ON THE FOLLOWING MEASURE:

H.B. NO. 2097, RELATING TO MEDICAL CANNABIS.

BEFORE THE:

HOUSE COMMITTEE ON HEALTH

DATE: Tuesday, February 4, 2020 **TIME:** 8:30 a.m.

LOCATION: State Capitol, Room 329

TESTIFIER(S): Clare E. Connors, Attorney General, or

Tara K.C.S. Molnar, Deputy Attorney General

Chair Mizuno and Members of the Committee:

The Department of the Attorney General offers the following comments on this bill.

This measure would: (1) amend the definition of "manufactured cannabis product" in section 329D-1, Hawaii Revised Statutes (HRS); (2) amend section 329D-8, HRS, to allow for the remediation and retesting of product; (3) amend section 329D-10, HRS, to allow for the production of edible cannabis products; and (4) amend section 329D-11, HRS, to allow a dispensary to provide educational and scientific materials related to cannabis and its products, and sponsor events about cannabis that would not be considered advertising.

Comments on section 3, amending section 329D-8, HRS, to allow for the remediation and retesting of product. (page 3, lines 4-7)

This bill amends section 329D-8, HRS, to allow for the remediation and retesting of product. However, the proposed wording "any batch of product" is vague. This ambiguity could be resolved by clarifying whether the term "product" refers only to manufactured cannabis products or both cannabis and manufactured cannabis products.

Comments on section 4, allowing a dispensary to produce edible cannabis products. (page 5, lines 16-18; page 6, line 1, through page 7, line 4)

Testimony of the Department of the Attorney General Thirtieth Legislature, 2020 Page 2 of 2

If the Committee is inclined to allow the production of edible cannabis products, we suggest, for the purposes of clarity, replacing the wording, on page 6, line 21, to page 7, line 2, "and not under section 328-1 as "food" and exempted from those further requirements," with "and not as "food" as defined and regulated in chapter 328."

Thank you for the opportunity to provide comments.



TESTIMONY BY:

JADE T. BUTAY DIRECTOR

Deputy Directors
LYNN A.S. ARAKI-REGAN
DEREK J. CHOW
ROSS M. HIGASHI
EDWIN H. SNIFFEN

STATE OF HAWAII DEPARTMENT OF TRANSPORTATION

869 PUNCHBOWL STREET HONOLULU, HAWAII 96813-5097

February 4, 2020 8:30 a.m. State Capitol, Room 329

H.B. 2097 RELATING TO MEDICAL CANNABIS

House Committee on Health

The Department of Transportation (DOT) opposes H.B. 2097.

Among other provisions, this bill allows licensed retail dispensaries to sell edible cannabis products. Edible marijuana is very different from "joints" and other marijuana products, and the effects of THC when consumed in edibles compared to smoking sometimes takes several hours. People are more likely to eat more than the recommended serving since they don't immediately feel the effects. These same people may get into a car and start driving, which may lead to serious or fatal consequences.

Cannabis can impair a driver's cognitive function, affecting a driver's time/space perception, reaction time, ability to concentrate, etc. Contrary to popular belief, marijuana does not make someone a better, more careful driver. According to the "Drug Recognition Expert (DRE) Examination Characteristics of Cannabis Impairment" study published in the July 2016 Accident Analysis & Prevention Journal, an evaluation of 302 toxicologically-confirmed cannabis-only DRE cases saw that in 72.3 percent of cases, one or more moving violations were listed as reasons for the traffic stop. Speeding was the number one violation (27.7 percent), followed by weaving (19.0 percent). Similarly, in a two-year study of THC in drivers in Orange County, California, published in the August 2016 Journal of Forensic Science, the top five moving violations were speeding (24 percent), unable to maintain lane position (23.2 percent), ran red light or stop sign (13.0 percent), unsafe lane change (8.7 percent) and involved in a collision (8.3 percent).

In Hawaii, a local study on motor vehicle crash fatalities and undercompensated care associated with legalization on medical marijuana finds that "THC positivity among driver fatalities increased since legalization, with a threefold increase from 1993-2000 to 2001-2015. THC positivity among all injured patients tested at our highest level trauma

center increased from 11% before to 20% after legalization. From 2011 to 2015, THC positive patients were significantly less likely to wear a seatbelt or helmet (33% vs 56%)." The study was published in the Journal of Trauma and Acute Care Surgery in May 2018.

