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Division of Dockets Management
HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852
submitted via the Federal eRulemaking Portal

Re: Docket No. FDA-2014-N-0189]
RIN 0910-AG38

Dear Sir or Madam:

The Oregon Health Authority's Public Health Division (OHA-PHD) is pleased to offer the following comments in response to the Food and Drug Administration's (FDA) proposed rule to 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; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products.

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) gave the Food and Drug Administration (FDA) the authority to regulate the manufacturing, distribution and marketing of tobacco products in the retail environment to protect the public's health. New rules proposed by the FDA would extend this authority to cover currently unregulated and marketed products, including cigars, pipe tobacco, nicotine gels, water pipe (hookah) tobacco, and dissolvables, hold great promise to help reduce tobacco's deadly toll on Oregonians.

Tobacco use is the No. 1 preventable cause of death and disease in Oregon, killing 7,000 people each year, and costing Oregonians $2.5 billion a year in medical expenditures and lost productivity due to premature death. All told, the financial burden of tobacco use is approximately $1,600 a year per Oregon household. Over time in Oregon, cigarette smoking prevalence has decreased by 22 percent among adults, 64 percent among 11th grade students, and 80 percent among 8th grade students. However, Oregonians, especially our youth, have

increased use of other tobacco productssuch as cigars, cigarillos, roll-your-own, hookah, and e-cigarettes, threatening to offset declines in overall combustible tobacco use.In 2013, 10 percent of Oregon 11th grade studentssmoked cigarettes whilenearly 20 percent usedother tobacco products.[1]

OHA-PHD supports the FDA in taking steps to regulate electronic cigarettes and additional products that meet the statutory definition of a tobacco product by releasing proposed deeming rules. The proposed rules are a first step toward lessening the appeal of other tobacco products, but the rules also contain gaps that will weaken the positive effect that these regulations could have on the public's health.

1) **Areas of the Proposed Rules OHA-PHD Supports:**

OHA-PHD supports registering newly deemed tobacco products with the FDA and reporting product and ingredient listings; banning the distribution of free samples; only making direct and implied claims of reduced risk if the FDA confirms that scientific evidence supports the claim and that marketing the product will benefit public health as a whole. These are logical requirements that help mitigate the appeal and health risks of these products.

PRODUCT AND INGREDIENT LISTINGS
Registering with the FDA and reporting product and ingredient listings have the potential to increase consumers' knowledge and promote safety. Two e-cigarettes, or any currently unregulated tobacco product, produced on the same line can be dramatically different. Manufacturers can make, market and sell these products without transparency or consistency. For example, most e-cigarettes currently are being manufactured overseas, where manufacturing and safety standards may differ, making it more difficult to know what is in e-cigarettes without regulation. Furthermore, studies have shown there is a wide variability of what is in electronic cigarette products versus what the product labeling states.[2]

CLAIMS
OHA-PHD strongly supports the prohibition of use of modified risk descriptors (e.g. "light" or "mild") and claims (e.g. one product is less harmful than another product) unless FDA issues an order permitting such a claim. This regulation will help protect the public from unsubstantiated claims. Despite the fact that FDA currently does not permit e-cigarette brands to be marketed as smoking cessation devices, cessation effectiveness claims permeate e-cigarette advertising. Companies still promote products with slogans that are proxies for

[1]Oregon Tobacco Facts. 2014.
https://public.health.oregon.gov/PreventionWellness/TobaccoPrevention/Documents/tobacco_facts/other_tobacco_products.pdf
[2]Trehy ML, et al. Journal of Liquid Chromatography & Related Technologies. August 2011

