



City Attorney Dennis Herrera News Release

For Immediate Release:
March 19, 2019
Contact: John Coté
(415) 554-4710

Herrera, Walton introduce package of legislation to protect youth from e-cigarettes

Chicago and New York join SF in urging the FDA to review the safety of e-cigarettes; legislation would bar the sale of e-cigarettes in SF until FDA acts

SAN FRANCISCO (March 19, 2019) — City Attorney Dennis Herrera and Supervisor Shamann Walton today announced joint steps to curb the epidemic of youth e-cigarette use, which has erased more than a decade’s worth of progress in reducing youth tobacco consumption.

“San Francisco has never been afraid to lead,” Herrera said, “and we’re certainly not afraid to do so when the health and lives of our children are at stake. E-cigarettes have wiped out the hard-fought gains we have made in curbing youth tobacco use. Today we are taking action to protect our kids. By law, before a new tobacco product goes to market, the Food and Drug Administration is supposed to conduct a review to evaluate its impact on public health. Inexplicably, the FDA has failed to do its job when it comes to e-cigarettes. Until the FDA does so, San Francisco has to step up. These products should not be on our shelves until the FDA has reviewed the threat they pose to public health.”

“E-cigarettes have been targeting our young people with their colors and flavors that entice adolescents and predatorily pull them towards addiction to nicotine,” Supervisor Shamann Walton said. “Companies like Juul are contributing to increased numbers of people addicted to nicotine — people who would have never picked up a cigarette. Banning vaping products that target young people and push them towards addiction to nicotine and tobacco is the only way to ensure the safety of our youth.”

There are four major parts to this initiative:

- San Francisco, along with the City of Chicago and the City of New York, sent a letter to the FDA this morning demanding that the FDA do its job and immediately conduct the required public health review of e-cigarettes that, by law, was supposed to happen before these products were on the market. By a companion letter, San Francisco requests that the FDA

[MORE]

turn over records on an expedited basis to the City Attorney's Office to help San Francisco independently determine whether legal action against the FDA is needed if the agency fails to undertake the required public health review.

- In coordination with the City Attorney's Office, Supervisor Walton is introducing groundbreaking legislation at the Board of Supervisors today that would prohibit the sale in San Francisco of any e-cigarette that has not undergone FDA review. Under this legislation, any e-cigarette that is required to have, but has not received, FDA premarket review could not be sold at a store in San Francisco or bought online and shipped to a San Francisco address until the FDA completes its review and allows the products to be sold.

This is not an outright ban on e-cigarettes. It's a prohibition against any e-cigarettes that haven't been reviewed by the FDA to confirm that they are appropriate for the protection of public health. So far, no e-cigarettes have been put through the review process that is required by law. Instead, the FDA has proposed extending the deadline for e-cigarette companies to submit applications for premarket review, which would allow e-cigarette products to be on the market for 15 years without the required public health review.

- In coordination with the City Attorney's Office, Supervisor Walton is introducing a separate piece of legislation today that would prohibit the sale, manufacture and distribution of all tobacco products, including e-cigarettes, on City property in San Francisco, including Port property. The legislation would prevent another situation like e-cigarette company Juul Labs subleasing property on San Francisco's waterfront or any other City property. It would also prevent Juul from expanding on City property if doing so would result in the company engaging in the above prohibited activity.
- The City Attorney, as part of his review of Juul's operations, sent notice today to Juul and the Pier 70 developer seeking an explanation for why Juul holds a tobacco distributor license at that property when it has maintained that it "does not engage in the sale of cigarettes or tobacco products" on the premises.

"The FDA has simply failed to do its job in unprecedented fashion," Herrera said. "These are prudent steps to ensure that we know the health and safety implications of products being sold here. If the FDA hasn't reviewed it, it shouldn't be on store shelves in San Francisco."

Tobacco use is the leading cause of preventable disease and death in the United States. Tobacco kills more than 480,000 people a year in this country. That's more than AIDS, alcohol, car accidents, illegal drugs, murders and suicides combined.

The percentage of middle and high school students using tobacco products was at an all-time low in 2017. But last year, according to the Centers for Disease Control and Prevention, tobacco use among youth rose for the first time since the 1990s.

This dramatic reversal is directly attributable to the nationwide surge in e-cigarette use by adolescents.

