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Testimony of the Department of Commerce and Consumer Affairs

Before the
House Committee on Consumer Protection and Commerce
Monday, March 29, 2021
2:00 p.m.
Via Videoconference

On the following measure:
H.C.R. 80, REQUESTING THE UNITED STATES FOOD AND DRUG ADMINISTRATION TO PROMOTE TRANSPARENCY AND ENFORCEMENT BY IMMEDIATELY PUBLISHING PREMARKET TOBACCO PRODUCT APPLICATIONS.

Chair Johanson 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 the FDA 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 the Department would collect those examples of non-compliant marketing 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.

DAVID Y. IGE
GOVERNOR OF HAWAII

ELIZABETH A. CHAR, M.D.
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Testimony COMMENTING on H.C.R. 80
REQUESTING THE UNITED STATES FOOD AND DRUG ADMINISTRATION TO PROMOTE TRANSPARENCY AND ENFORCEMENT BY IMMEDIATELY PUBLISHING PREMARKET TOBACCO PRODUCT APPLICATIONS

REPRESENTATIVE AARON LING JOHANSON, CHAIR
HOUSE COMMITTEE ON CONSUMER PROTECTION AND COMMERCE

Hearing Date: March 29, 2021 Room Number: Videoconference

Fiscal Implications: None

Department Testimony: The Department of Health (DOH) offers comments on House Concurrent Resolution 80 (H.C.R. 80) that proposes an official request by the Hawaii State House of Representatives, Thirty-first Legislature, to the U.S. Food and Drug Administration (FDA) to promote transparency and enforcement by immediately publishing Premarket Tobacco Product Applications (PMTA).

By court order, PMTA for new tobacco products, including electronic smoking devices (ESDs), certain cigars, and hookah products currently on the market, were to be submitted to the FDA by September 9, 2020. The products for which applications met the due date have been allowed to remain on the market for one year pending the FDA review. Upon completion of processing steps followed by science-based review and oversight by the FDA, only deemed new products will be available for sale.

The DOH supports the premise of this resolution encouraging the FDA to release information to the states regarding the list of PMTA submissions and final action whether the products are legally on the market. However, recent public notices from the FDA describe its

current progress on meeting the obligation toward transparency. A report[1] from Mitch Zeller, Director of the FDA's Center on Tobacco Products published on February 16, 2021, updated the status of the three phases of processing and reviewing the applications (Acceptance; Notification/Filing; Review; and Action). As of mid-January, the FDA had completed the processing step for applications representing 4.8 million products from 230 companies. Given the unprecedented number of applications and other factors, the likelihood is low the FDA will complete the review of all applications by September 9, 2021.

The FDA confirms that it is continuing to enforce against ESD products currently being sold without submitted applications. Warning letters were issued in January by the FDA to ten ESD product manufacturers who illegally operated websites, manufactured, and delivered their unauthorized new tobacco products without the requisite PMTA. None of the ten firms in violation was from Hawaii.[2] Specific reports currently available include, "A Deemed New Product Application List,"[3] and "The Tobacco Product Applications: Metrics and Reporting."[4]

The DOH is closely monitoring the rulemaking, enforcement, and scientific review process by the FDA at the national level, and it is clear that national efforts alone are not sufficient to protect Hawaii's youth from the proliferation and marketing of ESDs in our state. The lack of regulation of ESDs through licensing, permitting, and taxation in our state in comparison to combustible tobacco products represents a serious inadequacy. Underage youth have been able to access ESDs illegally, contributing to the alarming vaping epidemic. State

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[1] Perspective: FDA's Progress on Review of Tobacco Product Applications Submitted by the Sept. 9, 2020 Deadline accessed at https://www.fda.gov/tobacco-products/ctp-newsroom/perspective-fdas-progress-review-tobacco-product-applications-submitted-sept-9-2020-deadline?utm_source=CTPEblast&utm_medium=email&utm_term=stratout&utm_content=landingpage&utm_campaign=ctp-sept9

[2] News release on warning letters at FDA Warns Firms to Remove Unauthorized E-liquid Products from Market in First Letters Issued to Manufacturers that Did Not Submit Premarket Applications by Deadline | FDA

[3] Deemed New Tobacco Product Application List/FDA accessed at https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/deemed-new-tobacco-product-applications-list?utm_source=CTPEblast&utm_medium=email&utm_term=stratout&utm_content=landingpage&utm_campaign=ctp-sept9

[4] Tobacco Product Applications: Metrics & Reporting accessed at https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-product-applications-metrics-reporting?utm_source=CTPEblast&utm_medium=email&utm_term=stratout&utm_content=landingpage&utm_campaign=ctp-sept9

regulation along with the FDA disclosure of PMTA data would increase consumer protection against illegally marketed ESD products in Hawaii.

Thank you for the opportunity to testify on this resolution.

Offered Amendments: None

Date: March 28, 2021

To: Representative Aaron Ling Johanson, Chair
Representative Lisa Kitagawa, Vice Chair
Members of the House Committee on Consumer Protection and Commerce

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 29, 2021 at 2:00 PM 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

Date: March 26, 2021

To: The Honorable Aaron Ling Johanson, Chair
The Honorable Lisa Kitagawa, Vice Chair
Members of the House Committee on Consumer Protection & Commerce

Re: **Strong Support for HCR80/HR67**

Hrg: March 29, 2021 at 2:00 PM via Videoconference in Conference Room 329

Aloha House Committee on Consumer Protection & Commerce,

As a parent, community member and healthcare professional I am writing in **strong support of HCR80/HR67**, requesting the US Food and Drug Administration (FDA) to promote transparency and enforcement by immediately publishing premarket tobacco product applications.

Hawai‘i is in the midst of a youth vaping epidemic. Approximately 31% of Hawai‘i high school students and 18% of Hawai‘i middle schoolers are current e-cigarette users. For Native Hawaiian and Pacific Island youth these numbers climb to 40% for high school and 30% for middle school students. Yet, these products remain *unregulated*.

With enactment of the 2016 tobacco deeming rule FDA gained authority to regulate electronic smoking devices (ESDs) as tobacco products.

Under the deeming rule, manufacturers were required to submit premarket tobacco product applications (PMTAs) for every ESD product by September 9, 2020 in order for them to remain legally on the market.

Products with submitted PMTAs can be sold for a year while their applications are being reviewed. Products for which PMTAs were not submitted are now illegal.

However, FDA has yet to release a list of products for which PMTAs were submitted by the September 9, 2020 deadline. Without this information it is difficult for retailers and consumers to know which ESD products are legal for sale and which are not.

I **strongly support HCR80/HR67** and respectfully ask you to pass this resolution out of committee.

Many thanks for your consideration,

Forrest Batz, PharmD
Kea‘au, HI