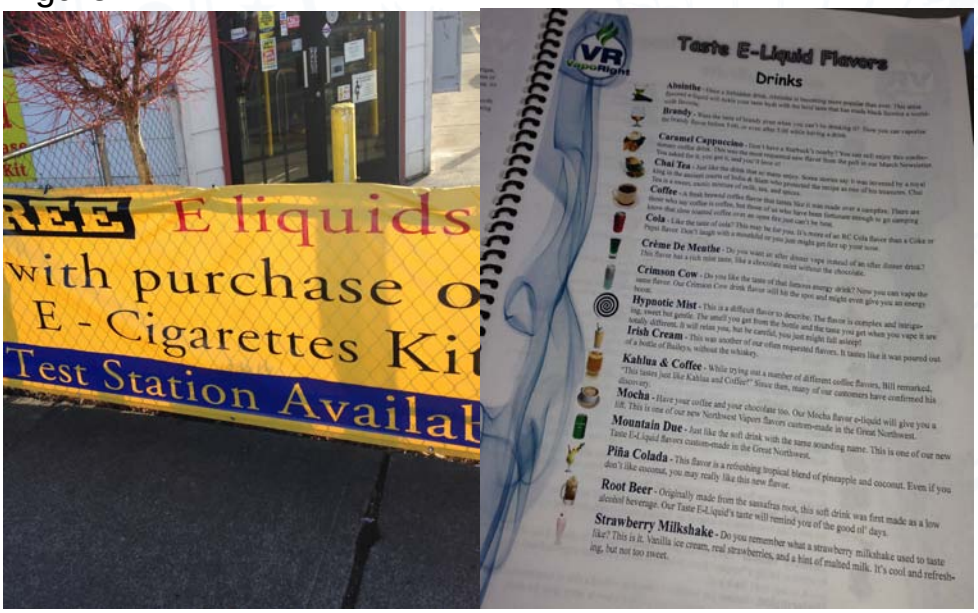
quitting such as “smoking alternative,” “switch,” “change,” “it works!,” “kiss tobacco goodbye,” and “kick some ash.” Some explicit claims of cessation efficacy appear in the form of testimonials on blogs and forums of e-cigarette companies and are likelyoffered by sales people in brick and mortar vapor stores.OHA-PHD recommends that the FDA apply the modified risk provisions with rigor, particularly in light of the health claims often made for electronic cigarettes.

SAMPLING

OHA-PHD strongly supportsbanning the distribution of free samples. Research and market data show that advertising and promotion of tobacco products causes the initiation and continuation of smoking among adolescents and young adults. One of the marketing and promotion strategies used by tobacco companies is the distribution of free samples of tobacco products (a practice known as “sampling”), particularly targeting youth and young adults in an effort to lure new customers.A recent survey of nine commonly sold e-cigarette brandsfoundthat eight of the e-cigarette brands had been promoted through sponsored or sampling events, many of which were youth-oriented. In 2012 and 2013, six of the surveyed companies sponsored or provided free samples at 347 events.Productsampling is particularly widespread at electronic cigarette/“vaping” shops across Oregon.

Field research in Oregon found that electronic cigarette retailers include the opportunity to sample the wide variety of flavored nicotine cartridges in their sales pitches. Signs, like the one pictured below, advertise a test station for free sampling (Figure 1).

Figure 1.



Electronic cigarette retailer advertises testing station for free sampling of electronic nicotine liquids.

There has been an increase in the number of electronic cigarette stores in Oregon. A recent search on the Secretary of State's (SOS) online business registry using the following search criteria: "vape, vapor, electronic cigarette and e-cig" resulted in 164 businesses. The same search done in April 2013 resulted in 75 vapor/electronic cigarette businesses; the 164 represents a 119% increase in only thirteen months.

2) Support with Additional Recommendations

MARKETING AFTER FDA REVIEW
Premarket review requirements are another logical requirement. Companies must seek and obtain FDA approval before they can sell new products, or make changes to existing products. This requirement is especially critical for e-cigarettes. E-cigarettes are relatively new to the domestic market, and product enhancements are common. OHA-PHD supports the criteria that companies must either show that: (1) the introduction of the new product is appropriate for the protection of public health; or (2) the product is identical to a product on the market in 2007, or (3) that the differences between the new and "grandfathered" products raise no new issues to public health.

