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Testimony of the Department of Commerce and Consumer Affairs

Before the
House Committee on Health, Human Services, and Homelessness
Tuesday, March 23, 2021
9:00 a.m.
Via Videoconference

On the following measure:
H.R. 67, REQUESTING THE UNITED STATES FOOD AND DRUG ADMINISTRATION TO PROMOTE TRANSPARENCY AND ENFORCEMENT BY IMMEDIATELY PUBLISHING PREMARKET TOBACCO PRODUCT APPLICATIONS.

Chair Yamane and Members of the Committee:

My name is Catherine Awakuni Colón, and I am the Director of the Department of Commerce and Consumer Affairs (DCCA or Department). The Department appreciates the intent of this resolution and offers comments.

The purpose of this resolution is to request the United States Food and Drug Administration (FDA) to promote transparency and enforcement by immediately publishing premarket tobacco product applications (PMTAs). The resolution requests that the FDA disclose applicant information from PMTAs to Hawaii and that the DCCA apply this data to identify businesses that are not complying with federal requests to continue the legal sale of e-cigarettes and electronic nicotine delivery systems (ENDS) products.

The Department lacks subject matter familiarity in e-cigarette and ENDS regulation. However, based on a review of the FDA website, it appears that the FDA in

2020 issued guidance for the industry on its enforcement priorities for ENDS and Other Deemed Products on the Market Without Premarket Authorization (Revised)[1]. Based on that guidance, the FDA prioritized its enforcement efforts on the marketing of any ENDS product that lacks a PMTA after September 9, 2020. In addition, consistent with its enforcement priorities, the FDA issued warning letters to 10 firms that manufacture and operate websites selling ENDS products without a pending PMTA[2].

The FDA provided a status update on its PMTA processing and enforcement on February 16, 2021[3]. That update includes information on the expanded data on its Tobacco Product Application Metrics & Reporting webpage and reports that it has received PMTAs for 4.8 million applicants from 230 companies. The update further states that given the unprecedented number of PMTAs, the likelihood of the FDA reviewing all the applications by September 9, 2021,[4] is low.

Given the volume of pending PMTAs that have not yet completed, and the ability of companies to market products while applications are under FDA review, it is unclear what type of ENDS product marketing would be "illegal" as referenced on page 3, line 2, of this resolution. Also, if the language on page 3, lines 7 and 8, is intended to identify companies that are marketing ENDS products in the State without a pending or an approved PMTA by comparing instances of marketing in the State against a list of products pending FDA review, it is unclear how those examples of non-compliant marketing would be collected by the Department and, once collected, whether the intent is that the Department would then report these instances to the FDA.

The Department respectfully suggests that instead of placing responsibility for identifying companies operating in violation of the PMTA process in the State, the

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[1] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-priorities-electronic-nicotine-delivery-system-ends-and-other-deemed-products-market.
[2] https://www.fda.gov/news-events/press-announcements/fda-warns-firms-remove-unauthorized-e-liquid-products-market-first-letters-issued-manufacturers-did#:~:text=Today%2C%20the%20U.S.%20Food%20and,illegal%2C%20and%20therefore%20they%20cannot. See also, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters.
[3] https://www.fda.gov/tobacco-products/ctp-newsroom/perspective-fdas-progress-review-tobacco-product-applications-submitted-sept-9-2020-deadline.
[4] Products for which applications were submitted by September 9, 2020, may remain on the market for up to a year pending FDA review, although they remain subject to FDA enforcement.

resolution urge the federal government to devote sufficient staffing and resources to timely complete the PMTA review and decision making while encouraging ongoing transparency as the PMTAs move through the process.

Thank you for the opportunity to testify on this resolution.

Date: March 22, 2021

To: Representative Ryan I. Yamane, Chair
Representative Adrian K. Tam, Vice Chair
Members of the House Committee on Health, Human Services, and Homelessness

Re: Support for HCR 80/HR 67, Requesting the United States Food and Drug Administration to promote transparency and enforcement by immediately publishing premarket tobacco product applications.

Hrg: March 23, 2021 at 9:00 AM via Videoconference

The Coalition for a Tobacco-Free Hawai'i, a program of the Hawai'i Public Health Institute[i] **supports HCR 80/HR 67,** which urges the United States Food and Drug Administration (FDA) to publish the list of premarket tobacco product applications (PMTAs) to promote transparency and enforcement.

Electronic smoking device products that did not submit a PMTA are not allowed to be on the market.
In 2016, the FDA finalized its deeming rule, giving them the authority to regulate electronic smoking devices as tobacco products[ii]. With this rule, all electronic smoking devices would be need to submit a PMTA in order to stay on the market, with the original deadline of August 8, 2018.

After years of delays, the deadline for the FDA's PMTA finally came in September 2020. The FDA now has a year to review the PMTAs to ensure these tobacco products are "appropriate for the protection of public health." In the meantime, these products can remain on the market, despite the epidemic-levels of youth e-cigarette use driven by the abundance of kid-friendly flavors. In addition, any products that did not submit a PMTA are not legally allowed to be sold in the US. As of March 2021, the FDA has yet to release a list of products that have submitted a PMTA, making it difficult for agencies to determine if products are being sold illegally.

The Coalition supports the enforcement of current tobacco product regulations, and the publishing of the list of PMTA applications will help both consumers and retailers determine if products are legal. In addition to this resolution, we note that states have the authority and opportunity to

enact regulations on electronic smoking devices that are proven to be effective at reducing tobacco use. This year, the Hawai'i State legislature is considering numerous bills to regulate e-cigarettes through taxation[iii], removing flavors from tobacco products[iv], and restricting online sales to licensed tobacco retailers. These proven strategies reduce the appeal of and access to tobacco products by youth, as well as robust cessation and prevention education programs.

Thank you for the opportunity to provide testimony in **support of HCR 80/HR 67**.

Mahalo,

Jaylen Murakami
Advocacy and Outreach Coordinator

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[i] The Coalition for a Tobacco-Free Hawai'i (Coalition) is a program of the Hawai'i Public Health Institute (HIPHI) that is dedicated to reducing tobacco use through education, policy, and advocacy. With more than two decades of history in Hawai'i, the Coalition has led several campaigns on enacting smoke-free environments, including being the first state in the nation to prohibit the sale of tobacco and electronic smoking devices to purchasers under 21 years of age.

The Hawai'i Public Health Institute is a hub for building healthy communities, providing issue-based advocacy, education, and technical assistance through partnerships with government, academia, foundations, business, and community-based organizations.

[ii] U.S. Food and Drug Administration. (2020, June 3). Retrieved from https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/fdas-deeming-regulations-e-cigarettes-cigars-and-all-other-tobacco-products.

[iii] Centers for Disease Control and Prevention. Response to increases in cigarette prices by race/ethnicity, income, and age groups--United States, 1976-1993. *MMWR Morbidity and mortality weekly report*. 1998;47(29):605-609.

[iv] Rossheim, M. E., Livingston, M. D., Krall, J. R., Barnett, T. E., Thombs, D. L., McDonald, K. K., & Gimm, G. W. (2020). Cigarette Use Before and After the 2009 Flavored Cigarette Ban. *Journal of Adolescent Health*, *67*(3), 432–437. https://doi.org/10.1016/j.jadohealth.2020.06.022