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**STATE OF HAWAII
OFFICE OF THE DIRECTOR
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS**

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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.C.R. 80, 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 PMTA².

The FDA provided a status update on its PMTA processing and enforcement on February 16, 2021³. 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

¹ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-priorities-electronic-nicotine-delivery-system-ends-and-other-deemed-products-market>.

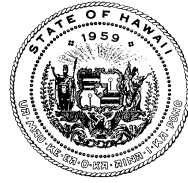
² <https://www.fda.gov/news-events/press-announcements/fda-warns-firms-remove-unauthorized-e-liquid-products-market-first-letters-issued-manufacturers>-
did#:~:text=Today%2C%20the%20U.S.%20Food%20and,illegal%2C%20and%20therefore%20they%20c
annot. See also, [https://www.fda.gov/inspections-compliance-enforcement-and-criminal-](https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters)
[investigations/compliance-actions-and-activities/warning-letters](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.



STATE OF HAWAII
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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 RYAN I. YAMANE, CHAIR
HOUSE COMMITTEE ON HEALTH, HUMAN SERVICES, AND HOMELESSNESS

Hearing Date: 3/23/2021

Room Number: Videoconference

1 **Fiscal Implications:** None

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

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

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

1 progress on meeting the obligation toward transparency. A report¹ from Mitch Zeller, Director
2 of the FDA’s Center on Tobacco Products published on February 16, 2021, updated the status of
3 the three phases of processing and reviewing the applications (Acceptance; Notification/Filing;
4 Review; and Action). As of mid-January, FDA had completed the processing step for
5 applications representing 4.8 million products from 230 companies. Further, given the
6 unprecedented number of applications and other factors, the likelihood is low of FDA reviewing
7 all the applications by September 9, 2021. However, while processing, the FDA confirms that it
8 is continuing to enforce against ESD products currently being sold without submitted
9 applications. Specific reports currently available include, “A Deemed New Product Application
10 List,”² and “The Tobacco Product Applications: Metrics and Reporting.”³

11 The DOH has closely monitored the rulemaking, enforcement, and scientific review
12 process by the FDA at the national level and it is clear that national efforts alone are not
13 sufficient to protect Hawaii’s youth from the proliferation and marketing of ESDs in our state.
14 The lack of regulation of ESDs through licensing, permitting, and taxation in comparison to
15 combustible tobacco products represents a serious inadequacy. Underage youth have been able
16 to access ESDs illegally, contributing to the alarming vaping epidemic. State regulation along
17 with FDA disclosure of PMTA data would increase consumer protection against illegally
18 marketed ESD products in Hawaii.

19 Thank you for the opportunity to testify on this resolution.

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 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

³ 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

1 **Offered Amendments:** None



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March 21, 2021

Honorable Chair Senator Yamane
Honorable Vice-Chair Tam
Members of the Health, Human Services and Homelessness

RE: **Strong Support of HCR80/HR67 regarding Premarket Tobacco Product Applications**

Dear Senators Yamane and Tam and members of the Health, Human Services and Homelessness Committee,

This measure is extremely critical to helping our state, retailers and consumers to know whether a product is legal or not as to whether or not there is a valid Pre-Market Tobacco Application (PMTA). Please vote in favor of HCR80/HR67.

I am Executive Director of the Hawaii COPD Coalition and serve over 45,000 Hawaii adults diagnosed with COPD in Hawaii (with an estimated equal number still undiagnosed). Chronic Obstructive Pulmonary Disease or COPD is an umbrella of diseases which include emphysema, chronic bronchitis and chronic asthma. Since 2007, I have worked in Hawaii, nationally and internationally with countless people who have had their lungs and lives horribly affected by tobacco and nicotine. Many of these people have become disabled and unable to perform jobs and hobbies they enjoyed, spending a lot more time and resources with healthcare providers than they or any of us would like.

With the deeming rule in 2016, the FDA gained authority to regulate electronic smoking devices as tobacco products. All electronic smoking devices needed to submit PMTAs to stay on the market by September 9, 2020. Products which had PMTAs submitted could be sold for a year while the application was being reviewed but products which did NOT submit a PMTA are illegal. To date, there have been no FDA list of those products which submitted a PMTA.

Please vote in favor of HCR80/HR67, so that retailers and consumers can know which products are legal and which are not. Thank you very much for taking action on this most important issue.

Very truly yours,

Valerie Chang

Valerie Chang
Executive Director



HIPHI Board

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*Misty Pacheco, DrPH
University of Hawai'i at Hilo,
Department of Kinesiology and
Exercise Sciences*

*Garret Sugai
Kaiser Permanente*

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 Instituteⁱ **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 productsⁱⁱ. 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 taxationⁱⁱⁱ, 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

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 19, 2021

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

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

Hrg: March 23, 2021 at 9:00 AM via Videoconference in Conference Room 329

Aloha House Committee on Health, Human Services & Homelessness,

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

HCR-80

Submitted on: 3/20/2021 11:15:30 AM

Testimony for HHH on 3/23/2021 9:00:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
Bryan Mih	Individual	Support	No

Comments:

Dear Committee Members:

As a pediatrician and medical director of the Kapi'olani Smokefree Families Program, I support this bill, which requests the FDA to publish a list of products with Pre-Market Tobacco Applications (PMTAs).

The FDA established authority via the deeming rule in 2016 to regulate electronic smoking devices as tobacco products. All electronic smoking devices that did not submit a PMTA by September 9, 2020, are now illegal. However, the FDA has not yet released a list of products that submitted a PMTA. This information is necessary for retailers and the public to know which products are legal or not.

The American Academy of Pediatrics strongly supports regulation of electronic smoking devices to prevent initiation of use, especially by young people. Hawaii has one of the highest rates of middle schoolers (18%) and high schoolers (31%) currently using e-cigarettes. For Native Hawaiian and Pacific Island youth the rates are even higher: 30% for middle schoolers and 40% for high schoolers. Requiring the FDA to provide the list of products with a PMTA will help in the appropriate regulation of these electronic smoking devices.

Mahalo for your consideration and support of this measure.

Sincerely,

Bryan Mih, MD, MPH, FAAP

Pediatrician