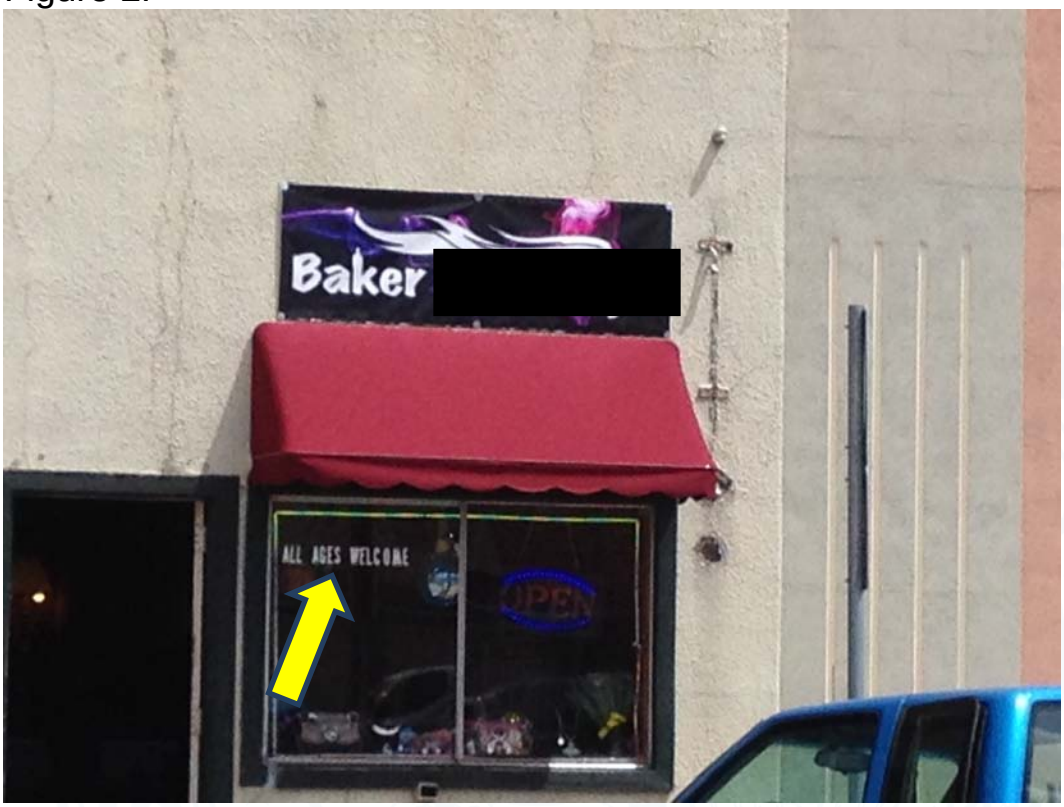
However, OHA-PHD is concerned about the delay in premarket approval. The proposed regulation delays premarket approval for two years after the regulations takeeffect. Companies can submit premarket approval or substantial equivalence reports within that two-year period, and as long as they have done so, could continue to market the product until the FDA acts on the application, which may be well beyond the 24-month period. The industry continues to adapt and market new products and there is potential for increased marketing during the two-year window.A similar timeframe for premarket approvalwas established during the passage of the Tobacco Control Act for cigarettes and smokeless tobacco products. The FDA received 3,517 applications, andthree years later has only issued an order removing four products from the market. After the withdrawal of 117 applications, tobacco companies are still able to market the unapproved products represented by the 3,396 outstanding applications. OHA-PHD encourages the FDA to eliminate the delay in premarket approval to avoid repeating this problem in the future.

AGE RESTRICTIONS
Minimum age and identification restrictions to prevent tobacco product sales to underage youth are very important. The Surgeon General's 2012 report states that youth are sensitive to nicotine and experience nicotine dependence earlier

than adults. Because of nicotine addiction, about three out of four teen smokers end up smoking into adulthood, even if they intend to quit after a few years.[3]

Current use of e-cigarettes among youth is increasing at a rapid rate. E-cigarette use by Oregon 11th grade students increased from two percent to five percent from 2011 to 2013. Unrestricted youth access to these products has likely contributed to this increase. In Eastern Oregon, signs advertising “all ages welcome” are displayed on a “vape shop” window (Figure 2).

Figure 2.



Vape show displays “All ages welcome” sign in window.

However, evidence shows sales restrictions alone will not change youth use of e-cigarettes. In Utah, where age restrictions for e-cigarette purchase and use have been in place since 2010, e-cigarette use has more than doubled among kids, and kids are three times more likely to have used e-cigarettes than adults.[4] To prevent children from using tobacco, a comprehensive approach,including raising the price, limiting marketing, restricting flavoring and increasing the minimum legal sales age to 21should be employed.

Nearly all smokers start as kids or young adults, and these age groups are heavily targeted by the tobacco industry. Increasing the sale age to 21 will help

[3]2012 Surgeon General’s Report.http://www.surgeongeneral.gov/library/reports/preventing-youth-tobacco-use/full-report.pdf

[4]Utah Health Status Update: Electronic cigarette use among Utah students (Grades 8, 10, and 12) and adults. December 2013. See: *http://health.utah.gov/opha/publications/hsu/1312_ECig.pdf*. (Accessed 9 Jan 2014).

prevent young people from ever starting to smoke and reduce the deaths, disease and health care costs caused by tobacco use.

The ages of 18 to 21 are a critical period when many smokers move from experimental smoking to regular, daily use. Nicotine is incredibly addictive, and adolescents and young adults are more susceptible to its effects because their brains are still developing.

Research shows that kids often turn to older friends and classmates as sources of tobacco. Younger kids have regular contact with older students who can legally purchase tobacco for them. Among Oregon 8th grade students who smoke cigarettes, 37 percent report obtaining tobacco from friends that are 18 years-old or older. Raising the tobacco sale age to 21 would reduce the likelihood that a high school student will be able to legally purchase tobacco products for other students and underage friends. OHA-PHD supports raising the minimum legal age for purchasing all tobacco products to 21. New York City, Hawaii County, Utah, Colorado and New Jersey are in process of implementing this policy.