In 2018, the number of middle and high school students who reported being current users of tobacco products increased 36%. Last year [4.9 million American students reported they were using](#)

[tobacco products, up from 3.6 million students in 2017. Use of e-cigarettes increased by 77.8% for high school students, and 48.5% for middle school students.](#)

“These companies may hide behind the veneer of harm reduction, but let’s be clear: their product is addiction,” Herrera said. “Like the cigarette companies, they are in the business of getting people addicted to nicotine or keeping them addicted to it. That’s particularly true when it comes to young people. Any purported health benefit of these devices over conventional cigarettes, even if proven at some point to be true for some smokers, is not an excuse to turn another generation of kids into addicts. Common-sense regulations to prevent youth addiction need to be in place — and should have been in place from the get go.”

Information about effective ways to quit smoking can be found at [smokefree.gov](#).

More information can be found on the City Attorney’s website: [www.sfcityattorney.org](#)

#



DENNIS J. HERRERA
Attorney

DIRECT DIAL: (415) 554-4748
E-MAIL: brittany.feitelberg@sfcityattorney.org

March 19, 2019

Dr. Scott Gottlieb
Commissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Dear Commissioner Gottlieb,

San Francisco, New York City, Chicago, and other cities and counties across the country face a crisis: the growing epidemic of e-cigarette use by middle and high school students that has already caused significant harm. Yet while the Food and Drug Administration (“FDA” or “Agency”) has criticized e-cigarette companies for fueling a teen vaping “epidemic,” it has largely failed to take action, giving e-cigarettes a marketplace to grow, resulting in the nicotine addiction of millions of children and teens. The Family Smoking Prevention and Tobacco Control Act (the “Tobacco Control Act”) grants the FDA exclusive jurisdiction to establish tobacco product standards, but the FDA has failed to conduct the health and safety review federal law requires before any new tobacco product can be placed on the market. We call on the FDA do its job, stop abdicating its statutory duty, and immediately conduct the review that by law was supposed to happen before these products went to market.

Tobacco use is the leading cause of preventable disease and death in the United States. Tobacco kills more than 480,000 people annually—more than AIDS, alcohol, car accidents, illegal drugs, murders, and suicides combined. And nearly all tobacco product use begins during youth or young adulthood. As a result, the Surgeon General, local governments, health advocates and others have undertaken enormous efforts to reduce youth tobacco use. Until recently those efforts were succeeding. Cigarette smoking among youth had steadily declined over the past two decades. The percentage of middle and high school students using conventional cigarettes and other tobacco products was at an all-time low in 2017. But last year tobacco use among youth rose for the first time since the 1990s. According to the Centers for Disease Control and Prevention (“CDC”), the number of middle and high school students who reported being current users of tobacco products increased 36%—from 3.6 million to 4.9 million students—between 2017 and 2018. This dramatic reversal is directly attributable to a nationwide surge in e-cigarette use by adolescents.

The health implications of this disturbing new trend are deeply troubling. Although there is evidence that e-cigarettes have the potential under certain circumstances to benefit adult smokers if used as a complete substitute for regular cigarettes, the Surgeon General has warned that e-cigarettes pose a significant health risk to young people. Nicotine exposure during adolescence can harm the developing brain—adversely impacting learning, memory, and attention—and can also increase risk for future addiction to other tobacco products and other drugs. Moreover, the aerosol that users inhale and exhale from e-cigarettes can potentially expose both themselves and bystanders to other harmful substances,

Letter to Dr. Scott Gottlieb
Page 2
March 19, 2019

including heavy metals, volatile organic compounds, and ultrafine particles that can be inhaled deeply into the lungs and cause long-term cardiovascular and pulmonary health harms.

The FDA has the authority and ability to curb this crisis. To date, it has not.

When Congress enacted the Tobacco Control Act in 2009, it gave the FDA expansive authority to protect public health by regulating tobacco products. Congress required that before a new tobacco product is introduced to the market, the FDA must conduct a premarket review to determine whether the product is beneficial to the population as a whole. If the FDA concludes that the tobacco product is appropriate for the protection of public health, it may issue an order permitting marketing of that product. Unless and until the FDA issues such an order, the product may not be legally marketed.

