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DATE: August 22, 2018

TO: Hearing Attendees and Commenters –
Oregon Administrative Rules chapter 333, division 15 – "Inhalant delivery systems packaged in a manner attractive to minors"

FROM: Jana Fussell, Hearing Officer

cc: Karen Girard, Manager
Health Promotion and Chronic Disease Prevention Section
Brittany Hall, Administrative Rules Coordinator

SUBJECT: Presiding Hearing Officer's Report on Rulemaking Hearings and Public Comment Period

Hearing Officer Report

Date of Hearing: July 17, 2018

Purpose of Hearing: To receive testimony regarding the Oregon Health Authority's proposed revision of administrative rules to refine the meaning of "packaged in a manner attractive to minors" as it relates to inhalant delivery systems (IDS) (also known as e-cigarettes), as used in Oregon Administrative Rules (OAR) 333-015-0300 to 333-015-0375.

Hearing Officer: Jana Fussell

Testimony Received: Two individuals provided oral testimony at the hearing. This testimony is briefly summarized as follows:

Matthew Freeman, Zephyr Vapors LLC

Mr. Freeman is a business owner in the Portland area. He stated that he has had to redesign his labels multiple times and has had to throw away labels, which is costly. He testified that his major concern is that he understands that the proposed rules will prohibit food names and that this a problem for him because his products are called what they taste like. Mr. Freeman stated that he can't change the names at the federal

level and that this will pose a problem if he is required to change them for the State. He opined that adults gravitate towards dessert or fruit flavors.

Agency response:

The Division thanks Mr. Freeman for his review of the rules and his testimony at the hearing. The Division is mindful of the opposition to the portion of the rule (OAR 333-015-0340 to 0355) prohibiting “packaging attractive to minors.” However, OHA is required, by state law, to adopt rules prohibiting packaging that is attractive to minors and the rules are implementing this statute (ORS 431A.175(2)(f)). The Inhalant Delivery System Packaging in a Manner Attractive to Minors Rules Advisory Committee (RAC) spent considerable time discussing various definitions and standards to implement this statutory requirement. The final language for “packaging attractive to minors” is a compilation of input from the RAC, review of the literature and adherence to legislative intent. OHA does not see the changes to the rules that are being proposed as significantly different from the current requirement; rather the changes are intended to make the type of packaging that is attractive to minors more clear.

In response to Mr. Freeman’s concern about changing product names at the federal level, the Food and Drug Administration’s Center for Tobacco Products (FDA-CTP) confirmed that there is a free, online process to change the name of currently registered e-products.

Michael Adamson, Vapor Vandals LLC

Mr. Adamson is a local business owner. Like Mr. Freeman, he stated that he has had to change labels multiple times with the associated expense. He opined that it is disturbing because there is a lack of definitions in regard to what is a bright color or what is attractive to minors. Mr. Adamson testified that local businesses such as his have been undercut by out-of-state businesses and uncertainty about labeling requirements puts his business at risk. He requested clarity and a reasonable clear discussion.

Agency response:

The Division thanks Mr. Adamson for his review of the rules and his testimony at the hearing. The Division is mindful of the opposition to the portion of the rule (OAR 333-015-0340 to 0355) prohibiting “packaging attractive to minors.” However, OHA is required, by state law, to adopt rules prohibiting packaging that is attractive to minors and the rules are implementing this statute (ORS 431A.175(2)(f)). The Inhalant Delivery System Packaging in a Manner Attractive to Minors Rules Advisory Committee (RAC) spent considerable time discussing various definitions and standards to implement this statutory requirement. The final language for “packaging attractive to minors” is a

compilation of input from the RAC, review of the literature and adherence to legislative intent. OHA does not see the changes to the rules that are being proposed as significantly different from the current requirement; rather the changes are intended to make the type of packaging that is attractive to minors more clear.