INTERNET SALES

FDA's proposed prohibition on the sale of deemed products to minors applies to all retailers, including Internet retailers, however the proposed rule does not explicitly impose any age verification requirements on Internet sellers. Internet and social media marketing of tobacco products, including the more recent additions of e-cigarettes and other new products, is rapidly increasing, which has caused Internet sales of e-cigarettes and other tobacco products to increase as well.[5] Among Oregon 11th grade students, 40 percent report seeing an advertisement for tobacco products online.

In a recent survey of popular e-cigarette manufacturers reported by the staff of several U.S. Congressional leaders, seven of the nine surveyed companies sell their products online, and there was wide variation in the use of age-verification to limit access to their websites and to purchase their products. Three companies allowed access to their sites without age verification or confirmation, and three companies only required buyers to click a button verifying that they are at least 18 years old.[6]

The purported goal of the proposed minimum age and identification restrictions, according to the FDA, is to "reduce youth initiation of tobacco use, thereby reducing the number of people who suffer from tobacco-related illnesses and death." However, OHA-PHD believes this goal cannot be achieved if FDA does

[5]Herzog, B., &Gerberi, J. (2013).*Equity research: E-Cigs revolutionizing the tobacco industry.* New York: Wells Fargo Securities
[6]Durbin, R., Waxman, H., Harkin, T et al.*Gateway to Addiction?A Survey of Popular Electronic Cigarette Manufacturers and Targeted Marketing to Youth.* April 14, 2014

not restrict internet sales of newly covered products such as e-cigarettes which are aggressively marketed and sold online to youth.

VENDING MACHINES

The proposed rules prohibit vending machine sales, unless the vending machine in located in a facility where the retailer ensures that individuals under 18 years of age are prohibited from entering at any time. OHA-PHD recommends a complete prohibition of all tobacco products and tobacco product components in vending machines. It is not enough to exempt facilities that do not admit youth or facilities that sell device components or parts that do not contain nicotine.

Many facilities that do notadmit youth, serve alcohol. People crave nicotine more when they are drinking alcohol, and crave alcohol more when they are smoking.[7] Having easy access to vending machines while drinking alcohol potentially increases tobacco use in these facilities and nearby spaces outdoors.

Restrictions related to vending machines apply to newlycovered tobacco products, but not to the product components or parts that do not contain nicotine.This proposed exemption could create compliance and enforcement problems, especially related to e-cigarettes. It will be difficult to enforce these requirements and restrictions on nicotine-containing e-cigarettes and nicotine refill cartridges, but not for any part of an e-cigarette device that contains no liquid or refill cartridgesthat are free of nicotine.

Areas not addressed in proposed regulation

CHILD-PROOF CONTAINERS

The proposed rule does not address nicotine liquid used in e-cigarettes and related products that are soldin containers with no-child resistant features. Recent poison control reports indicate that children are exposed to toxic concentrations of nicotine in the solutions used to generate the nicotine aerosol (also known as e-juice, e-liquid). From 2011–2013, the Oregon Poison Center received 31 calls related to unintended exposure or over-exposure to nicotine from e-cigarettes. This demonstrates a need for child-resistant packaging and other child safety precautions.

SURGEON GENERAL

The 2014 Surgeon General's Report (SGR), The Health Consequences of Smoking: 50 Years of Progress[8] is not referenced in the FDA's proposed

[7] Nicotine Decreases Ethanol-Induced Dopamine Signaling and Increases Self-Administration via Stress Hormones. Doyon W., Dong Y, Ostroumov A, Thomas A, Zhang T, Dani J. Published: July 18, 2013DOI: http://dx.doi.org/10.1016/j.neuron.2013.06.006

[8]2014 Surgeon General's Report http://www.surgeongeneral.gov/library/reports/50-years-of-progress/index.html

deeming rule. This report contains important information that is directly relevant to the proposed deeming rule. The 2014 SGR shows that changes to cigarettes that were thought to reduce harm actually increased harm. OHA-PHD encourages FDA toconsider theserelevant findingsand abandon its "continuum of risk" approach until empirical evidence suggests that products as used in the population can reduce health risks. The 2014 SGR shows that the health risks of nicotine are more serious than previously thought; OHA-PHD encourages the FDA to considerthis information when determiningthe effects of the deeming rule on vulnerable populations, such as young people and developing fetuseș.

ADVERTISING AND MARKETING RESTRICTIONS

There is strong and consistent evidence that marketing influences adolescent smoking behavior, including selection of brands, initiation of smoking, and overall consumption of cigarettes. The 2014 SGR concludes that "advertising and promotional activities by tobacco companies cause the onset and continuation of smoking among adolescents and young adults." The FDA deeming rule does not apply several important sales and marketing restrictions to other tobacco products that currently exist for cigarettes. Some of these marketing and promotion restrictions include celebrity product endorsements and point of sale marketing and promotion of tobacco products.