DOT is primarily concerned about improving highway safety and protecting the lives of our community members and visitors. DOT coordinates specialized training and certifies law enforcement officers to recognize impairment in drivers under the influence of drugs through its DRE program to combat this issue.

Thank you for the opportunity to provide testimony.



TO: Committee on Health

FROM: Miles Wesley Tuttle & Adealani Wesley HEARING DATE: 4 February 2020, 8:30 AM

RE: HB2097, Relating to Medical Cannabis, STRONG SUPPORT

Dear Chair Mizuno, Vice Chair Kobayashi, and Members of the Committee,

The introduction of manufactured, cannabis-infused edible products to the list of approved cannabis products in the state of Hawaii presents many positive solutions to patient health and preference. This introduction also raises concerns about the possible negative consequences, mostly the unintentional ingestion of edible cannabis-infused products by Hawaii's children. Following two years of a state Medical Dispensary Program, it is becoming apparent that Hawaii's Medical Cannabis patients and Out-of-State Patients (OSP) are asking for edible Cannabisinfused products more frequently to serve as an alternate method of ingesting their medicine. To better inform all parties involved in this process of considering the approval of Cannabis-infused edible products, we are conducting a Health Impact Assessment focused on preventing the unintended ingestion of edible Cannabisinfused products by Hawaii's children, the potential role that child-resistant packaging, a mandatory edible-specialist/patient consultation, and a systematic addition or narrowing of allowable edible types of products could play in mitigating the problem. After reviewing the scientific evidence and incorporating stakeholder input, we make the following recommendations:

- 1. Require Certified Child-Resistant Packaging that is non-attractive to children and possess a Universal Warning Symbol.
- 2. Implement Accurate and Proper Labeling Requirements.
- 3. Systematic addition of types of edible products, beginning with Chocolated Medicinal Pieces.
- 4. Mandatory Consultation with Cannabis-infused edibles safety specialist.
- 5. Specify a maximum milligram/container content for edibles.
- 6. Access to educational material provided to patients regarding the consumption of edibles.

Background

The introduction and allowance of retail sale of Cannabis-infused edible products has been on the legislative table for a couple of years. Act 116 Medical Cannabis Outstanding Issues Working Group was established by the legislature pursuant to H.B. 2729, H.D. 2, S.D. 2, C.D. 1, Act 116 (2018). The working group was convened by the Department of Health, Office of Medical Cannabis Control, and Regulators to consider and make recommendations regarding edible products. Their recommendation was focused on the authorization and regulation of the manufacture and dispensing of edible cannabis products by a licensed medical cannabis dispensary.

This Working Group concluded the following recommendations:

- 1. Amend the definition of "manufactured medical cannabis product" to differentiate edibles from other manufactured products.
- 2. Eliminate edible products that are not shelf-stable, are potentially hazardous, may increase the toxicity of cannabis, may create an unsafe combination with other psychoactive substances, or any item attractive to children.
- 3. Amend edibles product-packaging requirements to include the use of a universal symbol.
- 4. Implement a system of reporting product complaints, such as a State Poison Control Hotline toll free number included on edible cannabis packaging.
- 5. Specify cannabis edible product labeling requirements to include information applicable to consumption, such as estimated activation time, serving size, number of servings per container, cannabinoid content per serving, and ingredients.
- 6. Require product packaging to be continually child-resistant.
- 7. Incorporate appropriate provisions for manufacturing protocol.
- 8. Implement manufacturing standards, including limitations of cannabinoid concentration per serving, and providing tools to help with portioning.
- 9. Create a process for the systematic addition of product categories to help control uniform distribution of cannabanoids within each product.
- 10. Implement a product recall system.
- 11. Establish mandatory pre-purchasing education protocol for patients new to the purchase of edibles.

The Need for Cannabis-Infused Edibles

During the last two years of operation, the Medical Cannabis Dispensaries in the state of Hawai'i have had multiple requests for the availability of ready-to-eat cannabis products. Patients who try to make their own edible products at home have found that it is a difficult process to properly and accurately extract cannabanoids from the Cannabis flower provided in Medical Dispensaries, and/or accurately dose and homogenize the cooking oil provided as well.

A majority of Hawaii's Medical Cannabis patients use cannabis to help relieve their chronic and severe pain. Through research, it has been found that THC ingested via the gastrointestinal tract provides a longer lasting effect, and is more suitable for overnight relief than a smoked Cannabis product.

