August 12, 2016

Rick Garza
Director -- Washington State Liquor and Cannabis Board
P.O. Box 43080
Olympia, WA 98504

Dear Mr. Garza:

We write to express our concern regarding the State Liquor and Cannabis Board's implementation of ESSB 6328, particularly Section 13 ('Labeling') and Section 19 ('Tastings'). We believe that the Board has misinterpreted pertinent sections of both the state statute and federal law. We respectfully request that you answer the questions that close this letter and publish guidance clarifying the true applicability of Section 13 and Section 19 of ESSB 6328 in light of recently finalized regulations from the Food & Drug Administration (FDA).

We note that our frame of reference for the Board's current position is derived from the language on the Board's website, as well the Board's letter of June 22nd to the Secretary of the Senate and the Chief Clerk of the House of Representatives on the implementation of the law.[1] If the Board's interpretations have changed since then, please kindly inform us.

I. LABELING

A. Washington's Labeling Provisions Are Preempted as of August 8, 2016, by Washington's Own Law

In its letter of June 22, the Board asserts that the labeling requirements of Section 13 will not be preempted until the FDA's labeling and advertising warnings begin to be enforced on May 10, 2018.

However, as of August 8, 2018, the FDA requires that all manufacturers, distributors, and retailers of vapor products abide by specific advertising requirements. The labeling language of Section 13 contains an explicit preemption clause that comes into effect once "advertising requirements" are in place at the federal level. As such, we believe the Section 13 is now preempted.

[1] "RE: ESSB 6328 – Vapor Products Notification". June 22, 2016.
<http://lcb.wa.gov/publications/enforcement/vapor/Notice-From-Board_ESSB-6328.pdf>

This Board's directly contravenes the Washington statute. Section 13(3)(a) of ESSB 6328's express preemption provision calls for preemption to begin "when such [federal-level] regulations mandate warning or advertisement requirements for vapor products."

The FDA's deeming regulation provides for at least two specific labeling and advertising requirements for vapor products, both of which came into effect on August 8, 2016. First, Section 903(a)(3) of the Federal Food, Drug & Cosmetic Act (FFDCA) requires that no vapor product have "labeling [that] is false or misleading in any particular." Second, Section 911 of the law requires a manufacture to obtain a marketing order from the FDA before selling any product with a label, labeling, or advertising claim that the product is "lower risk," "less harmful," or "contain a reduced level of a substance" than another commercially marketed tobacco product.

Both of these facets of FDA regulation "mandate labeling or advertisement requirements for vapor products." As a result, Washington's labeling provisions are now preempted by the language of Washington's own law. The Board should take prompt action to inform retailers that Section 13 is no longer being enforced.

B. Washington's Labeling Provisions are Preempted by Federal Law

In addition to the language in Washington's own law, the labeling language is also preempted by Section 916 of the FFDCA. Section 916 prohibits state and local governments from "establish[ing] or continu[ing] in effect" requirements "relating to tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products" if those requirements are "different from or in addition to" what has been imposed by the FFDCA.

As explained above, the FDA has already mandated requirements relating to labeling by applying Sections 903 and 911 to all newly deemed tobacco as of August 8, 2016. Moreover, even though particularized warning labels are not required until May 10, 2018, it nonetheless remains the case that these labeling requirements are "mandated" by federal law.

Section 13 is a requirement "in addition to" one that has already been imposed by the FFDCA. As a result, we believe that federal law also preempts Washington's labeling standard.

C. Washington's Labeling Provisions Only Apply to Nicotine Vapor Products

In its letter of June 22, the Board incorrectly claims that it has the authority to require the labeling of products that do not contain nicotine. The authors contend that even if preemption did apply to nicotine-containing products, the State would nevertheless retain authority over products that it believes the FDA is not asserting jurisdiction over (i.e., nicotine-free products).

This interpretation is contrary to the clear language of ESSB 6328. Section 13 refers explicitly to "liquid nicotine containers." In Section 4 of the bill, "liquid nicotine container" is defined to only include products which contain nicotine. No reasonable reading of this language could lead to a conclusion that nicotine-free liquids are included within this definition.

The specific language used by the Legislature makes it even clearer that the section is only applicable to nicotine-containing products. Section 13 requires a warning "regarding the

harmful effects of nicotine." It would be both nonsensical and problematic under the First Amendment to compel manufacturers to warn against the harmful effects of nicotine on the label of a product that does not contain nicotine.

Section 13 was clearly directed to address nicotine vapor products. Since that language is now preempted by both state and federal law, we urge the Board to issue guidance clarifying that Section 13 as a whole is preempted and will not be enforced against any product, regardless of nicotine content.

II. TASTING

A. FDA's Rule Does Not Prohibit Tastings of Nicotine Vapor Products

On its website, the Board advises:

> After the FDA ban takes effect on August 8, 2016, tastings of vapor products that do not contain any nicotine may continue under the state vapor products law as described above. Tastings of vapor products that contain nicotine are banned.

The FDA rule does prohibit retailers from providing "free" samples of newly deemed tobacco products. However, the practice of sampling ('tasting') is not banned, though, so long as the sample provided is not free. The FDA agrees.

This question has been posed to FDA on numerous occasions. For example, during an FDA webinar, "The 'Deeming Regulation: Q&A Webinar for Retailers." the following exchange took place between the moderator and Ele Ibarra-Pratt, Division Director of the Office of Compliance and Enforcement for the FDA Center for Tobacco Products.

> Moderator: "We've got a question about paying for a free sample. Does the restriction apply if they charge a customer, let's say, for a taste?"
>
> Ms Ibarra-Pratt: "Yes, so [if you're] charging to sample your tobacco product, in essence, would not be considered a free sample."[2]

As an organization, we have generally advised vape shops that they should charge a set fee per visit to sample both nicotine-containing and nicotine-free products. In our view, this complies fully with both Washington state law and federal regulations.

[2] FDA Webinar (approximately 11 minutes, 40 seconds in) <http://fda.yorkcast.com/webcast/Play/9deb553b7de34fb59ed839cbd934ec8d1d>

New Guidance is Needed to Clarify the Law's Applicability

The final version of Washington State's new vapor products law, as passed by the Senate and House, was the product of much discussion and thought. Washington retailers are eager to come into compliance and continue serving their customers and communities.

In order to facilitate enforcement, we ask you to please answer the following questions:

- Are Section 13's labeling requirements for liquid nicotine containers now preempted and not being enforced?

- Does Section 13's labeling requirement apply to bottles of liquids that do not contain nicotine?

- Assuming other requirements of Section 19 are satisfied, if a customer has paid a fee for the privilege, may a retailer allow a customer to sample a nicotine-containing product under Washington law?

Thank you in advance for your answers. Please feel free to reach out to me via phone or email.

Sincerely,

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