Electronic cigarette brands are using celebrities to endorse their products, including rock star Courtney Love for NJOY and actor Steven Dorff for Blu. For the past four years, e-cigarettes have even been given out at the Oscars in their “swag bags” (Krave-2010, Blu-2011, Vapor Trim 2012, V2 and Vapor Couture-2012, and NJOY-2013). Even the image of dead celebrities has been exploited for e-cigarette marketing purposes including Marilyn Monroe, John Lennon, James Dean, and Benjamin Franklin.

The proposed rule does not address the advertising of newly deemed products, including electronic cigarettes, in ways and in venues that may be targeting youth, or make any specific proposals for restricting the advertising and promotion of these products.In a recent Oregon county tobacco retail assessment, one out of every four tobacco retailers had branded tobacco signs displayed below three feet (at the eye level of a child) (Figure 3), and one out of every three retailers had tobacco products displayed within 12 inches of toys, candy, or gum inside the store (Figure 4).

Figure 3.

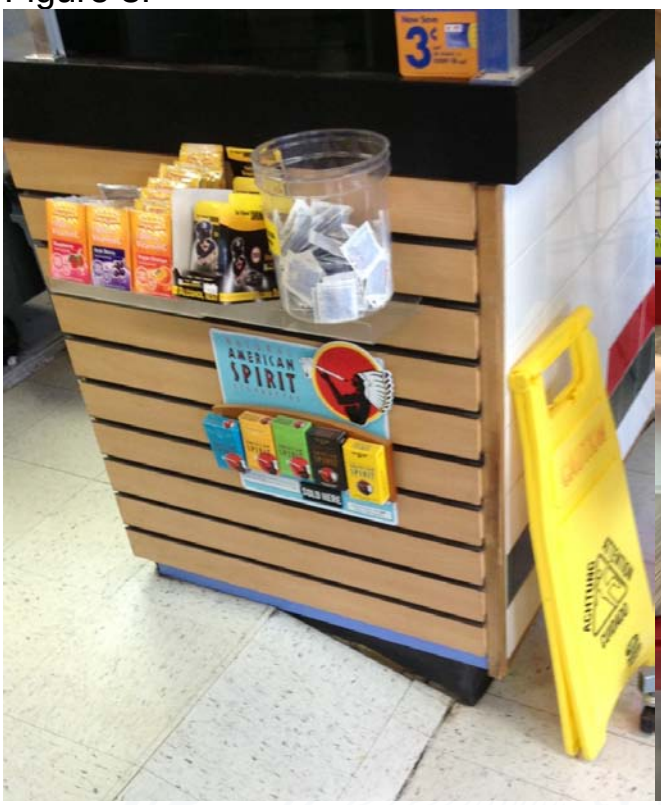
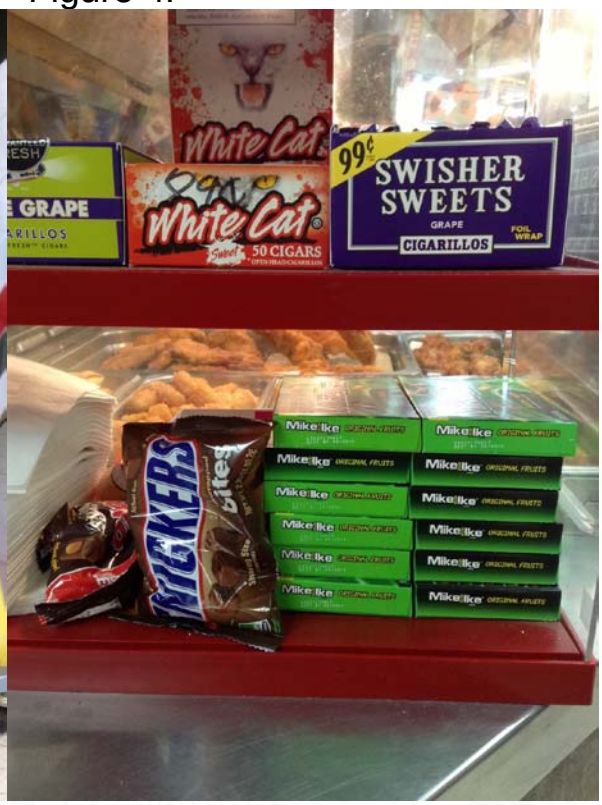


Figure 4.



Tobacco product display within three feet of the floorFlavored tobacco products displayed next to candy

Electronic cigarette advertising expenditures tripled from $6.4 million in 2011 to $18.3 million in 2012, with spending highest in magazines and television.[9] There is high awareness of e-cigarette advertising among youth; 60% of teenagers ages 13-17 say they see e-cigarette advertising at stores, supermarkets or gas stations, 45% see e-cigarette ads on television, and 43% see e-cigarette ads on the Internet.[10] In 2013, e-cigarette television ads reached 14.1 million teens (ages 12-17 years) and print ads reached 9.5 million teenagers, with ads running on youth-centric networks like ABC Family, MTV, VH1 and shows like South Park and Futurama.

