products increased on April 1, 2009. The federal tax on cigarettes is now \$1.01 per 20 pack. The federal taxes on cigars and smokeless tobacco are calculated according to weight.

EXCEPTION: There are 4 categories of exemptions from the federal tobacco tax: tobacco furnished for employee use or experimental purposes; certain tobacco products transferred or removed from domestic factories and export warehouses; certain tobacco products released from customs custody; and tobacco products exported and returned.

Enforcement: The federal tax laws are enforced by federal law enforcement agencies.

Note: In July 2012, Congress amended the federal Internal Revenue Code's definition of "manufacturer of tobacco products." The revised definition adds retailers who, for commercial purposes, provide consumers with access to roll-your-own tobacco machines. These retailers now must pay the same federal excise taxes and comply with the same permitting processes as mass manufacturers. The amendment closes a tax loophole for retailers that allowed consumers to use high-speed machines to produce cartons of cigarettes that were similar to other mass-produced cigarettes. A "manufacturer of tobacco products" does not include a person who sells a roll-your-own tobacco machine to a consumer for personal home use.

Note: The federal tax status of the entity that provides consumers with access to roll-your-own tobacco machines (ie, nonprofit vs. for-profit) is not relevant in determining whether the entity is providing that access for a "commercial purpose." Federal tax liability can apply to "nonprofit" organizations and "social clubs" that make these machines available. *Enforcement Efforts in Connection with Cigarette-Making Machines* (Aug. 2013), www.ttb. gov/announcements/ttb-announcement-cigarette-making-machines-announcement.pdf.

PENALTY: There are a range of civil and criminal penalties that attach to a failure to comply with the federal tobacco tax laws. In addition, any property intended for use in violating the federal tobacco tax laws is subject to forfeiture.

90. REPORTING REQUIREMENTS: THE JENKINS ACT

15 United States Code Sections 375-378

Scope: The Jenkins Act applies to cigarette and smokeless tobacco sellers who ship or advertise to buyers in another state who are not distributors. Such sellers must make 2 filings with the state into which they are shipping or advertising. First, sellers must file their name and address. Second, sellers must file a monthly report documenting every shipment

into the state. The report must include the name and address of each buyer, the brand, and the quantity shipped.

Enforcement: The Jenkins Act may be enforced by federal law enforcement agencies.

Note: Courts in 2 states have held that state law enforcement agencies may bring a civil action to enforce the Jenkins Act reporting requirements. See Washington v. WWW. Dirtcheapcigs.com, Inc., 260 F. Supp. 2d 1048, 1053–55 (W.D. Wash. 2003); Angelica Co. v. Goodman, 276 N.Y.S.2d 766, 769 (1966). California Code of Civil Procedure Section 1021.10 authorizes the state of California to sue to enforce the Jenkins Act to the extent not expressly prohibited by federal law.

PENALTY: Violators are subject to criminal penalties of up to 3 years imprisonment. Violators are also subject to civil penalties in an amount not to exceed the greater of \$5,000 for a first violation and \$10,000 for a subsequent violation, or 2% of their gross sales of cigarettes or smokeless tobacco during the 1-year period ending on the date of the violation.

91. REPORTING REQUIREMENTS: THE PACT ACT

15 United States Code Sections 375, 376a, 377, 378 18 United States Code Section 1716E

Scope: The Prevent All Cigarette Trafficking Act (the PACT Act) requires cigarette or smokeless tobacco product sellers to make the filings specified in the Jenkins Act with the U.S. Attorney General, who will compile a list of delivery sellers that have not registered or not complied with this law. Common carriers (eg, UPS, FedEx) are prohibited from delivering packages for delivery sellers that are on the list.

ENFORCEMENT: The U.S. Attorney General shall administer and enforce this chapter.

PENALTY: Violators are subject to criminal penalties of up to 3 years imprisonment. Violators are also subject to civil penalties in an amount not to exceed the greater of \$5,000 for a first violation and \$10,000 for a subsequent violation, or 2% of their gross sales of cigarettes or smokeless tobacco during the 1-year period ending on the date of the violation.

Common carriers or other delivery services that intentionally violate the new law are subject to civil penalties in an amount not to exceed \$2,500 for a first violation and \$5,000 for any violation within 1 year of a prior violation.

92. CALIFORNIA STATE TOBACCO TAX

California Revenue and Taxation Code Sections 30001-30483 California Health and Safety Code Sections 104350-104480, 104500-104545, 130100-130155

Scope: Under the Cigarette and Tobacco Products Tax Law, California imposes 4 taxes on the distribution of cigarettes and other tobacco products, including:

- A tax of 12 cents per package of 20 cigarettes, of which 2 cents are earmarked for breast cancer research and control.
- A Proposition 99 surtax of 25 cents per package of 20 cigarettes (with an equivalent surtax on other tobacco products), all of which is allocated to the Cigarette and Tobacco Products Surtax Fund. The revenues are earmarked for tobacco health education, tobacco related disease research, health care for medically indigent families, and certain types of environmental programs. The revenues are deposited according to the following formula: 20% in the Health Education Account; 35% in the Hospital Services Account; 10% in the Physician Services Account; 5% in the Research Account; 5% in the Public Resources Account; and 25% in the Unallocated Account. This surtax became effective on January 1, 1989. Proposition 99 funds are allocated to school-based programs through a single competitive grant process for tobacco education and cessation programs for grades 6 through 12.
- A Proposition 10 surtax of 50 cents per package of 20 cigarettes (with an equivalent surtax on other tobacco products), all of which is allocated to the California Children and Families Program to support early childhood development programs. This surtax became effective on January 1, 1999.
- Effective April 1, 2017, a Proposition 56 surtax of 2 dollars per package of 20 cigarettes (with an equivalent surtax on other tobacco products, including electronic cigarettes, to be determined in forthcoming regulations). Proposition 56 revenue will be allocated based on the following process:
 - 1. Revenue will first be used to replenish Proposition 99 and Proposition 10 funds, inasmuch as they are reduced due to lower tobacco consumption resulting directly from Proposition 56's tax increase;
 - 2. Up to 5% of the total remaining revenue will pay the costs of administering the tax;
 - 3. Revenue will then be used to replenish state and local government sales and use tax revenues, inasmuch as they are reduced due to lower tobacco consumption resulting directly from Proposition 56's tax increase;
 - 4. After the prior calculations have been made, \$48 million will be allocated to enforcement efforts related to tobacco laws; \$40 million will be allocated to physician training through the University of California; \$30 million will be allocated to preventing and treating dental diseases; and \$400,000 will be allocated to the California State Auditor to audit funds from the new tax:
 - 5. Finally, 82% of the remaining funds will be allocated toward services related to Medi-Cal's Healthcare Treatment Fund; 13% will be allocated to tobacco-use prevention and control programs through the California Departments of Public Health and Education; 5% will be allocated toward research into cancer, heart and lung diseases, and other tobacco-related diseases through the University of California.

Distributors are responsible for paying state cigarette taxes through the use of tax stamps or meter impressions (see entry 93). Non-cigarette tobacco products are subject to a surtax that is set annually by the state Board of Equalization (BOE). The surtax rate is calculated to be equivalent to the total tax on cigarettes. Distributors are responsible for paying state tobacco taxes.

93. CIGARETTE TAX STAMPS/METER IMPRESSIONS

California Revenue and Taxation Code Sections 30161–30165 California Code of Regulations Title 18, Sections 4048, 4054, 4081

Scope: Distributors pay cigarette taxes through the use of stamps or meter impressions. The state Board of Equalization (BOE) sells stamps and meter register settings for approved metering machines. A stamp or meter impression must appear on each package of cigarettes prior to distribution. Stamps shall be affixed to the bottom end of each standard package of 20 cigarettes or to the lid or top of each individual package of flats or rounds. Stamps may not be affixed to cartons or larger containers of cigarettes. Meter impressions shall be clearly imprinted on the bottom end of each standard package of 20 cigarettes. Meter impressions may not be imprinted on any other size of package, carton, or container of cigarettes. Stamps and meter impressions may not be affixed to any package of cigarettes if any one of the following occurs:

- The package does not comply with federal laws requiring health warnings (see entries 83–84);
- The package is labeled with wording indicating that the manufacturer did not intend that the product be sold in the United States;
- The package has been altered by adding or deleting federal warnings or labels;
- The package was imported into the United States after January 1, 2000, in violation of federal tobacco importation law, 26 United States Code Section 5754; or
- The package bears a brand name of a participating manufacturer in the Master Settlement Agreement and is imported by an entity other than the participating manufacturer.

EXCEPTION: Stamps or meter impressions need not appear on tobacco products legally given away as samples. However, the manufacturer giving away such samples must notify the BOE in advance of the sampling, report the distribution, and pay the tax due. Each package of samples must be clearly marked as a sample and must contain the wording "Not for sale. Applicable state tax has been paid."

Note: Sampling is restricted under California and federal laws (see entries 76–78).

Enforcement: The BOE is authorized to enforce this law.

PENALTIES: The BOE shall revoke the license issued to a distributor under the Revenue and Taxation Code if the distributor violates this law (see entries 94–97, 105, and 107 for penalties that attach to various violations relating to tax stamps and meter impressions). In addition, the penalties listed in entry 107 may apply.

94. MAIL ORDER/INTERNET CIGARETTE TAXATION

California Revenue and Taxation Code Section 30101.7

Scope: In order to sell cigarettes or tobacco products, including any article or product containing at least 50% tobacco, to a person in California over the internet, over the phone, or via any other non–face-to-face sales method, the seller must meet all of the following conditions: (1) it must fully comply with all of the requirements of the Jenkins Act (see entry 91); (2) it must obtain and maintain any applicable license under the California Business and Professions Code, as if the delivery-sale occurred entirely within California; and (3) it must comply with any applicable state law that imposes escrow or other payment obligations on tobacco product manufacturers.

The state Board of Equalization must provide information to the state Attorney General (AG) regarding a seller's failure or attempt to comply with the Jenkins Act. The AG must provide an annual report to the Legislature regarding all actions taken to comply with, and enforce, the Jenkins Act. The AG may require a seller to report its delivery sales of cigarettes and tobacco products to consumers within California.

EXCEPTION: This law does not apply to cigars.

ENFORCEMENT: The AG, a city attorney, a county counsel, or a district attorney may bring a civil action to enforce this law.

PENALTY: Any violation of the above requirements is a misdemeanor, punishable by a maximum fine of \$5,000, imprisonment of up to 1 year in county jail, or both. Violators are also liable for a civil penalty of between \$1,000 and \$2,000 for a first violation; \$2,500 and \$3,500 for a second violation within a 5-year period; \$4,000 and \$5,000 for a third violation within a 5-year period; \$5,500 and \$6,500 for a fourth violation within a 5-year period; and \$10,000 for a fifth or subsequent violation within a 5-year period.

95. BLACK MARKET AND COUNTERFEIT CIGARETTES

California Revenue and Taxation Code Sections 30474, 30474.5

Scope: It is illegal to knowingly hold for sale, offer for sale, or sell any packages of cigarettes without the required tax stamp or meter impression (see entry 93 for a summary of the tax stamp and meter impression requirements).

ENFORCEMENT: The state Board of Equalization (BOE) and local law enforcement agencies are authorized to enforce this law.

PENALTY: Violators are guilty of a misdemeanor punishable by a fine of no more than \$25,000 and/or imprisonment for up to 1 year. Moreover, violators shall pay 2 fines, each amounting to \$100 per violating carton of 200 cigarettes or portion thereof. The first fine shall be divided evenly between the local prosecuting jurisdiction and the BOE. The second fine shall be deposited in the Unlawful Sales Reduction Fund, which shall be used to support local grantees in multiagency efforts to reduce sales of untaxed cigarettes.

In addition, the penalties listed in entry 107 may apply.

California Revenue and Taxation Code Sections 30474.1, 30477

Scope: Notwithstanding any other provision of law, the sale or possession for sale of counterfeit cigarettes and tobacco products, including any article or product containing at least 50% tobacco, is illegal. Counterfeit tobacco products include tobacco products with false manufacturing labels and/or fraudulent tax stamps or meter impressions.

ENFORCEMENT: The state Board of Equalization and local law enforcement agencies are authorized to enforce this law.

PENALTY: The illegal products are subject to seizure and forfeiture, and violators are guilty of a misdemeanor. If less than two cartons are seized, violators are subject to a fine of up to \$5,000 and/or imprisonment not to exceed 1 year, as well as revocation of a distributor, wholesaler, or manufacturer license. If 2 or more cartons are seized, violators are subject to a fine of up to \$50,000 and/or imprisonment not to exceed 1 year, as well as revocation of a distributor, wholesaler, or manufacturer license (see entries 102–108 for more information on distributor, wholesaler, and manufacturer licenses).

In addition, the penalties listed in entry 107 may apply.

California Business and Professions Code Sections 22974.3(a), 22978.2(a)

Scope: It is illegal to possess, store, own, or sell a package of cigarettes that bears a counterfeit tax stamp or meter impression or that lacks a tax stamp or meter impression (see entry 93 for more information on tax stamps and meter impressions).

ENFORCEMENT: The state Board of Equalization and local law enforcement agencies are authorized to enforce this law.

PENALTY: The unstamped packages are subject to seizure and forfeiture, and violators are guilty of a misdemeanor punishable by the following:

- If fewer than 20 packages are seized: For a first violation, a fine of \$1,000 and/or imprisonment not to exceed 1 year; for a second or subsequent violation within 5 years, a fine of \$2,000 to \$5,000 and/or imprisonment not to exceed 1 year, and revocation of a retailer, distributor, or wholesaler license (see entries 102–108 for more information on retailer, distributor, and wholesaler licenses).
- If 20 or more packages are seized: For a first violation, a fine of \$2,000 and/or imprisonment not to exceed 1 year; for a second or subsequent violation within 5 years,

- a fine of \$5,000 to \$50,000 and/or imprisonment not to exceed 1 year, and revocation of a retailer, distributor, or wholesaler license (see entries 102–108 for more information on retailer, distributor, and wholesaler licenses).
- In addition, the penalties listed in entry 107 may apply.

California Business and Professions Code Sections 22974.3(b), 22978.2(b), 22981

Scope: It is illegal to possess, store, own, or sell a tobacco product on which tax is due. Retailers, distributors, wholesalers, and others in possession of tobacco products have the burden of proving that the tax has been paid.