Other Comments: Nine individuals or organization submitted written comments to the Authority within the period allotted for public comment. These comments are briefly summarized as follows:

Clarice Amorim Freitas, Health Equity Coordinator, Linn Benton Health Equity Alliance

Ms. Freitas voiced her organization’s support for the proposed rule language related to inhalant delivery system packaging that is attractive to minors. She explained that: “We do this because of the well-documented fact that tobacco use, as well as the disease and mortality burden caused by tobacco use, affects certain specific populations not only differently, but disproportionately.” She opined that: “We believe that all tobacco control policies should recognize and prioritize these considerations.” Ms. Freitas noted research findings and wrote that: “Stricter language around inhalant systems – which are particularly attractive to children and youth and are often marketed specifically toward them – is essential to protect the most vulnerable of our children and youth living in lower-income neighborhoods or communities with larger numbers of people of color and immigrants.” Ms. Freitas’ written comments are attached to this report as “Exhibit 1”.

Agency response:

The Division thanks Ms. Freitas for her review of these rules and her written comments.

Allie Bieker, Program Manager, Interns, Providence School Outreach-Oregon Region

Ms. Bieker voiced her “concern over the marketing of many tobacco products to youth.” She wrote that: “The candy-like flavors, product placement, and ‘fun’ packaging are all influencing the sale to minors, and we need to protect them from this.” She advocated giving children “as fair a chance as possible to make a good decision.” Ms. Bieker’s written comments are attached to this report as “Exhibit 2”.

Agency response:

The Division thanks Ms. Bieker for her review of these rules and her written comments.

Alfonso Ramirez, Trauma Informed Specialist Coordinator, Tigard High School

Mr. Ramirez voiced his support “of regulations that would restrict colorful and creative packaging which appeals to youth, who are at most risk to start using tobacco.” He

wrote that: “Many students use these types of inhalant delivery systems in schools and they are detrimental to their behavior, learning and health.” Mr. Ramirez’s written comments are attached to this report as “Exhibit 3”.

Agency response:

The Division thanks Mr. Ramirez for his review of these rules and his written comments.

Jamicia Williams, Providence Health & Services

Ms. Williams is a youth advocate for A Tobacco Free Oregon and is in support of amending the required rule for inhalant delivery systems packaging so that “colorful and creative packaging” does not appeal to youth, who are at the most risk for starting to use tobacco. Ms. Williams writes that anything that can be done to lessen that exposure is supported. Ms. Williams’ written comments are attached to this report as “Exhibit 4”.

Agency response:

The Division thanks Ms. Williams for her review of these rules and her written comments.

Zeenia Junkeer, ND, Director, Oregon Health Equity Alliance

Dr. Junkeer wrote in support of the proposed rules. Referencing “marketing that leverages cartoon characters and bright primary colors to peak interest and make products more relatable to youth”, she stated that: “Families and children deserve to not be used as a leverage point to sell tobacco products.” Dr. Junkeer’s written comments are attached to this report as “Exhibit 5”.

Agency response:

The Division thanks Dr. Junkeer for her review of these rules and her written comments.

Debby Jones, CPS, Wasco County Prevention Specialist

Ms. Jones wrote that she supports any efforts to decrease the appeal and the ease of access of children and youth to products such as tobacco, alcohol and marijuana. She opined that an easy first step is “making sure that inhalant delivery systems are packaged appropriately and not in a manner attractive to children and teens.” Ms. Jones’ written comments are attached to this report as “Exhibit 6”.

Agency response:

The Division thanks Ms. Jones for her review of these rules and her written comments.

Jeffrey Weiss, General Counsel and EVP of Government Affairs, NJOY LLC (“NJOY”)

Mr. Weiss identified NJOY as one of the largest independent Electronic Nicotine Delivery System companies in the United States and recounted his client’s past interactions with the agency. His written comments, attached to this report as “Exhibit 7”, extensively detail why he believes that the proposed rules are “invalid”. He opined that the proposed rules are preempted by federal law and would “violate constitutional provisions and exceed the statutory authority of the OHA.” Mr. Weiss wrote that; “NJOY respectfully requests that the OHA promptly withdraw and further revise the proposed revisions to bring the regulations into legal compliance, and advise enforcement agencies across the state to suspend enforcement during the review and continued revision process.”

Agency response:

The Division thanks Mr. Weiss for his review of these rules and his written comments.

In response to the comment about the proposed rules being preempted by federal law, the Division modified the draft rules after the Food and Drug Administration (FDA) released final rules regulating electronic cigarettes, including labels (21 CFR Parts 1100, 1140 and 1143, *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*). The revised text aligns all labeling requirements with the FDA Deeming rule. The Division disagrees that the proposed rules are preempted by federal law, are inconsistent with state law or run afoul of Oregon’s constitution. The rules are narrowly tailored to prevent minors from being attracted to these products or being able to access the product.