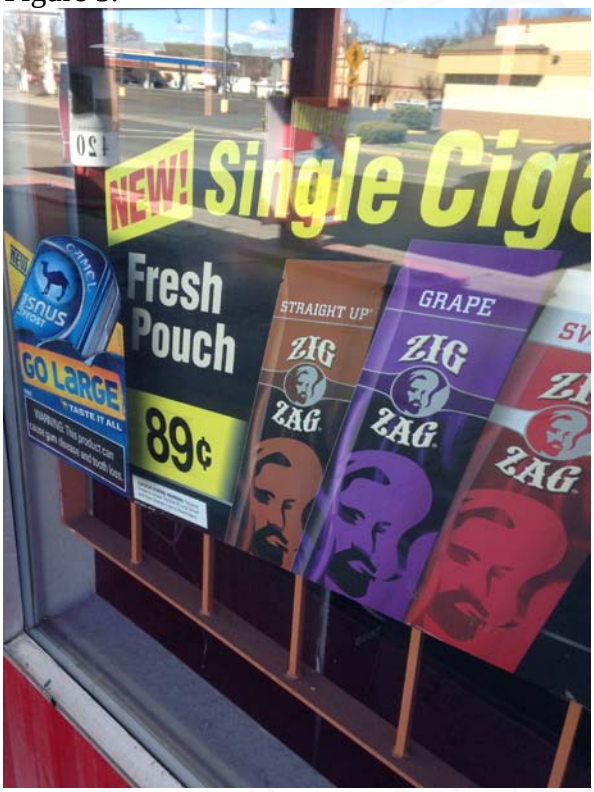
OHA-PHD urgesthe FDA to prohibit such advertising of new products as part of this rule. Advertising and promotion of these products to youth will continue to increase in the time it will take to develop, issue, and defend a follow-up rule.

[9]Kim AE, Arnold KY, Makarenko O. E-cigarette advertising expenditures in the U.S., 2011-2012.*Am J Prev Med.* 2014;46(4):409-12. doi: 10.1016/j.amepre.2013.11.003.

[10]Legacy.Vaporized: e-cigarettes, advertising and youth.Available at http://legacyforhealth.org/content/download/4542/63436/version/1/file/LEG-Vaporized-E-cig_Report-May2014.pdf.Published May 2014.Accessed May 28, 2014.

CONSISTENCY IN PROVISIONS ON PACK SIZE AND BRAND NAMES
OHA-PHD supports extending the cigarette provisions on minimum pack size requirements, prohibition of breaking packages by retailers, prohibition on tobacco brand names on non-tobacco products, and prohibition ofsponsorshipto all products under FDA's proposed deeming rules. There is no reason why the provisions for cigarettes should not apply to all tobacco products. The absence of these provisions creates legal loopholes, and confusion for the consumer and retailer. For example, while cigarettes must come in packs of 20 or 25, there are no proposed regulations on minimum pack sizes for cigars and cigarillos. This allows companies to sell these products at low prices relative to other tobacco products, making them appealing to price-sensitive populations like youth (Figure 5).

Figure 5.



A single, flavored little cigar is advertised for 89 cents at an Oregon tobacco retailer

3) Questions specifically identified by the FDA

WHETHER PREMIUM CIGARS SHOULD BE REGULATED, AND IF THEY SHOULD BE REGULATED THE SAME AS OTHER CIGARS

FDA's proposed deeming rule states, "all cigars are harmful and potentially addictive"[11] and "all cigars, regardless of size, produce higher levels of

[11]79 Fed. Reg. at 23150

carcinogenic tobacco-specific nitrosamines per gram in mainstream cigar smoke than cigarettes produce in mainstream cigarette smoke."[12] According to the National Cancer Institute and the U.S. Surgeon General, cigar smoking causes cancer, heart disease and chronic obstructive pulmonary disease (COPD).[13] Studies have shown that some cigar smokers inhale, thereby absorbing smoke into their lungs and bloodstream and depositing smoke particles in their lungs, as well as their stomachs and digestive tract.[14]

Based on previous industry practices, if the FDA regulates premium large cigars differently than other cigars it can be expected that the industry will find ways to manipulate products to be classified as a large cigar to avoid regulation. This is evidenced by the tax inequity between pipe tobacco and large cigars and other combustible products created when the Federal tobacco excise tax was increased in 2009, which made pipe tobacco less expensive than roll-your-own tobacco and manufactured cigarettes, and large cigars less heavily taxed than small cigars and manufactured cigarettes.[15] After the tax changes became effective, manufacturers began to re-label roll-your-own tobacco as pipe tobacco, making these products available to consumers at a lower price. For cigars, manufacturers were able to increase the per-unit weight of certain small cigars, often using fillers such as the clay found in cat litter, to take advantage of a lower tax when classified as large cigars.