ENFORCEMENT: The state Board of Equalization and local law enforcement agencies are authorized to enforce this law.

PENALTY: Violators are guilty of a misdemeanor punishable by a fine not to exceed \$5,000 and/or imprisonment not to exceed 1 year. Illegal packages are subject to seizure and forfeiture.

In addition, the penalties listed in entries 106–107 may apply.

96. FORGERY OF FALSE STAMPS/METER IMPRESSIONS

California Revenue and Taxation Code Section 30473

Scope: It is illegal to fraudulently make, forge, alter, reuse, or counterfeit any tax stamp or meter impression (see entry 93 for more information on tax stamps and meter impressions).

Enforcement: The state Board of Equalization and local law enforcement agencies are authorized to enforce this law.

PENALTY: Violators are guilty of a felony and subject to imprisonment for 2, 3, or 4 years, and/or to a fine of not less than \$1,000 and not more than \$25,000.

In addition, the penalties listed in entry 107 may apply.

97. POSSESSION OR SALE OF FALSE STAMPS/METER IMPRESSIONS

California Revenue and Taxation Code Section 30473.5

Scope: It is illegal to possess, sell, offer to sell, buy, or offer to buy any false, fraudulent, or unaffixed tax stamps or meter impressions (see entry 93 for more information on tax stamps and meter impressions).

EXCEPTION: In the possession of a licensed distributor, "unaffixed stamps" do not include unused and unapplied stamps acquired from the state Board of Equalization (BOE) or its authorized agent.

ENFORCEMENT: The state BOE and local law enforcement agencies are authorized to enforce this law.

PENALTY: Violators are guilty of a misdemeanor punishable by: (1) for false or fraudulent tax stamps or meter impressions in a quantity of less than 2,000, a fine not to exceed \$5,000 and/or imprisonment not to exceed 1 year; (2) for false or fraudulent tax stamps or meter impressions in a quantity of 2,000 or greater, a fine not to exceed \$50,000 and/or imprisonment not to exceed 1 year. The BOE shall destroy any stamps seized under this law. In addition, the penalties listed in entry 107 may apply.

98. TOBACCO RETAILER LICENSE

California Business and Professions Code Sections 22971–22971.7, 22972–22973.3, 22980.2, 22981, 229900.7

SCOPE: Tobacco retailers must be licensed by the state Board of Equalization (BOE) for each tobacco retail location. For the purposes of this law, a retailer is someone who sells tobacco products from a building or a vending machine. Each retailer must apply for a 12-month license and pay a license fee of \$265 for each retail location. Beginning on and after January 1, 2017, retailers must apply to renew their licenses with a \$265 fee.

As of January 1, 2017, retailers of electronic smoking devices are required to comply with tobacco retailer licensing requirements under state law. Retailers may also sell these products under any existing, valid tobacco retailer license.

A tobacco retailer license is not assignable or transferable. A retailer may not obtain a license if the retailer has been issued a license that is currently suspended or revoked. Licenses will not be issued for any location where a license has been revoked in the last 5 years, unless a new owner obtained the property in an arms-length transaction.

The state licensing law does not preempt or supersede any local tobacco control law other than those related to the collection of state taxes. Local tobacco retailer licensing laws may provide for the suspension or revocation of the local license for any violation of a state tobacco control law.

Note: The state licensing law focuses on protecting state revenue by targeting tax evasion. Local jurisdictions can pass tobacco retailer licensing laws that focus on protecting the public's health by, for example, providing for the suspension of tobacco retailer licenses for illegal sales to underage individuals.

Note: In 2012, the BOE implemented a new policy based on a legal opinion that determined that catering trucks, lunch wagons, and other mobile facilities cannot be licensed as retail locations. Tobacco products cannot be sold from a mobile location. *Mobile Sellers of Cigarettes and Tobacco Products* (undated), www.boe.ca.gov/pdf/Mobile_Seller_Letter.pdf.

Enforcement: The BOE is authorized to enforce this law. No later than January 1, 2019, the BOE must report to the Legislature regarding the adequacy of funding for the Cigarette and Tobacco Products Licensing Act of 2003, including recommendations for funding levels sufficient to maintain an effective enforcement program. Local law enforcement agencies have the general authority to enforce this law under California Penal Code Section 830.1.

PENALTY: Unlicensed retailers are guilty of a misdemeanor and subject to a fine not to exceed \$5,000 and/or imprisonment not to exceed 1 year. Each day of continued sales or gifting without a valid license after notification by a law enforcement agency that a valid license is required constitutes a separate violation. Continued sales or gifting after notification by the BOE that a license has been suspended or revoked shall result in the seizure and forfeiture of all tobacco products in the possession of the person making such sales.

In addition, the penalties listed in entry 107 may apply.

99. RETAILER LICENSE DISPLAY

California Business and Professions Code Sections 22972, 22974.5, 22980.5

Scope: A retailer shall conspicuously display the license at each retail location in a manner visible to the public. A retailer whose license has been suspended or revoked by the state Board of Equalization (BOE) must conspicuously post a notice of that suspension or revocation at each public entrance to the retail location and at each cash register and other point of sale. The notice must be posted for the duration of the suspension or for 30 days following the effective date of a revocation.

Enforcement: The BOE is authorized to enforce this law.

PENALTY: A retailer who fails to display the license is liable for a \$500 fine. A retailer who removes, alters, or fails to post required notices of suspension or revocation shall be subject to a civil penalty of \$1,000 for each offense.

In addition, the penalties listed in entry 107 may apply.

100. LICENSING PENALTIES FOR ILLEGAL SALES TO UNDERAGE INDIVIDUALS

California Business and Professions Code Section 22958

Scope: Retailers convicted of a STAKE Act violation (see entries 25–26, 28–29, 31–33, 39, 54, 58, 100, and 102) shall be subject to license-related penalties.

ENFORCEMENT: The state Board of Equalization (BOE) is charged with enforcing this law.

PENALTY: The following penalties apply:

- Upon a first conviction, the retailer shall be fined \$400 to \$600.
- Upon a second conviction within a 5-year period, the retailer shall be fined \$900 to \$1,000.
- Upon a third conviction within a 5-year period, the retailer shall be fined \$1,200 to \$1,800. The California Department of Public Health is required to notify the BOE. The retailer shall be assessed an additional \$250 penalty by the BOE, and the BOE shall suspend the retailer's license for 45 days.

- Upon a fourth conviction within a 5-year period, the retailer shall be fined \$3,000 to \$4,000. The California Department of Public Health is required to notify the BOE. The retailer shall be assessed an additional \$250 penalty by the BOE, and the BOE shall suspend the retailer's license for 90 days.
- Upon a fifth conviction within a 5-year period, the retailer shall be fined \$5,000 to \$6,000. The California Department of Public Health is required to notify the BOE. The retailer shall be assessed an additional \$250 penalty by the BOE, and the BOE shall revoke the retailer's license.

The BOE must give a retailer at least 10 days' written notice of a pending suspension or revocation and an opportunity to appeal the suspension, revocation, and/or civil penalty, but only for the purpose of correcting a mistake or clerical error.

Convictions by a retailer at one retail location are not accumulated against other locations owned by that retailer. Convictions accumulated against a prior retail owner of a franchise location are not accumulated against a new retail owner of the same franchise location.

In addition, the penalties listed in entry 107 may apply.

101. DISTRIBUTOR AND WHOLESALER LICENSES

California Business and Professions Code Sections 22971, 22975-22978.8, 22980.2, 22981

Scope: Tobacco distributors and wholesalers must be licensed by the state Board of Equalization (BOE). Each distributor or wholesaler must pay a license fee of \$1,200. A \$1,000 license renewal fee is required each year. Starting January 1, 2017, the license renewal fee is \$1,200. This license requirement is in addition to the California Revenue and Taxation Code license requirements described below in this entry.

Enforcement: The BOE is authorized to enforce this law. No later than January 1, 2019, the BOE must report to the Legislature regarding the adequacy of funding for the Cigarette and Tobacco Products Licensing Act of 2003, including recommendations for funding levels sufficient to maintain an effective enforcement program. Local law enforcement agencies have the general authority to enforce this law under California Penal Code Section 830.1.

PENALTY: Unlicensed distributors and wholesalers are guilty of a misdemeanor and subject to a fine not to exceed \$5,000 and/or imprisonment not to exceed 1 year. Each day of continued sales or gifting without a valid license after notification by a law enforcement agency that a valid license is required constitutes a separate violation. Continued sales or gifting after notification by the BOE that a license has been suspended or revoked shall result in the seizure and forfeiture of all tobacco products in the possession of the person making such sales. The BOE shall include on its website the name of any distributor or wholesaler whose license has been suspended or revoked.

In addition, the penalties listed in entry 107 may apply.

California Revenue and Taxation Code Sections 30140-30149

Scope: Tobacco distributors must be licensed by the state Board of Equalization (BOE) for each place of business. This license requirement is in addition to the California Business and Professions Code license requirements described above in this entry. License applicants must submit a security deposit (minimum of \$1,000) to the BOE. The security is conditioned upon the lawful performance of all tobacco tax related requirements.

Enforcement: The BOE is authorized to enforce this law.

PENALTY: The license may be revoked for failure to comply with applicable rules and regulations. Distributing without a license is a misdemeanor.

In addition, the penalties listed in entry 107 may apply.

California Revenue and Taxation Code Sections 30155-30159

Scope: Tobacco wholesalers must be licensed at no cost separately for each place of business. This license requirement is in addition to the California Business and Professions Code license requirements described above in this entry. This license must be prominently displayed at each place of business.

Enforcement: The state Board of Equalization is authorized to enforce this law.

PENALTY: The license may be suspended or revoked for failure to comply with applicable rules and regulations. Engaging in wholesaling without a license is a misdemeanor.

In addition, the penalties listed in entry 107 may apply.

102. DISTRIBUTOR AND WHOLESALER REPORTING

California Business and Professions Code Sections 22954, 22957 (STAKE Act)
California Government Code Sections 6250–6276.48

Scope: Tobacco distributors, tobacco wholesalers, and cigarette vending machine operators shall report annually to the California Department of Public Health (CDPH) the names and addresses of those persons to whom they provide tobacco products. The data provided shall be deemed confidential by CDPH and shall be exempt from disclosure under the California Public Records Act.

Enforcement: Primary enforcement responsibility rests with CDPH. However, this requirement may also be enforced by any "enforcing agency" authorized to enforce the STAKE Act, including the California Attorney General's office and local law enforcement agencies.

PENALTY: Not specified.

103. MANUFACTURER AND IMPORTER LICENSE AND REPORTING

California Business and Professions Code Sections 22971, 22971.7, 22979, 22979.21-22979.24, 22979.7, 22980.2

California Government Code Sections 6250-6276.48

Scope: Tobacco manufacturers and importers must be licensed by the state Board of Equalization (BOE). In order to obtain and maintain a license, the manufacturer or importer must supply the BOE with specified lists, certifications, and consents.

Every manufacturer or importer of chewing tobacco or snuff must pay a one-time license fee of \$10,000, and every manufacturer or importer of other tobacco products must pay a onetime license fee of \$2,000.

Every tobacco manufacturer and importer must file a monthly report to the BOE that includes a list of all licensed distributors to which the manufacturer or importer shipped its products and the total wholesale cost of the products. The data provided shall be deemed confidential and shall be exempt from disclosure under the California Public Records Act.

In order to be eligible to obtain a license, every tobacco manufacturer or importer must do either of the following: (1) waive any sovereign immunity defense that may apply to any enforcement action brought by the Attorney General or the BOE to enforce state manufacturer and importer licensing requirements, the manufacturer requirements relating to the Master Settlement Agreement (MSA), or state tobacco tax laws; or (2) file a surety bond with the Attorney General in favor of the State of California that is conditioned on the manufacturer's performance of its duties and obligations.

ENFORCEMENT: The BOE is authorized to enforce this law. Local law enforcement agencies have the general authority to enforce this law under California Penal Code Section 830.1.

Every tobacco manufacturer or importer must consent to the jurisdiction of the California courts for enforcement of the MSA and the Cigarette and Tobacco Products Tax Law, must appoint a registered agent for service of process in California, and must identify the registered agent to the BOE and the state Attorney General.

PENALTY: Unlicensed manufacturers and importers are guilty of a misdemeanor and subject to a fine of up to \$5,000 and/or imprisonment not to exceed 1 year. For a first offense, the BOE may revoke or suspend the license or licenses of the manufacturer or importer pursuant to the procedures applicable to the revocation of a license, which include a written notice and an opportunity for a hearing. The procedures for revocation are set forth in Section 30148 of the California Revenue and Taxation Code.

Each day of continued sales or gifting without a valid license after notification by a law enforcement agency that a valid license is required constitutes a separate violation. Continued sales or gifting must result in the seizure and forfeiture of all tobacco products in the possession of the person making such sales. Gifting is defined as any transfer of title or possession without consideration, exchange, or barter.

In addition, the penalties listed in entry 107 may apply.

104. RECORD RETENTION BY STATE LICENSEES

California Business and Professions Code Sections 22974, 22978.1, 22979.4, 22979.5, 22981

Scope: Each retailer, distributor, wholesaler, manufacturer, and importer must retain purchase and sale invoices for tobacco products for a period of 4 years. Such records shall be kept at the location identified in the license for a period of 1 year and shall be made available for inspection upon request of the state Board of Equalization (BOE) or by a law enforcement agency.

Enforcement: The BOE is authorized to enforce this law. Local law enforcement agencies have the general authority to enforce this law under California Penal Code Section 830.1.

PENALTY: Violators are guilty of a misdemeanor punishable by a fine not to exceed \$5,000 and/or imprisonment not to exceed 1 year.

In addition, the penalties listed in entry 107 may apply.

105. INSPECTIONS

California Business and Professions Code Sections 22980, 22981

Scope: Any peace officer or authorized state Board of Equalization (BOE) employee may enter and inspect any place where tobacco products are sold, produced, or stored; any site where evidence of activities involving evasion of tobacco product taxes may be discovered; or any site where there is evidence of a violation of Section 30165.1 of the California Revenue and Taxation Code, which prohibits the sale of tobacco products that are not included on the state Attorney General's directory of tobacco product manufacturers and brands.

