FILE NO. 190312

LEGISLATIVE DIGEST

[Health Code - Restricting the Sale, Manufacture, and Distribution of Tobacco Products, Including Electronic Cigarettes]

Ordinance amending the Health Code to prohibit the sale by tobacco retail establishments of electronic cigarettes that require, but have not received, an order from the Food and Drug Administration (FDA) approving their marketing; and prohibiting the sale and distribution to any person in San Francisco of flavored tobacco products and electronic cigarettes that require, but have not received, an FDA order approving their marketing.

Existing Law

Local law requires that all retail establishments in San Francisco that sell tobacco products, including electronic cigarettes, obtain a permit from the Department of Public Health to do so. (Health Code Article 19H). Local law also prohibits permitted tobacco retail establishments from selling flavored tobacco products, including electronic cigarettes, to any person. (Health Code Article19Q).

At the federal level, the Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act") authorizes the U.S. Food and Drug Administration ("FDA") to set national standards governing the manufacture of tobacco products, to limit levels of harmful components in tobacco products and to require manufacturers to disclose information and research relating to the products' health effects.

A central requirement of the Tobacco Control Act is premarket review of all new tobacco products. Specifically, every "new tobacco product"—defined to include any tobacco product not on the market in the United States as of February 15, 2007—must be authorized by the FDA for sale in the United States before it may enter the marketplace. A new tobacco product may not be marketed until the FDA has found that the product is: (1) appropriate for the protection of the public health upon review of a premarket tobacco application; (2) substantially equivalent to a grandfathered product; or (3) exempt from substantial equivalence requirements.

In determining whether the marketing of a tobacco product is appropriate for the protection of the public health, federal law requires that the FDA consider the risks and benefits of the product to the population as a whole, including users and nonusers of the product, and taking into account the increased or decreased likelihood that existing users of tobacco products will stop using tobacco products and the increased or decreased likelihood that those who do not use tobacco products will start using them. Where there is a lack of showing that permitting the sale of a tobacco product would be appropriate for the protection of the public health, the Tobacco Control Act requires that the FDA deny an application for premarket review.

Amendments to Current Law

The proposed ordinance would amend the Health Code to prohibit permitted tobacco retail establishments located in San Francisco from selling electronic cigarettes that require premarket review by the FDA, but have not undergone such review. It would also prohibit the sale to any person in San Francisco, including via mail or internet, of: 1) flavored tobacco products, including electronic cigarettes; and 2) electronic cigarettes that require FDA premarket review, but have not undergone such review.

Background Information

Despite progress in reducing smoking, tobacco use is still the leading cause of preventable death in the United States. Tobacco kills more than 480,000 people in this country annually – more than AIDS, alcohol, car accidents, illegal drugs, murders, and suicides combined.

Electronic cigarettes (or "e-cigarettes") entered the marketplace around 2007, and since 2014, they have been the most commonly used tobacco product among youth in the United States. 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 increase, which has erased past progress in reducing youth tobacco use, is directly attributable to a nationwide surge in e-cigarette use by adolescents. There were 1.5 million more youth e-cigarette users in 2018 than 2017, and those who were using e-cigarettes were using them more often. Frequent use of e-cigarettes increased from 20 percent in 2017 to 28 percent in 2018 among current high school e-cigarette users.

The widespread use of e-cigarettes by youth has significant public health consequences. As stated by the Surgeon General, "Most e-cigarettes contain nicotine – the addictive drug in regular cigarettes, cigars, and other tobacco products. Nicotine exposure during adolescence can harm the developing brain – which continues to develop until about age 25. Nicotine exposure during adolescence can impact learning, memory, and attention. Using nicotine in adolescence can also increase risk for future addiction to other drugs. In addition to nicotine, the aerosol that users inhale and exhale from e-cigarettes can potentially expose both themselves and bystanders to other harmful substances, including heavy metals, volatile organic compounds, and ultrafine particles that can be inhaled deeply into the lungs."

And while there is some evidence that the use of e-cigarettes by adults may support smoking cessation under certain circumstances, a 2018 National Academy of Sciences, Engineering, and Medicine report concluded that there was moderate evidence that e-cigarette use in fact increases the frequency and intensity of cigarette smoking in the future.

In addition, there is a growing body of research concluding that there are significant health risks associated with electronic cigarette use. For example, daily e-cigarette use is associated with increased odds of a heart attack. And the American Lung Association has

warned that the inhalation of harmful chemicals through vaping may cause irreversible lung damage and lung disease.

Notwithstanding the City's efforts to reduce youth tobacco use, San Francisco's youth still access and use tobacco products. According to the most recent Youth Risk Behavior Survey for which local data are available, in 2017, 16.7% of San Francisco's high school students had tried smoking, 25% had used an electronic cigarette (or "vaped"), and 7.1% reported current e-cigarette use, which is defined as use on at least one day in the past 30 days.

Among San Francisco high school students who reported currently using electronic cigarettes, 13.6% reported that they usually purchased their electronic cigarette products in a store. The remaining 86.4% reported that they obtained them from places other than the City's licensed tobacco retail establishments, including friends, other social sources, and internet e-cigarette vendors.

Virtually all electronic cigarettes that are sold today entered the market after 2007, but have not been reviewed by the FDA to determine if they are appropriate for the public health. In 2017, the FDA issued Guidance that purports to give electronic cigarette manufacturers until August 8, 2022 to submit their application for premarket review. The Guidance further purports to allow unapproved products to stay on the market indefinitely, until such time as the FDA complies with its statutory duty to conduct a premarket review to determine whether a new tobacco product poses a risk to public health.

By the time e-cigarette manufacturers will be required to submit their premarket review applications, e-cigarettes will have been on the market for as much as fifteen years without any FDA analysis of their safety and alleged benefit. If current trends continue, six million more youth in the United States will begin using e-cigarettes between now and then.

n:\legana\as2019\1900441\01345996.docx