For these reasons and the FDA's own recognition of the inherent hazards and addictiveness of any cigar, OHA-PHD supports Option 1 of the proposal tobring all cigars, including premium, under the FDA's jurisdiction.

WHETHER A TOBACCO PRODUCT MEETS THE DEFINITION OF 'CIGARETTE' AS OPPOSED TO ANOTHER TOBACCO PRODUCT (E.G. A LITTLE CIGAR), AND THEREFORE SHOULD BE REGULATED AS A CIGARETTE

Some cigars are now structurally very similar to cigarettes, and the ability to flavor cigars translates into the continued availability of flavored cigarette-like products. Cigar smoke contains the same toxins as cigarette smoke, and many new cigar products are more easily smoked and inhaled just like cigarettes.

[12] *Id*. at 23151
[13] Boon, Ann. Campaign for Tobacco Free Kids, March 7, 2013. http://www.tobaccofreekids.org/research/factsheets/pdf/0333.pdf
[14] Rodriguez, J, et al., "The Association of Pipe and Cigar Use with Cotinine Levels, Lung Function, and Airflow Obstruction: A Cross-sectional Study," Annals of Internal Medicine152:201-210, 2010; McDonald, LJ, et al, "Deposition of Cigar Smoke Particles in the Lung: Evaluation with Ventilation Scan Using Tc Labeled Sulfur Colloid Particles," Journal of Nuclear Medicine 43:1591-1595, 2002.
[15] Tynan, M, McAfee T, Promoff,G., "Consumption of Cigarettes and Combustible Tobacco-United States, 2000-2011." Morbidity and Mortality Weekly Report 61(30);565-569, 2012.

While cigarettes sales have been declining in the U.S., cigar sales have increased significantly.[16] The surge in cigar sales has been driven by an increase in the number and types of smaller cigar products, many of which are flavored, priced and packaged to appeal to young people. Cigars today vary widely in sizes, shapes, flavors and prices, making them appealing to a broader audience, including kids. High school students and young adults smoke cigars at twice the rates of all adults. According to the 2012National Youth Tobacco Survey,12.6 percent of high school students smoked cigars in the past month. In contrast, the most recent national survey of adult cigar use (for 2011-2012) showed that 5.4 percent of all adults smoked cigars in the past month.[17] Young adults (ages 18-21) have the highest cigar smoking rate at 12 percent.In 2013, eight percent of Oregon 11th grade students smoked cigars in the past month.

OHA-PHD maintains the position that little cigars meet the definition of the term"cigarette," and thus, FDA should extend the current regulations for cigarettes to little cigars.

THE USE OF CHARACTERIZING FLAVORS IN TOBACCO PRODUCTS, ESPECIALLY THEIR ATTRACTION TO YOUTH AND LONG TERM EFFECTS
The FDA is not proposing any restriction on the sale of flavored cigars or e-cigarettes. Researchers at Portland State University found that tobacco companies are using the same flavor chemicals, and in higher concentrations than non-tobacco products, in their sweet-flavored tobacco products, including cigars of various sizes and smokeless tobacco, that are used in popular candy and drink products such as LifeSavers, Jolly Ranchers and Kool-Aid.[18]

According to an October 2013 Centers for Disease Control and Prevention study on youth use of flavored tobacco products, "Flavors can mask the natural harshness and taste of tobacco, making flavored tobacco products easier to use and increasing their appeal among youth. Advertising for flavored tobacco products has been targeted toward youth, and flavored product use may influence the establishment of lifelong tobacco-use patterns among younger individuals."[19]

The availability of cheap, candy- and fruit-flavoredcigars has likely contributed tothe increase in cigar sales even while cigarette sales have declined. Between

[16]National Cancer Institute (NCI) Cigars: Health Effects and Trends. Smoking and Tobacco Control Monograph No. 9,1998. Economic Research Service, U.S. Department of Agriculture (USDA). U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB), Tobacco Statistics.
[17]Substance Abuse and Mental Health Services Administration, Results from the 2012 National Survey on Drug Use and Health: Summary of National Findings, NSDUH Series H-46, HHS Publication No. (SMA) 13-4795. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2013.
[18] Brown, Jessica E. Luo, Wentai, Isabelle, Lorne M., Pankow, James F. Candy Flavorings in Tobacco. *New England Journal of Medicine*.http://www.nejm.org/doi/full/10.1056/NEJMc1403015
[19]Flavored-Little Cigar and Flavored-Cigarette Use Among U.S. Middle and High School Sudents. King, Brian, Tynan, Michael, Dube, Shanta, Arrazola Rene. 2014, January.*Journal of Adolescent Health*-(Vol. 54, Issue 1, Pages 40-46, DOI: 10.1016/j.jadohealth.2013.07.033)http://www.jahonline.org/article/S1054-139X(13)00415-1/fulltext