Enforcement: State and local law enforcement agencies and the BOE are authorized to enforce this law.

PENALTY: Anyone who fails to permit an inspection is guilty of a misdemeanor punishable by a fine not to exceed \$5,000 and/or imprisonment not to exceed 1 year.

In addition, the penalties listed in entry 107 may apply.

California Revenue and Taxation Code Sections 30435, 30471

Scope: State Board of Equalization (BOE) employees may enter and inspect any place where tobacco products are sold, produced, or stored, or any site where there is evidence of activities involving tobacco tax evasion or Master Settlement Agreement violations.

Enforcement: The BOE is authorized to enforce this law.

PENALTY: Refusal to allow an inspection is a misdemeanor punishable by a fine not to exceed \$1,000 for each offense.

In addition, the penalties listed in entry 107 may apply.

106. TRANSACTIONS WITH UNLICENSED ENTITIES

California Business and Professions Code Sections 22980.1, 22981 15 United States Code Section 1335a

Scope: No entity shall sell tobacco products to or purchase tobacco products from an entity that is illegally operating without a license or that has a suspended or revoked license. No entity shall acquire any package of cigarettes to which the required tax stamp or meter impression may not be properly affixed or that fails to comply with federal ingredient reporting provisions.

Enforcement: The state Board of Equalization is authorized to enforce this law. Local law enforcement agencies have the general authority to enforce this law under California Penal Code Section 830.1.

PENALTY: Violators are guilty of a misdemeanor punishable by a fine not to exceed \$5,000 and/or imprisonment not to exceed 1 year.

In addition, the penalties listed in entry 107 may apply.

107. ADMINISTRATIVE PENALTIES APPLICABLE TO ALL LICENSEES

California Business and Professions Code Sections 22974.7, 22978.7, 22979.7

Scope: In addition to any other penalties, violators of the California Cigarette and Tobacco Products Licensing Act of 2003, sections 22970–22991 of the California Business and Professions Code, are subject to administrative penalties (see entries 98–106 for summaries of relevant provisions of the California Cigarette and Tobacco Products Licensing Act).

As of January 1, 2017, retailers of electronic smoking devices are required to comply with licensing requirements under state law (see entries 98–100 and 105–106 for more information about these requirements).

Enforcement: The state Board of Equalization (BOE) is authorized to enforce this law.

PENALTY: The BOE may for a first offense, revoke or suspend a license; and for a second or subsequent offense, revoke or suspend a license, and impose a civil penalty not to exceed the greater of 5 times the retail value of the seized tobacco products or \$5,000.

Note: These provisions apply to retailers, distributors, wholesalers, manufacturers and importers.

California Business and Professions Code Section 22980.3

Scope: In addition to any other fines or penalties, violators of the tobacco tax laws or the California Cigarette and Tobacco Products Licensing Act of 2003, sections 22970–22991 of the California Business and Professions Code, may have their licenses suspended or revoked. After having received notice of suspension or revocation, violators may not sell, gift, or display for sale cigarettes or other tobacco products (see entries 95 and 98–106 for

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summaries of relevant provisions of the tobacco tax laws and the California Cigarette and Tobacco Products Licensing Act).

As of January 1, 2017, retailers of electronic smoking devices are required to comply with licensing requirements under state law (see entries 98–100 and 105 to 106 for more information about these requirements).

Enforcement: The state Board of Equalization (BOE) is authorized to enforce this law.

PENALTY: For a first conviction, the penalty is a written notice from the BOE detailing the suspension and revocation provisions of this law, and the BOE at its discretion may suspend the license for up to 30 days. For a second conviction within 4 years, the license shall be revoked, but a previously licensed applicant may apply for a new license 6 months after a revocation. Violations at one location are not counted against other locations of that same licensee or against a new owner at the same licensed location. Each day of continued sales without a valid license after notification by a law enforcement agency that a valid license is required constitutes a separate violation.

California Business and Professions Code Sections 22974.4, 22978.6

Scope: The license of a retailer, distributor, or wholesaler shall be revoked if (1) the license holder has been convicted of a felony pursuant to California Revenue and Taxation Code Sections 30473 (see entry 96) or 30480 (see entry 92); or (2) the license holder has had any permit or license revoked under any provision of the California Revenue and Taxation Code.

As of January 1, 2017, retailers of electronic smoking devices are required to comply with licensing requirements under state law (see entries 98–100 and 105–106 for more information about these requirements).

Enforcement: The state Board of Equalization is authorized to enforce this law.

PENALTY: Revocation of the license.

108. BOARD OF EQUALIZATION LICENSING DATABASE

California Business and Professions Code Sections 22973.2, 22978, 22979.3

Scope: Upon request, the state Board of Equalization shall provide its database of licenses issued to retailers, distributors, wholesalers, manufacturers, and importers to the California Department of Public Health, the state Attorney General, a law enforcement agency, or any agency authorized to enforce local tobacco control laws. The database may be used only for the purposes of enforcing tobacco control laws, and its use must adhere to all state laws, policies, and regulations governing the use of personal information and privacy.

Enforcement: Not applicable.

PENALTY: Not applicable.

109. MANUFACTURER CERTIFICATION

California Revenue and Taxation Code Sections 30165.1(b), 30165.1(c)(5), 30165.1(m)

Scope: A manufacturer must make an annual certification to the state Attorney General (AG) that it has signed the Master Settlement Agreement or has complied with California law regarding nonparticipating manufacturers. The certification must include a complete list of brand families.

For each manufacturer that has submitted the required certification, the AG shall provide a written acknowledgment of receipt within 7 business days. In turn, each manufacturer shall provide to each distributor to whom it sells or ships cigarettes a copy of the AG's receipt.

Enforcement: The state Board of Equalization and the AG are authorized to enforce this law.

PENALTY: False certifications knowingly made are a misdemeanor punishable by a fine of not more than \$1,000 and/or imprisonment for up to 1 year.

In addition, the penalties listed in entry 107 may apply.

California Revenue and Taxation Code Sections 30165.1(b), 30165.1(m)

Scope: Manufacturers located outside the United States must provide the state Attorney General (AG) with current contact information for all importers that sell their cigarettes in California, and must require these importers to provide the AG with copies of a valid importer permit issued by the U.S. Treasury and a valid importer license issued by the state Board of Equalization (BOE). Nonparticipating manufacturers who are newly qualified or whom the AG deems to pose an elevated risk for noncompliance must file a surety bond with the AG in favor of the state, in an amount equal to the greater of \$50,000 or the amount of escrow the manufacturer was required to deposit as a result of the largest of its most recent 5 calendar years' sales in California.

Enforcement: The BOE and the AG are authorized to enforce this law.

PENALTY: Any person who makes a certification pursuant to this subdivision that asserts the truth of any material matter that he or she knows to be false is guilty of a misdemeanor punishable by imprisonment of up to 1 year in the county jail, or a fine of not more than \$1,000, or both the imprisonment and the fine.

California Revenue and Taxation Code Sections 30165.1(c)-(l)

Scope: The state Attorney General (AG) shall publish and maintain a website directory listing manufacturers that have complied with the required certification and listing all certified brand families of the manufacturer. No one shall affix a tax stamp or meter impression to any package of cigarettes unless the brand family is included in the AG's directory. No one shall sell, offer, possess for sale, or import for personal consumption cigarettes of a brand family not included in the AG's directory. No one shall acquire, hold, own, possess, transport, or import cigarettes that the person knows or should know are intended to be distributed in

violation of the requirement that tax stamps and meter impressions may only be affixed to packages of cigarettes whose brand families are included on the AG's directory.

ENFORCEMENT: The state Board of Equalization (BOE) and the AG are authorized to enforce this law.

PENALTY: A violation constitutes a misdemeanor. In addition, distributors who violate this law are subject to a license revocation or suspension for a first offense. For a second or subsequent offense, the BOE may revoke or suspend the distributor's license and may impose a civil penalty not to exceed the greater of 5 times the retail value of the seized cigarettes or \$5,000.

In addition, the penalties listed in entry 107 may apply.

110. RECORD-KEEPING: THE TOBACCO CONTROL ACT

21 United States Code Sections 333, 372, 387t

21 Code of Federal Regulations Section 1100.3

Scope: The U.S. Department of Health and Human Services (HHS) must issue regulations regarding how any person who manufactures, processes, transports, distributes, receives, packages, holds, exports, or imports tobacco products should establish and maintain records. Some records must be furnished for inspection upon request by the government to aid an investigation about illicit trade, smuggling, or a counterfeit product.

EXCEPTION: Retailers do not have to maintain records for individual purchasers who purchase tobacco products for personal consumption. HHS must have the express written consent of an Indian tribe before inspecting records located in Indian country.

Enforcement: HHS is authorized to enforce this provision with the help of other federal agencies and state governments. The HHS Secretary may also consult with the U.S. Attorney General and the Secretary of the Treasury. Manufacturers and distributors of a tobacco product must notify the Attorney General and the Secretary of the Treasury if they have knowledge of illegal transactions.

PENALTY: Any person who violates this provision shall be subject to a civil penalty of up to \$15,000 for each violation and up to \$1 million for multiple violations ruled on in a single proceeding.

111. REGISTRATION OF TOBACCO ESTABLISHMENTS: THE TOBACCO CONTROL ACT

21 United States Code Sections 333, 372, 387e

21 Code of Federal Regulations Section 1100.3

Scope: Owners and operators engaged in the manufacture, preparation, compounding, or processing of a tobacco product sold or distributed must register their establishments,

both foreign and domestic, with the U.S. Department of Health and Human Services (HHS). Registration information shall be made available to the public.

Note: By December 31, 2016, the U.S. Food and Drug Administration (FDA) requires registration by all manufacturers and importers (to the extent that they repackage or change the packaging of any tobacco product) of tobacco products, including cigarettes, smokeless tobacco, electronic nicotine delivery systems containing anything made or derived from tobacco, cigars, pipe tobacco, hookah tobacco, gels, and dissolvables. At this time, the FDA plans to enforce registration requirements only for manufacturers and importers of newly-deemed *finished* tobacco products (see the overview on page 7 for more information about the FDA's deeming rule).

Enforcement: HHS is authorized to enforce this provision with the help of other federal agencies and state governments.

PENALTY: Any person who violates this provision shall be subject to a civil penalty of up to \$15,000 for each violation and up to \$1 million for multiple violations ruled on in a single proceeding.

112. USER FEES: THE TOBACCO CONTROL ACT

21 United States Code Sections 333, 372, 387s

21 Code of Federal Regulations Sections 1100.3, 1150

Scope: Tobacco manufacturers and importers must pay a quarterly fee that is earmarked for tobacco regulation activities. The annual fee varies by fiscal year and class of tobacco products.

Note: In order to assist the FDA in calculating user fees, domestic tobacco manufacturers and importers of certain classes of products are required monthly to submit information to the FDA (formerly submitted to the USDA) about product units removed into commerce and taxes paid per class of product. For example, no later than August 20, 2016, the FDA requires manufacturers and importers of newly deemed cigars and pipe tobacco to submit data to calculate fees and payments.

Enforcement: The U.S. Department of Health and Human Services is authorized to enforce this provision with the help of other federal agencies and state governments.

PENALTY: Any person who violates this provision shall be subject to a civil penalty of up to \$15,000 for each violation and up to \$1 million for multiple violations ruled on in a single proceeding.

113. REQUIRED DISCLOSURES TO THE U.S. FOOD AND DRUG ADMINISTRATION (FDA): THE TOBACCO CONTROL ACT

21 United States Code Sections 333, 372, 387, 387d, 387i, 387o

15 United States Code Section 1333

21 Code of Federal Regulations Sections 1100.3, 1150

Scope: Manufacturers and importers of cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco must provide the Food and Drug Administration (FDA) with:

- 1. A list of the ingredients used in each product;
- 2. A description of content, delivery, and form of nicotine;
- 3. A list of smoke constituents that are harmful or potentially harmful to health (HPHCs) and reports of required testing; and
- 4. All documents related to health, toxicological, behavioral, or physiological effects.

As of August 8, 2016, manufacturers and importers of newly deemed finished tobacco products, including cigars, pipe tobacco, hookah tobacco, gels, dissolvables, and electronic nicotine delivery systems containing anything made or derived from tobacco, are required to submit lists according to a schedule based on their release dates. The FDA has released a chart with the effective and compliance dates applicable to retailers, manufacturers, importers, and distributors of newly deemed tobacco products, available at www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm500778.htm (see the overview on page 7 for more information about the FDA's deeming rule):

EXCEPTIONS: Small manufacturers of tobacco products shall be exempt from testing and reporting requirements regarding tobacco product constituents, ingredients, and additives either for 2 years after final regulations are issued or when a compliance date is set by HHS for all other tobacco product manufacturers, whichever is later.

There are also reporting requirement exemptions for product manufacturers determined by the FDA to be "small scale." For products on the market on August 8, 2016, ingredient lists are due by August 8, 2017 for small-scale product manufacturers (a 6 month delay). Tobacco health documents are due August 8, 2017, for small-scale product manufacturers (a 6 month delay).

Note: At the request of the Department of Health and Human Services (HHS), tobacco manufacturers and importers must furnish any or all documents relating to particular research activities. In addition, tobacco product manufacturers or importers must maintain records and provide information to HHS upon request to assure that a tobacco product is not adulterated or misbranded, and to otherwise protect public health.

Note: In April 2012, the FDA issued a notice establishing a list of tobacco product constituents that the agency believes are harmful or potentially harmful to health. The notice includes the criteria the FDA used to develop the list and the reasons the FDA may add or remove constituents from the list. 77 Fed. Reg. 20,034 (Apr. 3, 2012). At the time of

publication, the FDA was gradually phasing in enforcement, starting with 20 constituents for which testing is already widely available. The FDA prepared guidance on this abbreviated list of harmful or potentially harmful constituents that tobacco product manufacturers and importers must report. Draft Guidance for Industry: Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under Section 904(a)(3) of the Federal Food, Drug, and Cosmetic Act (Mar. 2012), www.fda.gov/downloads/TobaccoProducts/ GuidanceComplianceRegulatoryInformation/UCM297828.pdf.

This guidance likely will be changed and/or withdrawn as the FDA begins to more fully enforce this provision.