In 2016, the FDA deemed e-cigarettes a tobacco product subject to the Agency's jurisdiction. At that point, the FDA could have—and given that e-cigarettes were already known to be a gateway product for kids *should* have—removed e-cigarettes from the market until the Agency completed its required public health review. But it did not. Instead, it granted e-cigarette manufacturers until 2018 to submit their applications for premarket review, allowing a class of products that were known to be appealing and harmful to kids to stay on the market without any review. Then, in August 2017, the FDA announced, without any meaningful explanation, that it was extending the premarket review application deadline *another four years* until *August 2022*. The FDA recently issued draft guidance proposing enforcement priorities that it hopes will “prompt[]” manufacturers of *flavored* e-cigarette products to submit their applications a year early, and soliciting comments on whether it should accelerate the compliance date. But the FDA has not actually changed the application deadline, even for these flavored products that have been particularly popular among youth and pernicious to children's health. And even if the FDA did advance it to 2021, the deadline would still be more than two years away.

Accordingly, by the time e-cigarette manufacturers will be required to submit their premarket review applications, e-cigarettes—which first emerged in 2007—will have been on the market for fifteen years without any FDA analysis of their safety and alleged benefit. If current trends continue, up to *six million more* youth will begin using e-cigarettes between now and then. Put simply, due to the FDA's failure to exercise its responsibilities under the Tobacco Control Act, a generation of children will become addicted to nicotine, and thousands will die from preventable diseases.

In the face of the FDA's inaction, we are doing what we can as cities to address this crisis.

For example, Chicago has taken significant legislative action directed at preventing young people from obtaining and using e-cigarettes. Since 2013, Chicago has amended its municipal code to, among other things, prohibit the sale of flavored tobacco products, including e-cigarettes, within 500 feet of a school; prohibit e-cigarette use in all publicly accessible indoor areas, including bars, restaurants, and other workplaces; raise the minimum legal sales age for tobacco products, including e-cigarettes, from 18 to 21; impose a municipal tax on e-cigarettes and liquid nicotine products; and require that all tobacco displays, including of e-cigarette products, be entirely behind the counter. In 2015, through its Department of Public Health, Chicago launched a public education and social media campaign dedicated to informing youth and families about the dangers of e-cigarettes. More recently, Chicago launched an investigation into the marketing and sales of e-cigarettes and “e-juices” to young people, which thus far has resulted in lawsuits against more than thirty online purveyors of e-cigarettes.

Letter to Dr. Scott Gottlieb
Page 3
March 19, 2019

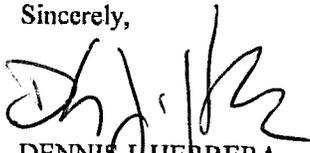
New York City has prohibited the use of e-cigarettes wherever smoking is banned by its Smoke Free Air Act, regulated where they are sold, and prohibited their sale to anyone under the age of 21. And, most recently, it extended its flavor ban to them.

San Francisco has amended its municipal code to, among other things: restrict the sale and use of electronic cigarettes in all places where traditional tobacco products are sold and used; prohibit the sale of all flavored tobacco products, including e-cigarettes, throughout the entire City; raise the minimum age for purchase of all tobacco products to 21; and impose a cap on the number of stores that sell tobacco products, including e-cigarettes, per neighborhood.

But Congress explicitly preempted state and local governments from conducting premarket reviews and preventing products that fail to meet public health standards from entering the national market. Accordingly, cities and counties—which end up shouldering many of the costs of medical care for tobacco related illnesses—need the FDA to do its job and fulfill its premarket review duties. As noted, the FDA's failure to do so has already placed millions of children at risk of addiction and disease. Millions more will follow if the FDA does not act now. The FDA must reconsider its compliance policy for e-cigarettes and immediately conduct the required premarket health and safety review.

Enclosed with this letter is a FOIA request seeking records regarding the FDA's decision to give e-cigarette manufacturers until 2022 to submit their applications for premarket review. We ask that you (1) expedite processing of that request under 28 C.F.R. Section 16.5(e), and (2) respond to this letter within 30 days, so that we may consider whether legal action will be necessary to force the FDA to fulfill its statutory duties and protect our youth.