Rachael Banks, MPA, Public Health Director, Multnomah County Health Department

Ms. Banks described Multnomah County’s experience in running its Tobacco Retail License program. She wrote that: “Having been in the field and working with inhalant delivery system retailers, we understand the difficulty in determining whether or not a product may be packaged in a way that may be ‘attractive to minors.’” She found that the “revised definitions of packaging in section 333-015-0305 (‘packaging,’ ‘inner package’ and ‘outer package’) help clarify what part of the inhalant delivery system falls under these rules.” Her written comments, attached to this report as “Exhibit 8”, provide a detailed discussion of where the County believes “that the revisions to the rules do not alleviate the difficulties that are inherent in the subjective nature of interpretation in the field, either for retailers trying to comply or for inspectors helping retailers come into compliance.” Ms. Banks also wrote that: “in section 333-015-0357(1)(c) of the proposed rules, we feel that adding descriptive terms to depictions of

food and beverage makes it more difficult to interpret rather than less clear” and she recommended “retaining ‘depicts food or beverage’ as used in 333-015-0305 (18)(d).” In relation to proposed OAR 333-015-0357(2)(d), she encouraged “including a reference to slang terms popular with youth (‘cool’, ‘fire’, ‘ice,’ ‘lit,’ ‘spiked,’ ‘poppin’, ‘juicy,’ etc.).” Ms. Bank’s written comments describe “two strategies that may better achieve the goal of preventing manufacturers and retailers from marketing products that youth may find desirable”: (1) The concept of plain packaging and if that is not feasible (2) The recommendation that the agency “create a packaging and labeling pre-approval process to assist retailers in compliance with these rules, much the way the Oregon Liquor Control Commission provides for retail marijuana products.”

Agency response:

The Division thanks Ms. Banks for her review of these rules and her written comments.

In response to the recommendation to include additional terms to describe flavors likely to appeal to minors, the Division has incorporated these suggestions into the rules.

In response to the plain packaging recommendation, the Division considers the rules to sufficiently describe what kinds of packaging is considered to be attractive to minors. The Inhalant Delivery System Packaging in a Manner Attractive to Minors Rules Advisory Committee (RAC) spent considerable time discussing various definitions and standards to implement this statutory requirement. The final language for “packaging attractive to minors” is a compilation of input from the RAC, review of the literature and adherence to legislative intent.

In response to the recommendation to leave “depicts food or beverage” in the rules, the Division considers the proposed, narrower definition in line with legislative intent for packaging attractive to minors.

In response to the recommendation that the Division pre-approve packaging and labeling of inhalant delivery systems, the Division lacks resources to fund this approval process. Oregon does not have statewide tobacco retail licensure. Therefore, inhalant delivery system manufacturers, retailers and distributors do not pay a license fee to sell tobacco products or inhalant delivery systems. The Oregon Liquor Control Commission pre-approval process is paid for through a licensing fee.

Mark Bonanno, JD, MPH, General Counsel and Vice President of Health Policy, Oregon Medical Association

Mr. Bonanno wrote that: “The OMA generally is concerned with any industry practice of designing and selling products in a form that is attractive to or appears harmless to children.” Mr. Bonanno's written comments detail concerns related to proposed OAR

333-015-0305, 0357, and 0375 and offer suggested revisions. Mr. Bonanno's written comments are attached to this report as "Exhibit 9".

Agency response:

The Division thanks Mr. Bonanno for his review of these rules and his written comments.

In response to the recommendation to clarify that the definition for "child-resistant" includes the inner and outer packaging, the Division notes that this significant change was not discussed among RAC members and the change could potentially be costly to implement.

In response to the recommendation to add "products of the type that are typically marketed to minors" to the "packaging attractive to minors" rule language, the Division believes this change is not needed because packaging that is presented in a manner that is attractive to minors or has a shape that is attractive to minors is covered in the proposed rules.

In response to the recommendation to clarify that the required warning letter is provided on the first violation, the Division has incorporated the suggested clarification language.