Note: In order to assist the FDA in calculating user fees, domestic tobacco manufacturers and importers of certain classes of products are also required monthly to submit information to the FDA (formerly submitted to the USDA) about product units removed into commerce and taxes paid per class of product.

Enforcement: HHS is authorized to enforce this provision with the help of other federal agencies and state governments.

PENALTY: Any person who violates this provision shall be subject to a civil penalty of up to \$15,000 for each violation and up to \$1 million for multiple violations ruled on in a single proceeding.

Any person who intentionally violates this provision shall be subject to a civil monetary penalty of up to \$250,000 per violation and up to \$1 million for multiple violations ruled on in a single proceeding. If violations continue after HHS provides written notice, the violator is subject to a penalty of \$250,000 for the first 30-day period, which doubles every 30 days thereafter that the violation continues, up to \$1 million in any 30-day period or \$10 million for all such violations ruled on in a single proceeding.

MASTER SETTLEMENT AGREEMENT (MSA) FUNDS

114. MSA PAYMENTS

Master Settlement Agreement (MSA) Sections IX, XI, VII(c); Exhibit A, VII

Scope: Under the MSA between the major tobacco companies and the attorneys general of 46 states, the settling companies are responsible for making annual payments to the settling states in perpetuity. These payments are distributed to the states based on formulas agreed to in the MSA.

Note: In recent years, California has usually received between \$700 and \$750 million per year (it received \$1.1 billion in 2013). Half of that money is allocated to the state and half to local governments within the state.

Enforcement: The state Attorney General (AG) may enforce these provisions.

PENALTY: The AG may seek a court order to enforce the provisions or stop a violation of the provisions. If such an order is violated, the AG may pursue monetary compensation, civil contempt charges, or criminal sanctions. The parties must first attempt to resolve alleged violations through discussion.

115. MSA BONDS

California Government Code Sections 63049-63049.55

Scope: California law allows state and local governments to generate revenue by selling tobacco bonds that are backed by the future flow of payments to the state by tobacco companies as required by the Master Settlement Agreement (MSA) (see entry 114 for a summary of the MSA payments).

Note: State and local agencies can use the proceeds to fund capital improvement projects and health care programs and facilities. There is no limit on the amount of tobacco securitization bonds that can be issued. From 2001 to 2007, state and local governments in California issued bonds totaling \$16.8 billion. See Cal. Debt and Investment Advisory Commission, Issue Brief: Tobacco Securitization Bond Issuance in California (June 2009), www.treasurer.ca.gov/cdiac/reports/tobacco.pdf. Some local governments have elected to borrow against expected future payments but haven't guaranteed to cover their debt with general fund revenue.

EXCEPTION: The sale of state tobacco bonds does not affect MSA funding received by California local governments.

Enforcement: Not applicable.

PENALTY: Not applicable.

116. APPEAL BONDS

California Health and Safety Code Section 104558

Scope: In a civil lawsuit involving a tobacco company that has signed the Master Settlement Agreement (MSA) or that involves a successor or affiliate of such a company, the amount of the bond to be furnished during the course of an appeal shall not exceed 100% of the verdict or \$150 million, whichever is less. The stated purpose of the appeal bond cap is to secure the funds owed to the state by tobacco companies as required by the MSA.

EXCEPTION: If the opposing party proves by a preponderance of the evidence that a tobacco company is intentionally dissipating or diverting assets outside the ordinary course of its business for the purpose of avoiding ultimate payment of the judgment, the cap may be lifted and the court may order any actions necessary to prevent dissipation or diversion of the assets.

Enforcement: The court shall set the amount of the appeal bond.

PENALTY: Not applicable.

RELATED

117. PRESERVATION OF STATE AND LOCAL AUTHORITY: THE TOBACCO CONTROL ACT

21 United States Code Section 387p

21 Code of Federal Regulations Section 1100.3

Scope: State and local governments are permitted to enact more stringent restrictions related to the sale, distribution, possession, use, availability, or advertising and promotion of tobacco products, including electronic nicotine delivery systems. The Tobacco Control Act also does not limit the existing ability of state and local governments to regulate the reporting of information to the state, fire safety standards for tobacco products, and taxation of tobacco products.

EXCEPTION: State and local governments cannot enact restrictions that are different from or in addition to the provisions in the Tobacco Control Act regarding tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products.

Enforcement: Not applicable.

PENALTY: Not applicable.

118. ADDITIONAL REGULATIONS: THE TOBACCO CONTROL ACT

21 United States Code Sections 372, 387f

21 Code of Federal Regulations Section 1100.3

Scope: The U.S. Department of Health and Human Services (HHS) may issue additional regulations restricting the sale and distribution of tobacco products, including restrictions on advertising and promotion. Regulations must be appropriate for the protection of the public health, which should be determined with respect to the risks and benefits to the population as a whole, taking into account whether individuals will likely either stop or start using tobacco products.

EXCEPTION: Federal regulations may not limit the sale or distribution of a tobacco product to prescription by licensed medical professionals; prohibit the sale of a tobacco product in face-to-face transactions by a specific category of retail outlets; or raise the minimum age for the sale of tobacco products above the age of 18.

Note: Restrictions on the advertising or promotion of a tobacco product must be consistent with the First Amendment to the U.S. Constitution.

Enforcement: HHS is authorized to enforce this provision with the help of other federal agencies and state governments.

PENALTY: Not applicable.

119. ADVISORY COMMITTEE: THE TOBACCO CONTROL ACT

21 United States Code Section 387q

Scope: The U.S. Department of Health and Human Services shall appoint 12 people to a Tobacco Products Scientific Advisory Committee (Advisory Committee) to provide advice, information, and recommendations. The members will include 7 individuals from the medical, dental, scientific, and health care industries; 1 government employee; 1 member of the general public; and 3 nonvoting members representing the tobacco manufacturing industry, the small business tobacco manufacturing industry, and tobacco growers.

EXCEPTION: Full-time employees of the U.S. Food and Drug Administration or any agency responsible for enforcing the Tobacco Control Act may not be appointed to this Advisory Committee.

Note: In 2011, 2 tobacco companies, Lorillard and R.J. Reynolds, challenged the make-up of the Advisory Committee, claiming that several members were biased against the tobacco industry and should not be allowed to continue to serve in this capacity. While the companies were initially successful and the committee was enjoined for a time, *Lorillard, Inc. v. United States Food & Drug Admin.*, 56 F. Supp. 3d 37 (D.D.C. 2014), ultimately the court of appeals held that the harms alleged by the companies were too remote and uncertain, and approved the make-up of the Committee. *R.J. Reynolds Tobacco Co. v. United States Food & Drug Admin.*, No. 14-5226 (D.C. Cir. Jan. 15, 2016).

Enforcement: Not applicable.

120. FEDERAL AMERICANS WITH DISABILITIES ACT (ADA)

42 United States Code Sections 1981a, 2000e-5, 12101–12213, 12181-12182 28 Code of Federal Regulations Part 36, Appendices A, C

Scope: The federal Americans with Disabilities Act (ADA) prohibits discrimination against a person with a disability. 42 United States Code Section 12112(a). The law applies to public entities, including schools and public transportation, employers with at least 15 employees, and entities that operate places of public accommodation as defined in the federal regulations, such as social service center establishments, restaurants, hotels, and theaters.

Note: The ADA does not apply to private housing, which is covered by the federal Fair Housing Act (entry 121).

The ADA defines a *disability* as: (1) a physical or mental impairment that substantially limits one or more of a person's major life activities; (2) a record of having such an impairment; or (3) being regarded as having such an impairment. Breathing is specifically listed as one of the major life activities covered by the ADA and a major life activity is also defined as the operation of a major bodily function, including respiratory functions.

An impairment that is episodic or in remission is a disability if it would substantially limit a *major life activity* when active. Even if the person's breathing is substantially improved through the use of oxygen therapy equipment, he or she would still be considered disabled under the ADA.

Note: For example, a person may be disabled under the ADA if he or she has chronic obstructive pulmonary disease or severe asthma, which substantially limits breathing. *Equal Employment Opportunity Comm'n v. Supervalu, Inc.*, 674 F. Supp. 2d 1007, (N.D. Ill. 2009).

Under the ADA, employers must provide reasonable accommodation to the known physical or mental limitations of an otherwise qualified individual with a disability who is an applicant or employee unless that accommodation causes an undue hardship. In addition, places of public accommodation may not deny patrons with disabilities an equal opportunity to enjoy the goods, services, facilities, privileges, advantages, or accommodations of such a place.

Note: The ADA may be used by a person with a respiratory disability to enforce existing laws against smoking. For example, a California restaurant owner who knowingly allows smoking in the restaurant in the presence of an employee or patron with severe asthma may be violating the ADA, in addition to other laws.

Enforcement: Employees and tenants may file a complaint with the Equal Employment Opportunity Commission (EEOC) or with the California Department of Fair Employment and Housing (DFEH). The EEOC and DFEH are obligated to investigate the complaint. A private lawsuit may be filed if the EEOC and DFEH do not file an action based on the complaint. Patrons who believe a business has violated the ADA may also file a private lawsuit.

PENALTY: Available penalties include financial penalties (limited based on the number of employees), injunctive relief (a court order to stop the violation of the ADA), and attorneys' fees.

121. FEDERAL FAIR HOUSING ACT (FHA)

42 United States Code Sections 1437f, 3601–3619 24 Code of Federal Regulations Sections 100.200–100.205

Scope: The federal Fair Housing Act (FHA) prohibits discrimination based on handicap, which is defined as (1) a physical or mental impairment that substantially limits a person's major life activities; (2) a record of having such an impairment; or (3) being regarded as having such an impairment.

Note: The U.S. Department of Housing and Urban Development (HUD) has ruled that multiple chemical sensitivity disorder and environmental illness could qualify as a handicap under the FHA. HUD Memorandum, *Multiple Chemical Sensitivity Disorder and Environmental Illness as Handicaps*, doc. no. GME-0009 (Mar. 5, 1992), www.hud.gov/offices/adm/hudclips/lops/GME-0009LOPS.doc. A person may have a handicap under the

FHA if he or she is hypersensitive to tobacco smoke. *Vickers v. Veterans Administration*, 549 F. Supp. 85, 86–87 (W.D. Wash. 1982).

If a resident has a disability under the law, the FHA requires landlords and condominium associations to make reasonable accommodations in rules, practices, policies, and services that provide the resident with a disability an equal opportunity to use and enjoy the housing.

Note: Examples of reasonable accommodations that a tenant with a respiratory disability might request include: allowing the tenant to move to a vacant apartment to avoid exposure to drifting smoke; allowing the tenant to break a lease without penalty; or implementing a no-smoking policy for common areas or units.

The FHA applies to most private and federal government housing, including Section 8 housing.

Note: Section 8 housing refers to federal programs offering low-income housing assistance through payments to private landlords.

EXCEPTION: The law may not apply to buildings with 4 or fewer units if the owner lives on site or to single-family homes sold or rented by the owner.

Enforcement: Individuals may file a complaint with HUD or a state agency which is its substantial equivalent (California Department of Fair Employment and Housing) within 1 year of the discrimination and/or file a lawsuit in federal district court within 2 years of the discrimination.

PENALTY: Available relief includes actual damages, injunctive relief (a court order to stop the violation of the law), attorneys' fees, civil penalties, and other relief as appropriate.

122. CALIFORNIA FAIR EMPLOYMENT AND HOUSING ACT (FEHA)

California Government Code Sections 12900-12996

Scope: The state Fair Employment and Housing Act (FEHA) prohibits discrimination based on physical disability, mental disability, or medical condition. Under section 12926(k) of the law, a physical disability includes physiological and anatomical conditions that limit a person's ability to participate in major life activities.

Note: FEHA's definition of physical disability is broader than the definition in the federal Americans with Disabilities Act (ADA), which requires a disability to substantially limit a major life activity (see entry 120 for a summary of the ADA).

Note: A person may be disabled under FEHA if he or she is hypersensitive to tobacco and tobacco exposure interferes with a major life activity, such as breathing. *See County of Fresno v. Fair Employment & Housing Comm'n*, 226 Cal. App. 3d 1541, 1548–1550 (1991).

Under FEHA, both private and public employers with 5 or more employees must engage in an interactive process to determine what accommodation is reasonable. These employers

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must provide reasonable accommodation for the known physical or mental disability of an applicant or employee, unless that accommodation causes an undue hardship.

Note: FEHA may be used by an employee with a respiratory disability to enforce existing laws against smoking. For example, a California restaurant owner who knowingly allows smoking in the restaurant in the presence of an employee with severe asthma may be violating FEHA, in addition to other laws.

FEHA also applies to most housing accommodations, which are defined in sections 12927(d) and 12955 as any building, structure, or portion of a structure occupied or intended for occupancy as a residence by 1 or more families, and any vacant land that is offered for sale or lease for the construction of such buildings. FEHA requires landlords and condominium associations to make reasonable accommodations and/or modifications of policies for residents with disabilities in order to ensure equal access to and enjoyment of their housing.

Note: Examples of reasonable accommodations that a tenant with a respiratory disability might request include: allowing the tenant to move to a vacant apartment to avoid exposure to drifting smoke; allowing the tenant to break a lease without penalty; or implementing a no smoking policy for common areas and/or units.

Enforcement: Individuals may file a complaint with the California Department of Fair Employment and Housing (DFEH) and/or file a lawsuit in state court; however, before filing a lawsuit in state court individuals must exhaust administrative remedies by filing a complaint with DFEH and obtaining a right-to-sue notice.

PENALTY: Available relief includes actual damages, injunctive relief (a court order to stop the violation of the law), prospective relief (ongoing remedies to correct past illegal practices), attorneys' fees, and other relief as appropriate.

123. CALIFORNIA UNRUH CIVIL RIGHTS ACT

California Civil Code Sections 51-51.3

Scope: The state Unruh Civil Rights Act (Unruh Act) applies to all business establishments in California, including housing and public accommodations, and prohibits discrimination based on physical disability, mental disability, or medical condition, among other protected statuses. The Unruh Act's definitions of physical disability, mental disability, and medical condition mirror the definitions in the state Fair Employment and Housing Act (FEHA) (see entry 122 for more information about FEHA's definition of physical disability).

Note: While FEHA covers discrimination in employment and housing, the Unruh Act covers discrimination in housing and public accommodations. The Unruh Act requires full and equal accommodations, advantages, facilities, privileges, and services in all business establishments.