Sincerely,



DENNIS J. HERRERA
City Attorney of San Francisco



EDWARD N. SISKEL
Corporation Counsel of the City of Chicago



ZACHARY W. CARTER
Corporation Counsel of the City of New York

cc: Mitch Zeller, Director Center for Tobacco Products



DENNIS J. HERRERA
City Attorney

Direct Dial: (415) 554-4878
Email: brittany.feltelberg@stcityatty.org

March 19, 2019

Via U.S. Mail and Fax

Food and Drug Administration
Division of Freedom of Information
Office of the Executive Secretariat, OC
5630 Fishers Lane, Room 1035
Rockville, MD 20857

Fax Number: (301) 827-9267

Re: Freedom of Information Act Request by the City and County of San Francisco

This is a request under the Freedom of Information Act, 5 U.S.C. § 552, for information and documents related to the decision by the Food and Drug Administration (the "FDA") to grant e-cigarette manufacturers until 2022 to submit their applications for premarket review. This request is made by the City and County of San Francisco ("San Francisco"). San Francisco also requests that the processing of this request be expedited, and that all fees associated with this request be waived.

This request concerns information of vital and urgent importance to the public. Tobacco use is the leading cause of preventable disease and death in the United States. Tobacco kills more than 480,000 people annually—more than AIDS, alcohol, car accidents, illegal drugs, murders and suicides combined. And nearly all tobacco product use begins during youth or young adulthood. As a result, the Surgeon General, local governments, health advocates and others have undertaken enormous efforts to reduce youth tobacco use. Until recently those efforts were succeeding. Cigarette smoking among youth had steadily declined over the past two decades. The percentage of middle and high school students using conventional cigarettes and other tobacco products was at an all-time low in 2017. But last year tobacco use among youth rose for the first time since the 1990s. According to the Centers for Disease Control and Prevention, the number of middle and high school students who reported being current users of tobacco products increased 36%—from 3.6 million to 4.9 million students—between 2017 and 2018. This dramatic reversal is directly attributable to a surge in e-cigarette use by adolescents.

Nonetheless, the FDA has given manufacturers of e-cigarettes until August 2022 to submit applications for premarket review, allowing a class of products that were known to be appealing to kids to stay on the market without any review. This means that by the time e-cigarette manufacturers will be required to submit their applications, e-cigarettes—which first emerged in 2007—will have been on the market for *fifteen years* without any FDA analysis of their safety and alleged benefit.

Accordingly, San Francisco requests copies of any and all records created on or after May 10, 2016, that discuss, identify or evaluate:

Freedom of Information Act Request
Page 2
March 19, 2018

(1) whether to extend the compliance date for “new, newly deemed finished [noncombustible] tobacco products that were on the market as of August 8, 2016”—including electronic nicotine delivery systems (“ENDS”)—to August 8, 2022 as set forth in Table 2 of “Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule” and

(2) whether to accelerate the compliance date for any ENDS to a date earlier than August 8, 2022.

Additionally, San Francisco requests a waiver of all fees for this request. Disclosure of the information described in this request is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government. *See* 5 U.S.C. § 552(a)(4)(A)(iii). In the event that its request for a fee waiver is denied, San Francisco is willing to pay fees for this request up to a maximum of \$1,000. If you estimate that fees for this request will exceed \$1,000, please inform me first. San Francisco seeks the information described in this request for noncommercial use; thus, fees for this request are limited to reasonable standard charges for document search and duplication. 5 U.S.C. § 552(a)(4)(A)(ii)(III).

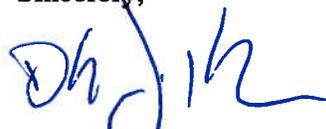
This request qualifies for expedited processing. Requests “shall be processed on an expedited basis whenever it is determined that they involve . . . [a] matter of widespread and exceptional media interest in which there exist possible questions about the government’s integrity that affect public confidence.” 28 C.F.R. § 16.5(e)(1), (e)(1)(iv). The request satisfies this standard. The agency’s inaction and the resulting public health crisis have generated widespread media attention. *See, e.g.,* Angelica LaVito, *US Lawmaker Faults FDA Chief for Lax Oversight of Teen Vaping*, CNBC, <https://www.cnn.com/2019/02/27/us-house-lawmaker-faults-fda-chief-for-lax-oversight-of-teen-vaping.html> (Feb. 27, 2019); Katelyn Newman, *CDC Blames Vaping for Teen Tobacco Use Spike*, U.S. News & World Report, <https://www.usnews.com/news/health-news/articles/2019-02-11/cdc-blames-e-cigarettes-vaping-for-teen-tobacco-use-spike> (Feb. 11, 2019).