2000 and 2013, cigar consumption increased by 114 percent, while cigarette consumption declined by 37 percent. In Oregon,eightpercent of 11th grade students currently smoke cigars (i.e., large cigars, cigarillos and small cigars). The most popular cigar brands among youth – including top three brands Black & Mild, Swisher Sweets and White Owl – come in a wide variety of flavors, such as peach, strawberry, chocolate, grape, blueberry, wild apple, pineapple and watermelon.

The use of flavoring in tobacco products appeals to young people and should not be permitted.OHA-PHD encourages the FDA to incorporate provisions governing flavorings in the final deeming rule.

INFORMATION ON ELECTRONIC CIGARETTES

E-cigarettes contain nicotine, which is very addictive, and adolescents and young adults are more susceptible to its effects because their brains are still developing. E-cigarette use has increased substantially among kids and adults over the past several years. Data analyzed by the Centers for Disease Control and Prevention (CDC) show that the number of adult Americans who have ever used e-cigarettes quadrupled from 2009 to 2010[20]. In Oregon, current e-cigarette use among 11th grade students rose from two percent to five percent from 2011 to 2013, even as current cigarette use continued to decline. Recent data also raise the concern that e-cigarettes are contributing to relapse among former smokers.[20, 21,22]

Available evidence indicates that a substantial portion of e-cigarette users of all ages use cigarettes at the same time.[23]Among Oregon 11th graders, 76 percent of electronic cigarette smokers also smoke cigarettes. This 'dual use' pattern raises the concern that e-cigarettes are being used as a "bridge product," bridging smokers from one cigarette to the next by providing nicotine in places where they cannot smoke. This pattern suggests that e-cigarettes are being used to perpetuate nicotine addiction, rather than break it, as industry advertising purports.

OHA-PHD supports sensible regulation that aligns with regulationsfor cigarettes including: FDA oversight, no sales to anyone less than 21 years-old, no flavors, prices high enough so kids cannot afford to buy e-cigarettes, no use where smoking is prohibited to avoid modeling of smoking for kids,and advertising

[20]Regan AK et al. Electronic nicotine delivery systems: adult use and awareness of the 'e-cigarette' in the USA.Tob Control 2013;22:19–23.
[21]King BA et al. Awareness and ever-use of electronic cigarettes among U.S. adults, 2010–2011. Nicotine Tob Res 2013;15:1623–7.
[22]McMillen R, Maduka J, and Winickoff J. Use of emerging tobacco products in the United States. J Environ Public Health 2012. See: *www.hindawi.com/journals/jeph/2012/989474*/
[23] Grana R, Benowitz N, Glantz SA. Background paper on e-cigarettes (Electronic Nicotine Delivery Systems). December 2013. See: *http://nicotinepolicy.net/documents/position_papers/ Grana_Glantz_WHO_ENDS_Report_Dec2013. pdf*. (Accessed: 8 Jan 2014).

restrictions consistent with other tobacco products so electronic cigarette use is not glamorized.

APPROPRIATE COMPLIANCE DATES FOR PROVISIONS

The FDA proposal would significantly delay the enforcement of several basic and important provisions in the Tobacco Control Act. These delays would apply to: required identification of the manufacturer on tobacco product packages, required submission of lists of tobacco product ingredients, required submission of lists of harmful and potentially harmful constituents, required submission of health information, required registration of manufacturers, required submission of product lists, prohibition on the terms “light,” “low,” “mild,” and similar descriptors. OHA-PHD urges the FDA to prioritize the health of the public by requiring immediate compliance.

CONCLUSION

OHA-PHD commends the FDA for taking initial steps to regulate electronic cigarettes and additional products that meet the statutory definition of a tobacco product. The proposed rules are necessary but are not enough to protect youth and adults from the dangers of tobacco and nicotine addiction. OHA-PHD supports a ban on characterizing flavors, raising the minimum legal age to 21, complete prohibition of all tobacco products and components in vending machines, strong advertising and marketing restrictions and a prohibition of Internet sales. OHA-PHD recommends that FDA issues a final deeming rule within one year of publishing the proposed rule, i.e. no later than April 25, 2015.

Thank you for consideration of these comments. If you have any questions or require additional information, please do not hesitate to contact Karen Girard, Health Promotion and Chronic Disease Prevention Section Manager at karen.e.girard@state.or.us or at 971-673-0984.

Sincerely,

Katrina Hedberg

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