Enforcement: Individuals may file a complaint with the California Department of Fair Employment and Housing (DFEH) and/or file a lawsuit in state court. The Unruh Act is

different from FEHA in that it is not necessary for individuals to exhaust administrative remedies prior to filing a lawsuit in state court. Individuals do not need to obtain a right-to-sue notice from DFEH before filing a lawsuit.

PENALTY: Available relief includes actual damages, injunctive relief (a court order to stop the violation of the law), attorneys' fees, and other relief as appropriate.

124. PROPOSITION 65

California Health and Safety Code Sections 25249.6-25249.13

Scope: The state Safe Drinking Water and Toxic Enforcement Act of 1986 requires notification to the public about exposure to chemicals known to the State of California to cause cancer or reproductive toxicity. This law applies to exposure to tobacco smoke. Warnings need not be made to each exposed individual. Instead, warnings may be provided by general methods such as posting clear and reasonable notices or labels on consumer products. The law requires businesses with at least 10 employees to post warnings when they knowingly or intentionally expose an individual to a chemical on the list.

Exception: The law applies only to exposures that are made knowingly and intentionally.

Enforcement: Actions may be brought by the state Attorney General, a district attorney, a city attorney of a city with a population larger than 750,000, a city prosecutor in any city having a full-time city prosecutor (with the consent of the district attorney), or an individual acting in the public interest.

PENALTY: Violators may be subject to an injunction to stop the violation and are liable for a civil penalty not to exceed \$2,500 per day for each violation.

125. UNFAIR COMPETITION LAW

California Business and Professions Code Sections 17200-17209

Scope: It is illegal to engage or propose to engage in an unfair, unlawful, or fraudulent business act or practice.

Note: This general law can be used as a mechanism to enforce many tobacco control laws that affect businesses, since a business that violates a tobacco control law is presumed to be in violation of the unfair competition law. For example, the law has been used against retailers who sell tobacco to underage individuals in violation of California Penal Code Section 308 (see entry 25 for a summary of Penal Code Section 308).

Enforcement: Actions may be brought by the state Attorney General, a district attorney, or, with the consent of the district attorney in certain cases, by a county counsel, city attorney, or city prosecutor. Actions also may be brought by anyone who has suffered injury in fact and has lost money or property as a result of the unfair competition.

PENALTY: Violators are subject to an injunction to stop the behavior and a civil penalty of up to \$2,500 for each violation.

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126. MEDI-CAL CESSATION, PREVENTION, AND EDUCATION SERVICES

California Welfare and Institutions Code Sections 14134.25, 15810-15818

Scope: Once appropriate federal approvals have been obtained, tobacco cessation services are covered benefits under the Medi-Cal program, starting January 1, 2017. The program covers medically necessary quit attempts, including 4 counseling sessions and FDA-approved treatment regimens. California requires the Medi-Cal Access Program under the Department of Social Services to develop protocols and to provide additional prevention and health education services relating to tobacco use.

Enforcement: Not specified.

PENALTY: Not specified.

127. PATIENT PROTECTION AND AFFORDABLE CARE ACT

42 United States Code Sections 300u-11, 300gg, 1395w-102(e), 1396d, 1396o, 1396r-8(d) (2)(E), 1396r-8(d)(7)(A), 1397e, 1397r-8

45 Code of Federal Regulations Sections 150.101(b)(1)-(2), 150.201, 150.301

Scope: The federal Patient Protection and Affordable Care Act (PPACA) generally expands tobacco cessation coverage in most health insurance plans. Specific requirements vary based on the type of health insurance. The PPACA and related federal materials provide the following guidance.

Private, Employer-Sponsored, and Marketplace Insurance: Health insurance plans provided by an employer, purchased through a PPACA Marketplace, or purchased directly from an insurer.

- These plans must provide coverage for tobacco cessation at no cost to the patient. This requirement does not apply to grandfathered plans in existence prior to March 23, 2010.
- Plans can satisfy this requirement by, for example, covering at least 2 cessation attempts per year, with each attempt including, at minimum, coverage for 4 counseling sessions and a 90-day supply of all U.S. Food and Drug Administration (FDA)-approved cessation medications. U.S. Dept. of Labor, FAQs About Affordable Care Act Implementation (Part XIX), Q5 (May 2014), www.dol.gov/ebsa/faqs/faq-aca19.html.

Medicare: Medicare is a public health insurance program that provides coverage for most individuals ages 65 or older, as well as certain individuals with disabilities.

- Medicare Part B covers up to 8 tobacco cessation counseling sessions per year. Centers
 for Medicare & Medicaid Services, Smoking & tobacco use cessation (counseling to
 stop smoking or using tobacco products), www.medicare.gov/coverage/smoking-andtobacco-use-cessation.html.
- Medicare Part D also covers prescription tobacco cessation drugs.
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Medicaid: Medicaid is a public health insurance program for many low-income populations, people with disabilities, and pregnant women. Medicaid limits eligibility based on an individual's income and assets; these limitations vary among the states.

- In all states, Medicaid covers tobacco cessation therapy and doctor-approved cessation medications for pregnant women and for people under the age of 21. Centers for Medicare & Medicaid Services, *Dear State Medicaid Director Letter, SDL # 11-007* (June 2011), https://downloads.cms.gov/cmsgov/archived-downloads/SMDL/downloads/SMD11-007.pdf.
- State Medicaid programs are prohibited from *excluding* coverage for tobacco cessation drugs. Centers for Medicare & Medicaid Services, *Medicaid Drug Rebate Program Notice Release No. 165* (Sept. 2013), www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Prescription-Drugs/Downloads/Rx-Releases/State-Releases/state-rel-165. pdf.
- In states expanding Medicaid under the PPACA, individuals in the expansion population, as well as other Medicaid beneficiaries receiving coverage through an Alternative Benefits Package, must receive coverage for tobacco cessation at no cost to the patients. Medicaid programs can satisfy this requirement by, for example, covering at least 2 cessation attempts per year, with each attempt including, at minimum, coverage for 4 counseling sessions and a 90-day supply of all FDA-approved cessation medications. U.S. Department of Labor, FAQs About Affordable Care Act Implementation (Part XIX), Q5 (May 2014), www.dol.gov/ebsa/faqs/faq-aca19.html.
- Medi-Cal, California's Medicaid program, provides nearly all beneficiaries coverage for tobacco cessation services, including counseling and FDA-approved cessation medications. Cal. Department of Health Care Services, *Policy Letter 14-006* (Sept. 2014), www.dhcs.ca.gov/formsandpubs/Documents/MMCDAPLsandPolicyLetters/PL2014/ PL14-006.pdf.

Under the PPACA, health insurers are permitted to vary their premium rates on the basis of tobacco use. However, California Insurance Code sections 10753.14 and 10965.9 allow insurers in the individual and small-group markets to use only age, geographic region, and family size for the purposes of establishing premium rates. As a result, in California, these insurers cannot charge an individual a higher premium based on the individual's tobacco use. The prohibition on differential premiums does not apply to certain "grandfathered" health care plans that were in effect on March 23, 2010.

The PPACA establishes a Prevention and Public Health Fund to be administered by the U.S. Department of Health and Human Services (HHS), which is made available to individual communities for tobacco prevention and other public health programs on a competitive basis. Information about funding distribution is available at www.hhs.gov/open/recordsandreports/prevention/.

ENFORCEMENT: Various federal and state agencies have oversight of different types of health plans covered by the PPACA.

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Related Laws

Generally, states have primary authority to enforce PPACA provisions against health insurance issuers, and the federal Centers for Medicare and Medicaid Services (CMS) has secondary enforcement authority. In California, under Chapter 2.2 of the Health and Safety Code, the state Department of Insurance and Department of Managed Health Care oversee private health insurance plans. The California Department of Health Care Services oversees Medi-Cal, California's Medicaid program.

At the federal level, the CMS has primary authority to enforce PPACA provisions against plans issued through nonfederal government employers (eg, state governments), Medicare, and Medicaid. The HHS, Department of Labor, Department of the Treasury, and the Internal Revenue Service also share oversight of private health insurance plans. U.S. Dept. of Labor, Affordable Care Act Implementation Frequently Asked Questions, www.dol.gov/ebsa/healthreform/regulations/acaimplementationfags.html.

PENALTY: Penalties vary for the different federal, state, and local actions affected by the requirements of the PPACA. If a health plan overseen by CMS fails to comply with federal requirements, the agency may impose civil fines on the health insurance issuer. Individual states determine the penalties for noncompliance by plans within their oversight. For example, sections 1386-1389 and 1390-1394.3 of California's Health and Safety Code authorize a variety of penalties for noncompliance with state and/or federal requirements, including civil (eg, fines), criminal (eg, jail), administrative (eg, revoking a license to sell insurance), and equitable remedies (eg, a court-ordered injunction).

128. TRICARE SMOKING CESSATION PROGRAM

32 Code of Federal Regulations Section 199.4(e)(30)

Scope: On February 27, 2013, the U.S. Department of Defense issued regulations regarding a smoking cessation program under TRICARE, which provides health benefits for military personnel, military retirees, and their dependents. The regulations state that smoking cessation medications are available through TRICARE at no cost to the beneficiary, and that TRICARE covers individual and group cessation counseling. Beneficiaries also have access to a toll-free quit line and web-based resources. Beneficiaries are entitled to 2 quit attempts per 12-month period. A third quit attempt may be covered with physician authorization.



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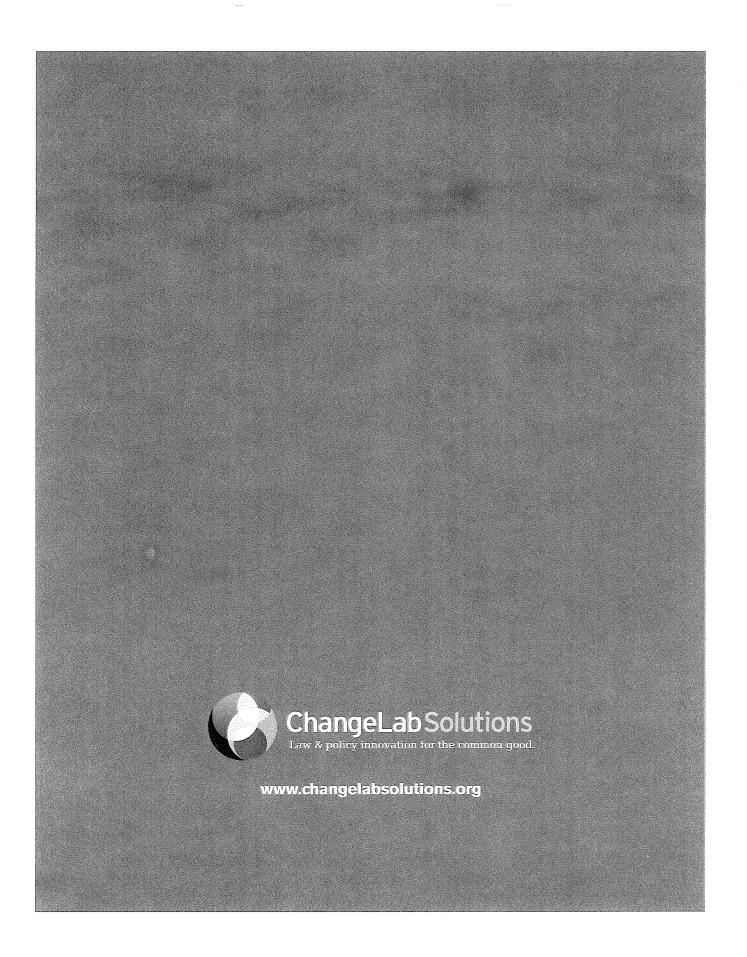
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Carroll, John (BOS)

From:

Somera, Alisa (BOS)

Sent:

Tuesday, June 13, 2017 4:22 PM

To:

Carroll, John (BOS): Major, Erica (BOS)

Subject:

FW: SF Chamber Letter on File No. 170441

Attachments:

6.13.17 Delay Action on File No. 170441, Banning Sale of Flavored Tobacco Products.pdf

Categories:

170441

For file

From: Calvillo, Angela (BOS)

Sent: Tuesday, June 13, 2017 2:35 PM

To: Somera, Alisa (BOS) <alisa.somera@sfgov.org> Subject: FW: SF Chamber Letter on File No. 170441

For the file, thx.

From: Alexander Mitra [mailto:amitra@sfchamber.com]

Sent: Tuesday, June 13, 2017 2:05 PM

To: Ronen, Hillary < hillary.ronen@sfgov.org>

Cc: Calvillo, Angela (BOS) <angela.calvillo@sfgov.org>; Elliott, Nicole (MYR) <nicole.elliott@sfgov.org>; Tugbenyoh, Mawuli (MYR) <mawuli.tugbenyoh@sfgov.org>; Fewer, Sandra (BOS) <sandra.fewer@SFGOV1.onmicrosoft.com>; Farrell, Mark (BOS) <mark.farrell@sfgov.org>; Peskin, Aaron (BOS) <aaron.peskin@sfgov.org>; Tang, Katy (BOS) <katy.tang@sfgov.org>; Breed, London (BOS) <london.breed@sfgov.org>; Kim, Jane (BOS) <jane.kim@sfgov.org>; Yee, Norman (BOS) <norman.yee@sfgov.org>; Sheehy, Jeff (BOS) <jeff.sheehy@sfgov.org>; Cohen, Malia (BOS) <malia.cohen@sfgov.org>; Safai, Ahsha (BOS) <ahsha.safai@sfgov.org>

Subject: SF Chamber Letter on File No. 170441

Dear Supervisor Ronen,

Please see the attached letter from the San Francisco Chamber of Commerce requesting that the Public Safety and Neighborhood Services Committee delay action on file number 170441.

Thank you,



Alex Mitra

Manager, Public Policy San Francisco Chamber of Commerce 235 Montgomery St., Ste. 760, San Francisco, CA 94104 (O) 415-352-8808 • (E) amitra@sfchamber.com

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June 13, 2017

The Honorable Hillary Ronen, Chair Board of Supervisors Public Safety and Neighborhood Services Committee 1 Dr. Carlton B. Goodlett Place, Room 244 San Francisco, CA 94102

RE: File No. 170441, Banning Sale of Flavored Tobacco Products

Dear Supervisor Ronen:

The San Francisco Chamber of Commerce, representing over 2,500 local businesses with over 200,000 employees, urges the Public Safety and Neighborhood Services Committee to delay action on the above noted ordinance further regulating the sale of tobacco products to adults.