San Francisco certifies that the information provided in this request is true and correct to the best of its knowledge. *See* 28 C.F.R. § 16.5(e)(3). If you have any questions regarding this request, please contact Deputy City Attorney Sara Eisenberg at (415) 554-4633. Please send all information released under this request to Ms. Eisenberg at the address below.

Sara Eisenberg
Deputy City Attorney
City Hall, Room 234
1 Dr. Carlton B. Goodlett Place
San Francisco, CA 94102-4682

Thank you for your prompt attention to this request.

Sincerely,



DENNIS J. HERRERA
City Attorney

cc: Mitch Zeller, Director Center for Tobacco Products



DENNIS J. HERRERA
City Attorney

DIRECT DIAL: (415) 554-4748
E-MAIL: brilltany.felitelberg@sfcityattty.org

March 19, 2019

VIA ELECTRONIC AND U.S. MAIL

Mark D. Lubin
Lubin Olson & Niewiadomski LLP
Transamerica Pyramid
600 Montgomery Street, 14th Floor
San Francisco, CA 94111
mlubin@lubinolson.com

Ronald E. Van Buskirk
Pillsbury Winthrop Shaw Pittman LLP
Four Embarcadero Center, 22nd Floor
San Francisco, CA 94111
ronald.vanbuskirk@pillsburylaw.com

RE: JUUL Labs, Inc.'s Use and Occupancy of Port Property

Dear Sirs:

Thank you for providing information and documents in response to my initial request, dated November 27, 2018. My office has reviewed the documentation you provided, and without limiting additional concerns we may have, I write now to clarify one of your responses and request an on-site inspection.

Specifically, in my request I asked for all information you have concerning JUUL's compliance with Section 43.5 of the Port's Master Lease, prohibiting the sale and advertising of tobacco products on the Leased Premises. By letter dated December 12, 2018, Mr. Lubin indicated that the JUUL leases expressly prohibit JUUL from engaging in the sale or advertising of tobacco products, that JUUL is acutely aware of these prohibitions, and that it is his client's information and belief that JUUL is in compliance with these prohibitions.

Also, by a later letter dated January 14, 2019, Mr. Van Buskirk acknowledged that both the Master Lease, and correlative provisions of the JUUL subleases, prohibit sales or advertising of cigarettes or tobacco products on the Premises, and asserted that JUUL Labs Inc. "has not engaged in sales or advertising of cigarettes or tobacco products on the Leased Premises" and that "there is no onsite retail function on the Leased Premises and it is not possible to physically purchase any JUUL products on the Leased Premises."

But my Office has come to learn that JUUL holds a tobacco distributor license for the location of the Leased Premises from the California Department of Tax and Fee Administration. A distributor license must be obtained and maintained for each location at which a person engages in the distribution of tobacco products, which includes the first sale,

Letter to Mick Mulvaney
Page 2
March 19, 2019

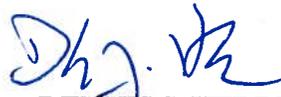
use or consumption of untaxed cigarettes or untaxed tobacco products in California, and the placing of untaxed cigarettes or untaxed tobacco products into a vending machine or retail stock in California.

In light of JUUL's possession of a tobacco distributor license for the Leased Premises, we ask that you clarify your response to my initial question concerning JUUL's compliance with Section 43.5 of the Master Lease. Does JUUL maintain that it does not engage in sales of tobacco products on the Leased Premises whatsoever, including the types of sales that a licensed tobacco distributor may make? Or, is it the case that JUUL does engage in the distribution of tobacco products, including the sale of untaxed tobacco products, but does not engage in any retail sales on the Leased Premises?

Also, to better understand the scope of JUUL's operations on City property and verify your assertions that they comply with applicable legal requirements, it would be helpful if my Office could schedule a time for representatives of my office, and possibly other City departments, to view the company's operations at the Leased Premises, at your convenience.

In addition to providing the clarification described above, which we ask that you direct to Michelle Sexton, Port General Counsel, and Yvonne Meré, Chief Attorney, Complex and Affirmative Litigation Team, please contact Deputy City Attorney Sexton at 415-274-0509 to identify a date and time that works for you.

Sincerely,



DENNIS J. HERRERA
City Attorney

cc: Elaine Forbes, Port Director