While the health impacts from the use of tobacco products are well known and both the State of California and City of San Francisco have taken significant steps to discourage smoking, especially underage smoking, at some point local prohibitions will constitute a "taking" of businesses selling legal products.

The pending ordinance will give retailers only a matter of a few months to adjust their flavored tobacco inventories to these new prohibitions on product sales. Beyond the issue of stock on hand, a retailer's entire business model may need to change in order to generate sufficient cash flow to meet the financial needs of his or her business. Before you threaten the livelihood of retailers in every neighborhood of the city, the Chamber urges you and your colleagues to look at other Bay Area legislation that, unlike this ordinance, takes into account the fiscal impact of tobacco sales regulations on small businesses.

Please do not lose sight of the fact that sufficient regulations are in place to control underage sale and use and funds exist to continue California's robust anti-smoking campaign. We urge you to consider the financial needs of a significant component of neighborhood retail in San Francisco before further hindering small retailers' ability to operate their businesses.

Sincerely,

Jim Lazarus

Senior Vice President of Public Policy

San Francisco Chamber of Commerce

cc: Mayor Ed Lee, Clerk of the Board to be distributed to all members of the Board of Supervisors

Carroll, John (BOS)

From:

Board of Supervisors, (BOS)

Sent:

Tuesday, June 13, 2017 10:34 AM

To:

BOS-Supervisors; Carroll, John (BOS)

Cc:

Major, Erica (BOS)

Subject:

Letter regarding File 170441

Attachments:

Letter regarding File No. 170441.pdf

Hello,

The Office of the Clerk of the Board is in receipt of the attached letter from The California Independent Oil Marketers Association (CIOMA) regarding File No. 170441.

Regards,

Board of Supervisors

1 Dr. Carlton B. Goodlett Place, City Hall, Room 244

San Francisco, CA 94102-4689

Phone: (415) 554-7703 | Fax: (415) 554-5163 Board.of.supervisors@sfgov.org | 415-554-5184





California Independent Oil Marketers Association

3835 North Freeway Blvd., Suite 240

Sacramento, CA 95834-1955

916,646,5999

June 9, 2017

San Francisco County Board of Supervisors 1 Dr. Carlton B. Goodlett Place San Francisco, CA 94102-4689

RE: Proposed Ordinance 17-0441, Version 1 - OPPOSE

Dear Members of the San Francisco Board of Supervisors:

The California Independent Oil Marketers Association (CIOMA) writes to express our opposition to the proposed tobacco ordinances before the Board, which would restrict the issuance of new tobacco retail licenses and add restrictions to the sale of tobacco products. We believe this is an overreach and could result in various unintended consequences that not only impact retailers, but the County as well.

CIOMA is the statewide trade association representing the fuel distribution supply chain in California all the way down to the community convenience stores. CIOMA represents about 300 members, including nearly 90% of all the independent petroleum marketers in the state and about one quarter of the state's 10,000 service stations. Petroleum marketers, also known as jobbers, buy fuel at a major oil company's terminal rack and distribute it to their customers. These customers are local governments, law enforcement, city and county fire departments, ambulances/emergency vehicles, school district bus fleets, construction firms, marinas, public and private transit companies, hospital emergency generators, trucking fleets, independent fuel retailers (small chains and mom-and-pop gas stations) and California agriculture, among others.

Convenience store owners operate on slim margins and rely on high-volume foot traffic. The proposed tobacco ban ordinance could force the closure of hundreds of locations throughout the Bay Area and put 3,911 of your constituents out of work. Further, the local impact to the county will be deeply felt given that convenience stores generate over \$885 million dollars in revenue within the county, and pay over \$65 million in labor expenses.

Tobacco Retail License Restrictions

The ordinance proposed for adoption would establish density and distance restrictions on tobacco retailers in the County. No new tobacco retailers would be allowed within 1,000 feet of a school or within 500 feet of an existing tobacco retailer. Existing retailers that currently operate within 500 feet of each other would be allowed to continue to operate. However, should one of these retailers decide to sell their business, the new owner would lose the right to sell tobacco. The ordinance also caps the number of tobacco retailers to 90 existing licensees. All these prohibitions will undoubtedly stunt economic growth as our members factor a number of elements when making decisions about where to grow and set up new stores. Taking away the ability for a potential new business to sell tobacco creates a significant disincentive for any company to consider coming into the County who also risks losing valuable sales tax revenues to neighboring jurisdictions that are more permissive of tobacco sales.

Sales Restriction on Flavored Tobacco Products

Our members support sensible solutions to address the illegal sale of tobacco to minors, but we strongly question whether banning the sale of flavored tobacco products will actually reduce youth smoking and overall smoking rates. The proposed ordinance inherently ignores the fact that our members provide employee training as a way of prevent youth from gaining access to tobacco. Failure to comply with these rules come with harsh consequences and our members take this issue very seriously.

It is imprudent to level accusations that retailers are the cause of youth access to tobacco products. Just this year, California restricted the sale of tobacco products to persons under the age of 21 and imposes heavy fines on retailers that violate the law. This new law means that a customer has to have been an "adult" for three years prior to being legally able to purchase tobacco products.

Furthermore, a 2016 study by the U.S. Food and Drug Administration confirmed that the vast majority of youth under the age of 17 obtain tobacco products from "social sources," including older friends, adult siblings and parents. And, lastly, on top of our own procedures and in-house undercover stings, the California Department of Public Health, California Tobacco Control Program 2015 Report indicates that retailers have about a 95%, or better, compliance rate for not selling products to California's youth.

CIOMA urges that Board to refrain from passing a hasty, and misdirected ordinance that will hurt the family- and minority-owned businesses in their communities.

Sincerely,

RYAN HANRETTY Executive Director,

CIOMA

From:

Board of Supervisors, (BOS)

Sent: To: Monday, June 12, 2017 10:09 AM BOS-Supervisors; Major, Erica (BOS)

Subject:

FW: 170441

Hello,

Thank you for your letter. I have sent it to the Board Members and it will appear in the Petitions and Communications section of our June 20, 2017 agenda. Looping in the Public Safety and Neighborhood Services Clerk to add to the official file.

Regards,

Board of Supervisors 1 Dr. Carlton B. Goodlett Place, City Hall, Room 244 San Francisco, CA 94102-4689 Phone: (415) 554-7703 | Fax: (415) 554-5163 Board.of.supervisors@sfgov.org | 415-554-5184

From: sbardell@aol.com [mailto:sbardell@aol.com]

Sent: Sunday, June 11, 2017 9:22 PM

To: Board of Supervisors, (BOS) <board.of.supervisors@sfgov.org>

Subject: 170441

Honorable Supervisors:

Given that my first appearances before this honorable board on this general topic occurred in the '80s, I hope I may be forgiven for being somewhat incredulous that I'm still posting messages such as this:

Please--for all the excellent scientific reasons you already know--vote to recommend banning all flavored tobacco products.

Surely no one still alive argues that such a ban will "hurt the poor!"

Thank you for your kind attention. I regret being unable to appear before you in person.

Sincerely,

Serena Bardell 1922 Filbert St San Francisco CA 94123 accountability and answers to no one and thus could do pretty much whatever they want.

In the last 15 years at SF DEM I have had 10 Directors and Deputy Directors who were in charge. Several of them were effective – sadly most were not. Every single one of said Directors was appointed by the Mayor and had an agenda which usually involved leaving for a better job elsewhere in a year or so. The one constant under all of those directors was SF DEM management; specifically HR, Maria Luna and Cecile Soto.

Maria and Cecile have been in charge at DEM for decades and under their rule it has continued to decline. For some insane reason the highly educated mayoral appointees have embraced their "knowledge" and their info and listened to Maria and Cecile. Maria is a bully and Cecile is an idiot and HR does whatever inappropriate, often illegal plan they hatch up. They display the most rigid and inflexible attitude and refuse to think outside the box. They foster an environment of racism, favoritism and abuse.

(For example: My biggest suggestion for 911 staffing was to have light duty firefighters return to the dispatch floor and work the fire side-this would go a long way to alleviate staffing shortages. As taking over the fire dispatching initially was Maria Luna's baby – she has always refused to consider it as an option – preferring instead to work the thinning dispatchers even more mandatory overtime).

We have begged for management to step in and answer calls – they were all once dispatchers – they also refused that as well – and just scheduled the dispatchers for more hours and days in a row. They refuse to even contemplate alternative or flexible schedules – their only solution to the staffing problem is to mandatory dispatchers more and more. This creates those under them to become sick, injured, and leave for other jobs. Management at SF DEM has created a hostile work environment – they have unfair practices that see some rewarded and not others, they play favorites, they are drunk with their own power. They take advantage of the system – taking 2 hour lunches, sitting in the break room for hours at time while the 911 bell is ringing...taking hundreds of smoke breaks a week, etc. Management treats the dispatchers as 2nd class citizens, one step above slaves actually.

I left SF DEM because of the management. I have counseled many of my co workers to do the same. The economy is doing well, there are many places paying competitive wages – people have options. Why stay somewhere where they are being abused?

If you want the truth at SF DEM – pay them a visit. DON'T talk to management. DON'T talk to the select few dispatchers management directs you to - roam the room – talk to random dispatchers. They will tell you the truth. Start at the top (and yes, Robert Smuts hasn't been a good fit – given his inability to make decisions good or bad) really clean house with management. That is the first step in making SF DEM a quality and happy place for people to spend a majority of their hours, days, weeks, months and years.

 $Good\ Luck\ with\ everything-you\ are\ going\ to\ need\ it.\ I\ am\ glad\ it\ is\ no\ longer\ my\ problem.$

Sincerely, Kellie Crumbliss

kelcrumbliss@att.net 415.233.1675

PS In the last several years SF DEM has had numerous employees who have requested to work part time. They were told no and as a result they quit all together. Since the short staffing has once again been brought to the attention of the Supervisors and the Mayor – several of my co workers have asked to return in a part time capacity and were told no by HR. Can the city really afford to be turning anyone away? You can talk about fixing DEM all you want to - but until you have full disclosure, accountability and cooperation from the management and HR at SF DEM – the problem won't be solved.

From:

Board of Supervisors, (BOS)

Sent:

Monday, June 12, 2017 12:56 PM

To: Cc: heilig@sfmms.org

CC.

Major, Erica (BOS)

Subject:

FW: Ban on Flavored Tobacco Products, Including Menhol - Support from San Francisco

Marin Medical Socidety - File No. 170441

Attachments:

Tobacco.pdf

Hello,

Thank you for your email. It will appear in the Petitions and Communications section of our June 20, 2017 agenda. Looping in the Public Safety and Neighborhood Services Clerk to add to the official file.

Regards,

Board of Supervisors

1 Dr. Carlton B. Goodlett Place, City Hall, Room 244

San Francisco, CA 94102-4689

Phone: (415) 554-7703 | Fax: (415) 554-5163 Board.of.supervisors@sfgov.org | 415-554-5184

From: Steve Heilig [mailto:heilig@sfmms.org]

Sent: Monday, June 12, 2017 10:59 AM

To: Cohen, Malia (BOS) <malia.cohen@sfgov.org>; Breed, London (BOS) <london.breed@sfgov.org>; Farrell, Mark (BOS) <mark.farrell@sfgov.org>; Tang, Katy (BOS) <katy.tang@sfgov.org>; Kim, Jane (BOS) <jane.kim@sfgov.org>; Wiener, Scott <scott.wiener@sfgov.org>; Yee, Norman (BOS) <norman.yee@sfgov.org>; Fewer, Sandra (BOS) <sandra.fewer@SFGOV1.onmicrosoft.com>; Ronen, Hillary <hillary.ronen@sfgov.org>; Peskin, Aaron (BOS) <aaron.peskin@sfgov.org>; Safai, Ahsha (BOS) <ahsha.safai@sfgov.org>; Sheehy, Jeff (BOS) <jeff.sheehy@sfgov.org> Cc: Board of Supervisors, (BOS) <box down to supervisors@sfgov.org>

Subject: Ban on Flavored Tobacco Products, Including Menhol - Support from San Francisco Marin Medical Socidety

June 9, 2017

RE: Sale of Flavored Tobacco Products;

Sponsors: Cohen; Safai, Breed, Farrell, Sheehy, Tang and Yee.

Dear Supervisors:

The San Francisco Marin Medical Society strongly supports a ban on sale of flavored tobacco products, including menthol, being sold in San Francisco.

In fact, we have supported such a policy for years, and convinced the California Medical Association to do likewise: our proposal to them resulted in their statement that "CMA supports a full ban on menthol additives in tobacco products in order to curb smoking."

You will no doubt hear the many reasons why this is an important public health policy. We want you to know that the medical community is very much in agreement that this is a policy whose time has come.

For the health of San Franciscans, we urge you to adopt this proposed ordinance, which is firmly in line with our city's long history of minimizing harm from tobacco.

Thank you very much.

Sincerely,

Man-Kit Leung, MD President

STEVE HEILIG, MPH (415)561-0850x270
San Francisco Marin Medical Society http://www.sfimms.org



June 9, 2017

RE: Sale of Flavored Tobacco Products;

Sponsors: Cohen; Safai, Breed, Farrell, Sheehy, Tang and Yee.

Dear Supervisors:

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You will no doubt hear the many reasons why this is an important public health policy. We want you to know that the medical community is very much in agreement that this is a policy whose time has come.

For the health of San Franciscans, we urge you to adopt this proposed ordinance, which is firmly in line with our city's long history of minimizing harm from tobacco.

Thank you very much.

Sincerely,

Man-Kit Leung, MD President From:

Board of Supervisors, (BOS)

Sent:

Thursday, June 08, 2017 4:26 PM

To:

BOS-Supervisors; Major, Erica (BOS)

FW: Proposed Tobacco Ordinance File No. 170441

Subject: Attachments:

CRA Letter SF June 2017.pdf

From: Angie Manetti [mailto:amanetti@calretailers.com]

Sent: Thursday, June 08, 2017 3:50 PM

To: Board of Supervisors, (BOS) < board.of.supervisors@sfgov.org>

Subject: Proposed Tobacco Ordinance

Good afternoon,

On behalf of the California Retailers Association, please accept our comments for the proposed tobacco ordinance for the record.

Sincerely,

Angie Manetti Director of Government Affairs California Retailers Association 980 Ninth Street, Suite 2100 Sacramento, CA 95814

P: (916) 443-1975 F: (916) 443-4218

E: amanetti@calretailers.com



June 8, 2017

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

Re: Proposed Tobacco Retail License Ordinance File No. 170441

Dear Members of the Board of Supervisors:

The California Retailers Association (CRA) writes to express our concerns with the proposed tobacco retail license ordinance before the Board, which would prohibit the sale of menthol cigarettes and flavored tobacco.

The California Retailers Association is the only statewide trade association representing all segments of the retail industry including general merchandise, department stores, mass merchandisers, restaurants, convenience stores, supermarkets and grocery stores, chain drug, and specialty retail such as auto, vision, jewelry, hardware and home stores. CRA works on behalf of California's retail industry, which currently operates over 418,840 retail establishments with a gross domestic product of \$330 billion annually and employs 3,211,805 people— one fourth of California's total employment.

CRA and our members support sensible solutions to address the illegal sale of tobacco to minors. In our collective commitment to that end, our members provide training to their employees and fully support the letter of the law. The proposed ordinance inherently ignores the fact that our members provide employee training as a way of prevent youth from gaining access to tobacco. Failure to comply with these rules comes with harsh consequences. Needless to say, our members take this issue very seriously.

This ordinance also ignores the fact that there are comprehensive state and local laws, that anti-tobacco advocates support as a means to curb youth access to tobacco, that are currently enforced. Namely, a local tobacco retail license that limits the distance of tobacco retailing 500 feet of schools and a cap on the number of licensees per supervisorial district. Collectively, with the new tobacco laws

approved last year to increase the minimum legal smoking age, tobacco retail license fees for renewal and additional locations, and a \$2 tax on tobacco products, we believe there are enough sufficient regulations in place to control potential illegal sales and use of these products.

If the ordinance goes into effect, it is also our concern that the County will lose valuable sales tax revenues to neighboring jurisdictions that do not have similar product bans in place. This policy has far-reaching unintended consequences and deserves closer scrutiny, especially given the City's projected budget deficit and \$5.5 billion in pension liabilities.

As you know, the retail industry is experiencing unprecedented upheaval. According to government data, over 89,000 jobs have been lost in general merchandise stores since last October. Ordinances that imposes a ban the sale of legal products throughout the City exacerbate an already challenging economic climate facing retailers and may lead to blight, higher unemployment and create an environment that encourages the black-market sale of tobacco products.

CRA is also concerned that the ordinance, if implemented, fails to provide impacted retailers with sufficient time to adjust their business models. The Healthy Retail SF program which has been in existence for over 4 years does not have sufficient funding to help retailers begin to attempt to change their business model as suggested by proponents. The program has only helped nine retailers offer more healthy choices and it does not ban products in their stores. The City of Berkeley limited its flavor ban to retailers within 600 feet of schools and provided impacted retailers 15 months-notice before enforcement. The Berkeley ordinance also provided impacted retailers the ability to obtain an exemption from the flavor ban for up to 3 years beginning January 1, 2017 if the retailer makes a showing that the application of the flavor ban would result in a taking.

For these reasons, CRA respectfully requests that you vote no on this ordinance. Should the Board move forward with this ordinance, we ask that consideration be given to adding provisions similar to Berkeley that only prohibit the sale of flavored tobacco in near schools and provide impacted retailers with 15 – 24 months before enforcement of the flavor ban.

Sincerely,

Angie Manetti

Director, Government Relations



BOARD OF SUPERINGSONS
2017 JUN -5 PM 3: 11

San Francisco Board of Supervisors 1 Dr. Carlton B. Goodlett Place City Hall, Room 244 San Francisco, Ca. 94102-4689

Dear Supervisors:

I own and operate a convenience store in the city. I am writing to express my opposition to the proposal that would ban menthol cigarettes and flavored tobacco products. Together, flavored tobacco is more than 1/3 of my overall tobacco sales. Approximately 40% of my overall business comes from tobacco sales. I carry these products because of adult customer demand. Like other retailers, I operate on a very thin profit margin. I don't make much money on these products, but they bring customers into my store and they buy other grocery items. That is why menthol cigarettes and flavored tobacco are an important part of my business and without them I would not be profitable.

Like virtually every other tobacco retailer in the city, I don't sell any tobacco products to minors and I have a perfect compliance rate. I doesn't make sense to say I am responsible enough to sell regular tobacco but not responsible enough to sell flavored tobacco. All tobacco products are behind the counter so minors don't have access to any tobacco products.

This ordinance is unnecessary. Last year the state adopted comprehensive restrictions on ecigarettes making them equivalent to tobacco and raised the age to sell all tobacco products to 21. The county already requires a tobacco license and limits the number of licenses in each supervisorial district. Please do not penalize law-abiding retailers who are selling legal products to adults.

A vast majority of independent markets are owned by minorities and immigrants to this country. Many of us are highly skilled professionals in our home countries, but we came to the United States as entrepreneurs and found convenience stores an opportunity to invest our life savings and raise our families. We also provide jobs to other recent immigrants looking for a new life in the U.S. If your intention is to hurt big tobacco, this ordinance misses its mark. It will destroy independent and minority-owned retail businesses that generate sales tax revenue for the city and provide local jobs.

I urge you to VOTE NO on this ordinance.

Sincerely,

SE, CA, 24108

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Musican Liguran & Dela 530 Maron st.

San Francisco Board of Supervisors 1 Dr. Carlton B. Goodlett Place City Hall, Room 244 San Francisco, Ca. 94102-4689

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A vast majority of independent markets are owned by minorities and immigrants to this country. Many of us are highly skilled professionals in our home countries, but we came to the United States as entrepreneurs and found convenience stores an opportunity to invest our life savings and raise our families. We also provide jobs to other recent immigrants looking for a new life in the U.S. If your intention is to hurt big tobacco, this ordinance misses its mark. It will destroy independent and minority-owned retail businesses that generate sales tax revenue for the city and provide local jobs.

I urge you to VOTE NO on this ordinance.

Sincerely, the Abeliable to Santransiseo Ca 94130

45 391-2299

3115

San Francisco Board of Supervisors 1 Dr. Carlton B. Goodlett Place City Hall, Room 244

San Francisco, Ca. 94102-4689

Dear Supervisors:

I own and operate a gas station in the city. I am writing to express my opposition to the proposal that would ban menthol cigarettes and flavored tobacco products. Together, flavored tobacco is more than 1/3 of my overall tobacco sales. Approximately 40% of my overall in-store business comes from tobacco sales and it helps drive gasoline sales. I carry these products because of adult customer demand. I don't make much money on these products, but they bring customers to my gas station and they buy other grocery items. That is why menthol

Like virtually every other tobacco retailer in the city, I don't sell any tobacco products to minors and I have a perfect compliance rate. I doesn't make sense to say I am responsible enough to sell regular tobacco but not responsible enough to sell flavored tobacco. All tobacco products are behind the counter so minors don't have access to any tobacco products.

cigarettes and flavored tobacco are an important part of my business.

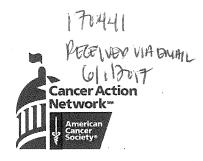
This ordinance is unnecessary. Last year the state adopted comprehensive restrictions on ecigarettes making them equivalent to tobacco and raised the age to sell all tobacco products to 21. The county already requires a tobacco license and limits the number of licenses in each supervisorial district. Please do not penalize law-abiding station owners who are selling legal products to adults.

My retirement and life savings are invested in my store. My family and I have sacrificed a great deal to make this business profitable and this ordinance threatens everything we have worked for. If your intention is to hurt big tobacco, this ordinance misses its mark. It will destroy minority-owned and independent gas stations that generate gas and sales tax revenue for the city and provide local jobs.

I urge you to VOTE NO on this ordinance.

Sincerely.

Silver Gas & Diesel 2400 San Bruno Alle San Francisco Co 94134



May 2, 2017

The Honorable Ed Lee 1 Dr. Carlton B. Goodlett Place City Hall, Room 244 San Francisco, CA 94102

Dear Mayor Lee and Members of the San Francisco Board of Supervisors:

The American Cancer Society Cancer Action Network is committed to protecting the health and well-being of the citizens of San Francisco through evidence-based policy and legislative solutions designed to eliminate cancer as a major health problem. As such, we are writing to support passage of the proposed amendment to the San Francisco tobacco retail license (TRL), which will prohibit sales of flavored tobacco products.

The 2014 Surgeon General's Report found that more than 43 million Americans still smoke, and tobacco will cause an estimated 480,000 deaths this year in the U.S. Of the 9 million youth currently living in our state, nearly 1.4 million of them will become smokers, and approximately 440,000 of those kids will die prematurely as a result of tobacco use.

In 2009, Congress, prohibited the sale of cigarettes with flavors other than tobacco or menthol. Tobacco companies responded by expanding the types of non-cigarette flavored tobacco products they offer, and now make most of those products available in a growing array of kidfriendly flavors. Little cigars, smokeless tobacco, and e-cigarettes are marketed in a wide array of sweet flavors and colorful packaging that appeals to youth. According to the California Department of Public Health, young people are much more likely to use candy and fruit flavored products than adults. Prohibiting the sale of flavored tobacco products, including menthol cigarettes, helps to remove some of the appeal of these products to beginning smokers.

Adolescents are still going through critical periods of brain growth and development, and they are especially vulnerable to the toxic effects of nicotine. Both opponents of smoking and purveyors of cigarettes have long recognized the significance of adolescence as the period during which smoking behaviors are typically developed. Tobacco companies have a long

American Cancer Society Cancer Action Network
700 Main Street, Suite 102 Fairfield CA 94533 707.290,0003

history of marketing to vulnerable populations, and target youth with imagery and by marketing appealing flavors. This has been particularly true in the African American population. In African American communities, the tobacco industry has aggressively marketed menthol flavored tobacco products to youth. More than 80% of African American smokers smoke menthol cigarettes, and African American men have the highest death rates from lung cancer, when compared to other demographic groups. The anesthetizing effect of menthol masks the harshness of tobacco, making menthol cigarettes more appealing to beginning smokers, and menthol smokers demonstrate greater dependence, and are less likely to quit.

While cigarette smoking has declined in the U.S., sales of menthol cigarettes have steadily increased in recent years, especially among young people and new smokers. Prohibiting the sale of flavored tobacco products can help to keep kids from ever starting to smoke, and can encourage those who do smoke to quit. We should be doing everything we can to protect young people from ever establishing this deadly addiction, and the cancer it causes, as well as supporting those who are trying to quit. ACS CAN appreciates San Francisco's leadership in bringing this issue forward, and we encourage the Board of Supervisors to pass this amendment to prohibit the sale of all flavored tobacco products in the City of San Francisco.

Sincerely,

Cassie Rav

Cassie Ray

Government Relations Director, Northern California American Cancer Society Cancer Action Network From:

Board of Supervisors, (BOS)

Sent:

Thursday, June 01, 2017 12:23 PM

To:

BOS-Supervisors; Major, Erica (BOS)

Subject:

FW: Support of Prohibiting the Sale of Flavored Tobacco - File No. 170441

Attachments:

San Francisco Flavors.pdf

From: Cassie Ray [mailto:cassie.ray@cancer.org]

Sent: Thursday, June 01, 2017 11:12 AM

To: Board of Supervisors, (BOS) <board.of.supervisors@sfgov.org>

Subject: Support of Prohibiting the Sale of Flavored Tobacco

Dear Mayor Lee and Members of the San Francisco Board of Supervisors:

Tobacco use remains the leading cause of preventable death in the U.S., and sadly, most people become addicted as youth—before they are even old enough to legally purchase tobacco—and most begin with flavored products. The tobacco industry has a long history of targeting vulnerable populations, especially young people in low income neighborhoods, communities of color and LGBTQ communities. Flavors, including menthol, are an important strategy used by the tobacco industry, whose own documents call these "starter products."

Attached is a letter urging a yes vote, in favor of prohibiting the sale of all flavored tobacco products, including menthol, in the City of San Francisco.

Thank you for your leadership on this important health issue.

Cassie Ray | Northern California Government Relations Director

American Cancer Society Cancer Action Network, Inc.

700 Main Street Suite 102

Suisun City, CA 94585

Phone: 707.290.0003 | Mobile: 707.290.0003 | Fax: 916.447.6931

acscan.org









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From:

Maron, Michele < Michele. Maron@jti.com>

Sent:

Tuesday, May 09, 2017 5:14 PM

To:

Fewer, Sandra (BOS); hilary.ronen@sfgov.org; Sheehy, Jeff (BOS)

Cc:

Major, Erica (BOS); Somera, Alisa (BOS)

Subject:

Proposed Ordinance on Flavored Tobacco Products

Attachments:

050917_Ordinance170441_JTIUSA.pdf

Dear Members of the Public Safety and Neighborhood Services Committee:

On behalf of JT International U.S.A., Inc., a small manufacturer of tobacco products in the US, please find attached our opposition to proposed Ordinance 170441, which seeks to ban the sale of flavored tobacco products, including menthol.

We would be pleased to speak with you or any Public Safety and Neighborhood Services Committee staff members to provide further information on this important policy issue.

Thank you in advance for your time.

Best regards, Michele Maron

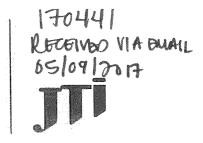
Michele Maron Manager Corporate Affairs & Communications

+12018082113 +12012745803 michele.maron@jti.com

JT International U.S.A., Inc. 500 Frank W Burr Blvd Suite 24, Teaneck, NJ 07666, USA

jti.com





TO:

San Francisco Board of Supervisors, Public Safety and Neighborhood Services

Committee

RE:

Potential ban of mentholated cigarette products

DATE:

May 9, 2017

Dear Supervisors:

JT International U.S.A., Inc. ("JTI USA"), a small manufacturer of tobacco products in the US, believes that tobacco products carry risks to health.

JTI also believes emphatically that:

- Minors should not smoke, and should not be able to obtain tobacco products.
- Adult smokers should be appropriately informed about the health risks of smoking before they begin smoking.

JTI USA supports appropriate and proportionate regulation which is based on evidence and sound science. However, the recently contemplated legislation, seeking to ban mentholated tobacco products in San Francisco, is not based on sound scientific evidence. There is no evidence that the use of menthol in tobacco products plays any role in minors' experimentation with smoking. Similarly, there is no evidence that smokers find it more difficult to quit tobacco products that contain menthol than those that do not. An outright ban on these products would thus amount to arbitrary regulation based on abstract concepts such as "attractiveness" or "appeal".

Menthol is used in a variety of foods, drugs and OTC health and cosmetic products such as chewing gum, cough drops, mouthwash and lip balms. JTI similarly uses ingredients, including menthol, to help ensure that its products meet the preferences of its adult consumers and to differentiate its products from those of its competition.

There is no evidence to suggest that menthol is "addictive". Nor does the available scientific evidence support such an assertion or conclusion:

- studies have repeatedly suggested that the inclusion of menthol has no effect on smoking prevalence, smoking behavior, or on quit rates; and
- mentholated cigarettes account for a much smaller market share than nonmentholated cigarettes.

JT International U.S.A., Inc. Glenpointe Centre West 500 Frank W. Burr Blvd. Suite 24 Teaneck, NJ 07666 U.S.A. 201 871 1210



If menthol cigarettes were in fact harder to quit, then logically you would expect them, over time, to enjoy a much greater market share than they do.

Despite years of investigating this issue, The Food and Drug Administration's (FDA's) Tobacco Products Scientific Advisory Committee (TPSAC) has not been able to produce science-based proposals to justify any menthol ban.

The FDA's TPSAC was tasked with investigating mentholated cigarettes and produced a report, which was invalidated as a result of a legal challenge.

That judgment concluded that the report was "at a minimum suspect and at worst untrustworthy" on the basis that members of the TPSAC committee had serious conflicts of interest.

With no science-based proposals to justify a menthol ban at a federal level, we believe it to be no different at a local level.

Finally, the proposed legislation will not work.

Prohibiting the sales of menthol cigarettes in San Francisco will simply push the existing demand for these products across the city limits, thus depriving the city and hardworking retailers of revenue.

At worst, this could open San Francisco up to illicit sales of menthol cigarettes by criminals, who have no regard for the law, regulatory compliance or age verification.

Rather than deny adult smokers the ability to legally purchase menthol cigarettes, we encourage the authorities to focus on enforcing the newly increased minimum purchase age restrictions to ensure that no minor can access or consume tobacco products.

It is on behalf of our employees, customers and adult consumers that we advocate this legislation be abandoned and we remain at your disposal to discuss any aspect of this letter. We look forward to being part of the debate around eradicating youth access to tobacco products in San Francisco.

Best regards,

Michele Maron

Corporate Affairs & Communications Manager

17044

From:

Roberts, Kevin < Kevin.Roberts@logicecig.com>

Sent:

Monday, May 01, 2017 4:26 PM

To:

Fewer, Sandra (BOS); Ronen, Hillary; Sheehy, Jeff (BOS)

Cc:

Major, Erica (BOS); Somera, Alisa (BOS)

Subject:

Concerning Opposition to Proposed Ordinance which seeks to ban flavored e-cigarettes

Attachments:

5 1 17 File 170441 Logic Opposition.pdf

Honorable Members of the Board of Supervisors Public Safety and Neighborhood Services Committee:

On behalf of Logic Technology Development, LLC, a New Jersey-based company and the third largest supplier of vapor products/electronic cigarettes in the country, please find attached correspondence detailing our opposition to File #170441, a proposed ordinance that seeks to ban the sale of flavored electronic cigarettes in San Francisco.

We would be pleased to meet or speak with you and/or an appropriate member of your staff(s), or any member or staff member of the Life Enrichment Committee, to provide further information at any stage on this important policy issue. Thank you in advance for your consideration.

Best, Kevin

Kevin Roberts
Director, Regulatory Affairs and Communications
Logic Technology Development, LLC
Kevin.Roberts@logicecig.com

Office: 609-525-4420 Mobile: 609-423-3406

,70441



May 1, 2017

VIA FAX & ELECTRONIC MAIL

Members of the San Francisco Board of Supervisors Public Safety and Neighborhood Services Committee:

Supervisor Sandra Lee Fewer, District 1

Supervisor Hillary Ronen, District 9

Supervisor Jeff Sheehy, District 8

Re: File # 170441; Proposed Ordinance banning the sale of flavored electronic cigarettes

Honorable Supervisors,

Logic Technology Development, LLC, headquartered in Princeton, New Jersey, is the third largest supplier of electronic cigarettes in the USA.

On behalf of our employees, customers, retailers and consumers, I am writing to state our opposition to the proposed legislation, File #170441, an ordinance that would ban the sale of flavored electronic cigarettes throughout the City of San Francisco.

Logic takes the issue of youth access seriously and believes, unequivocally, that minors under the legal purchase age should not have access to tobacco products or electronic cigarettes, irrespective of the flavor they are offered in. We support enforcement efforts and participate in efforts to bolster retail age of sale compliance training and educational resources as a member of the *WeCard* Manufacturer Advisory Council.

With respect to the proposed ban on flavored electronic cigarettes and other tobacco products, banning flavored electronic cigarettes will not achieve the policy objectives envisioned in the ordinance. Instead, these products will continue to be available for legal purchase outside city limits and on the internet. Ultimately this will only hurt San Francisco's small businesses, deprive adult smokers of alternatives to the known harms of combustible cigarettes, and subject consumers to the potential harm of an expanded underground and unregulated sales channel.

By forcibly removing these products from the shelves of responsible retailers, who act as a barrier to prevent underage sales, the bill will also potentially widen the access of minors to these products via illicit channels.

LOGIC 600 College Road East #1100 Princeton, NJ 08540 609-525-4420



Flavored electronic cigarette products have been developed to meet the preferences and demands of adult smokers who have decided to purchase these products as an alternative to combustible cigarettes. These adult smokers do not necessarily want an electronic cigarette that tastes identical to the products from which they are potentially trying to transition away, especially when it is inherently difficult to exactly replicate the flavor of a combustible cigarette in an electronic form.

This proposal would result in greater limitations of choice for adult consumers and undercut an emerging product that has been recognized among recent authoritative opinions which say that the use of e-cigarettes is likely to be less harmful to health than smoking.

A ban on flavored electronic cigarettes is not science based. This point is clearly illustrated by the fact that a ban runs counter to the approach that the FDA has set out in its own Deeming Rule that establishes Federal regulation over the electronic cigarette category. In that rule, the Agency acknowledged the lack of definitive data on flavored products and has instead adopted a "balanced" approach until the science is understood on the use of flavored products by adult smokers transitioning away from combusted tobacco use.

From Page 154 of the FDA's final Deeming Rule:

Over time, FDA expects to see additional data on the role of certain flavored products in supporting reduction in or abstinence from the use of combusted products, as well as further data on the role of flavored products in youth initiation, use, and dual use. Such data will help inform FDA's regulation of, and product standards for, these and other tobacco products.

The final rule published by the FDA acts accordingly, allowing flavored products to exist and to be evaluated in the context of the Agency's mandatory product review pathways for all newly regulated e-cigarette products wishing to remain on the market.

From Page 308 of the FDA's final Deeming Rule (emphasis added):

If additional evidence emerges that flavored [Electronic Nicotine Delivery Systems (ENDS)] make it more likely that smokers switch completely to ENDS, such evidence submitted as part of a PMTA would help support that application, as part of the analysis of whether the marketing of the product is appropriate for the protection of public health. Further, new data shows continued growth in youth and young adult usage of flavored tobacco products. FDA has balanced those concerns with preliminary data showing that some adults may potentially use flavored ENDS to transition from combusted tobacco use when developing the compliance policy for premarket review.



We urge you to abandon the current proposal that is not rooted in science or evidence, and to follow the FDA's lead in allowing the science and scientific consensus to develop on this subject, rather than act in haste with an arbitrary ban that lacks scientific justification.

In summary, it is clear that arbitrary restrictions on flavored electronic cigarettes, such as those contemplated by the proposed ordinance:

- Do not appear to be based on sound or complete science;
- Run counter to the FDA's own "balanced" approach in its treatment of flavored products, as it awaits further scientific review and data to become available;
- Ignore the clear demand that exists among adult smokers for these products;
- Will push demand for flavored products to where they are available, including underground suppliers in San Francisco, via the internet, and out-of-city jurisdictions where they will continue to remain legal;
- Will undoubtedly lead to an increase in unregulated and underground sales of these
 products, a reality that threatens to expose consumers to the far greater risk of acquiring
 products not held to product quality and safety standards; and,
- Will potentially push adult consumers from vapor products and electronic cigarettes back to the known harms of combustible tobacco product use.

The regulation of electronic cigarettes should primarily aim to keep products out of the hands of minors. Given that a minimum legal purchase age has been enacted for all ecigarettes, irrespective of flavor, we believe that it would be more appropriate and effective, at this time, for the City's leaders to ensure that these age restrictions are robustly enforced, including on the internet, rather than prohibiting flavored products.

We look forward to continued participation in this debate and would ask that the points we raise be taken into full consideration. We remain at your disposal to meet with you or your staff, or to provide further information at any stage.

Yours faithfully,

Anthony Hemsley

Head of Corporate Affairs

cc: Erica Major, Public Safety and Neighborhood Services Committee Clerk

BOARD of SUPERVISORS



City Hall
1 Dr. Carlton B. Goodlett Place, Room 244
San Francisco 94102-4689
Tel. No. 554-5184
Fax No. 554-5163
TDD/ITY No. 554-5227

MEMORANDUM

TO:	Youth Commission	
FROM:	Victor Young, Assistant Committee	ee Clerk
DATE:	May 11, 2017	
SUBJECT:	REFERRAL FROM BOARD OF	SUPERVISORS
Commission recommenda	is being referred as per Cha	lowing, which at the request of the Youth arter Section 4.124 for comment and vide any response it deems appropriate
File: 170441		
	amending the Health Code to pacco products, including menth	prohibit tobacco retailers from selling nol cigarettes.
	n this cover sheet with the Committee Clerk, Public Safety ar	ommission's response to Erica Major, nd Neighborhood Services.
******	·**********************************	**************
RESPONSE	FROM YOUTH COMMISSION	Date:
No Co	mment	
Recon	nmendation Attached	
		Chairperson, Youth Commission

BOARD of SUPERVISORS



City Hall
1 Dr. Carlton B. Goodlett Place, Room 244
San Francisco 94102-4689
Tel. No. 554-5184
Fax No. 554-5163
TDD/TTY No. 554-5227

MEMORANDUM

TO:

Regina Dick-Endrizzi, Director

Small Business Commission, City Hall, Room 448

FROM:

Erica Major, Assistant Clerk, Public Safety and Neighborhood Services

Committee, Board of Supervisors

DATE:

C:

April 24, 2017

SUBJECT:

REFERRAL FROM BOARD OF SUPERVISORS

Public Safety and Neighborhood Services Committee

The Board of Supervisors' Public Safety and Neighborhood Services Committee has received the following legislation, which is being referred to the Small Business Commission for comment and recommendation. The Commission may provide any response it deems appropriate within 12 days from the date of this referral.

File No. 170441

Ordinance amending the Health Code to prohibit tobacco retailers from selling flavored tobacco products, including menthol cigarettes.

Please return this cover sheet with the Commission's response to me at the Board of Supervisors, City Hall, Room 244, 1 Dr. Carlton B. Goodlett Place, San Francisco, CA 94102.

**************************************	**************************************
No Comment Recommendation Attached	
	Chairperson, Small Business Commission

Menaka Mahajan, Small Business Commission

BOARD of SUPERVISORS



City Hall
1 Dr. Carlton B. Goodlett Place, Room 244
San Francisco 94102-4689
Tel. No. 554-5184
Fax No. 554-5163
TDD/TTY No. 554-5227

MEMORANDUM

TO:

Myong Leigh, Interim Superintendent, San Francisco Unified School

District

Barbara A. Garcia, Director, Department of Public Health Mark Morewitz, Commission Secretary, Health Commission

FROM:

Erica Major, Assistant Clerk, Public Safety and Neighborhood Services

Committee, Board of Supervisors

DATE:

April 24, 2017

SUBJECT:

LEGISLATION INTRODUCED

The Board of Supervisors' Public Safety and Neighborhood Services Committee has received the following proposed legislation, introduced by Supervisor Cohen on April 18, 2017:

File No. 170441

Ordinance amending the Health Code to prohibit tobacco retailers from selling flavored tobacco products, including menthol cigarettes.

If you have any additional comments or reports to be included with the file, please forward them to me at the Board of Supervisors, City Hall, Room 244, 1 Dr. Carlton B. Goodlett Place, San Francisco, CA 94102.

c: Viva Mogi, San Francisco Unified School District Esther Casco, San Francisco Unified School District Danielle Houck, San Francisco Unified School District Greg Wagner, Department of Public Health Colleen Chawla, Department of Public Health

Introduction Form

By a Member of the Board of Supervisors or the Mayor



I her	eby submit the following item for introduction (select only one):	or meeting date			
\boxtimes	1. For reference to Committee. (An Ordinance, Resolution, Motion, or Charter Amendmen	nt)			
	2. Request for next printed agenda Without Reference to Committee.				
	3. Request for hearing on a subject matter at Committee.				
	4. Request for letter beginning "Supervisor] inquires"			
	5. City Attorney request.				
	6. Call File No. from Committee.				
	7. Budget Analyst request (attach written motion).				
	8. Substitute Legislation File No.				
	9. Reactivate File No.				
	10. Question(s) submitted for Mayoral Appearance before the BOS on				
	se check the appropriate boxes. The proposed legislation should be forwarded to the following Small Business Commission	ssion 1			
_					
L	n; Safai; Breed; Farrell; Sheehy; Tang				
Subject					
ž.	ance amending the Health Code to prohibit tobacco retailers from selling flavored tobacco problems of cigarettes	roducts, including			
The te	ext is listed below or attached:				
Attacl	ned.	1			
	Signature of Sponsoring Supervisor:				
For C	Clerk's Use Only:				

Page of