Other qualifying conditions that specifically recommend the usage of edible Cannabis products are Cachexia for nausea/vomiting and stimulating appetite; Multiple Sclerosis for spasticity; PTSD symptoms, and those suffering from lung disease, due to the inability to inhale Cannabis via smoking or vaporizing.

Hawai'i has an incredible tourist population throughout the year. Our Out-of-State Medical Cannabis program (OSP) is slowly becoming more popular with other Medical Cannabis patients throughout the United States that visit our islands, however these out-of-state patients are presented with a difficult situation as to where they are able to consume their medicine. Hotels and Condo-hotels are non-smoking residences, as are public places within the state. As Medical Dispensaries are currently not allowed to offer edibles, it leaves our out-of-state patients with purchased medicine and nowhere to medicate... legally.

Impact

The introduction of Cannabis-infused edible products into Hawaii's Medical Cannabis Program will have intended positive impacts as well as unintended negative impacts, the latter of which we hope to mitigate.

The main impact is presenting Hawaii's resident and out-of-state patients with an alternative form of ingestion of Cannabis. By making this alternate option available to patients, it will allow them the flexibility of using their medicine in a form that is complimentary to their specific qualifying condition, preference, environment, or activity/time of day. Patients with lung disease will be able to have an efficient and effective way to consume their Medical Cannabis. This positive impact of an alternative form of Cannabis ingestion could lead to an increase in the overall Medical Cannabis resident and out-of-state patient population in the State of Hawaii. This increase could lead to a higher number of legal patient purchases, and therefore would boost the Medical Cannabis Dispensary sales in the state and hopefully save the patients (who have no Cannabis cooking experience) the time, money and frustration of trying to make edibles themselves. This alternative form of ingestion would also solve the problem of out-of-state patients having no physical location to consume Cannabis due to public places and hotels being non-smoking environments. Resident patients would benefit from this impact as well, as many live in condominiums or apartments that do not allow smoking. A vast number of patients prefer edible consumption based on the longer lasting effect, especially beneficial for sleeping. This option of ingestion also eliminates the odor of Cannabis

smoke and the ongoing negative stigma toward Cannabis that many patients are still dealing with.

Another positive impact of the introduction of Cannabis-infused edible products into the Medical Cannabis Program in the state of Hawai'i is the ability of the Medical Cannabis Dispensaries to manufacture a regulated, quality product for its patients. As the Medical Dispensaries are strictly regulated by the Department of Health, they must have all of their products lab-tested and THC content accurately dosed. These dispensaries must operate in accordance with the Hawai'i State Food Safety Code. Based on the advanced technologies that the current production centers of the State Medical Cannabis Dispensaries already possess for the extraction/processing of other manufactured Cannabis products, achieving homogeneity within an edible product would be feasible: a task that is extremely difficult to accomplish in a home kitchen. The current dispensaries would also already have the capabilities to label the edible products appropriately to mitigate any misunderstanding of contents, as they already implement this practice for other Cannabis products. These standards that Hawaii's Medical Cannabis Dispensaries would be able to offer to its patients would ultimately lead to a healthier, safer edible product. This would make its consumption a positive experience, and decrease the number of patients who may suffer from the risks involved in the actual manufacturing or cooking of the edible Cannabis-infused product, and potentially over-medicating unintentionally.

An unintended negative impact of the introduction of Edible Cannabis-infused products is the potential increase in Cannabis use among youth, mainly in the form of unintentional ingestion by Hawaii's children. This is an issue that is incredibly important in every stakeholder's eyes. Edible foods, especially those that are worthy of the title "treat," are already more appealing to children than other forms Cannabis, such as flower or concentrated material. A Cannabis-infused "gummy bear" might look the same as a non-Cannabis-infused "gummy bear". The accessibility of edible Cannabis-infused products to children is a problem that could be a result of the adult patient's irresponsibility when considering its storage. It is up to the adult patient to protect their children or grandchildren from accessing Cannabis products, similar to other prescription medications that they may have to be responsible for. The dispensaries and doctors should be able to help their patients to be fully aware of how to accomplish this task, as well as inform the patients of the risks of this form of ingestion, such as overconsumption.

Another unintended negative impact of introducing Cannabis-infused edibles to the Hawaii Medical Cannabis Program is the potential overmedication of patients. This overmedication usually results from being under-informed in regards to the consumption and safety of edible Cannabis products. As edible products have a delayed response in the effects felt, it is common to be impatient and overmedicate. It is also sometimes difficult to dose or portion out pieces of edible products appropriately. Labeling of the product can be quite extensive, and there can be difficulty in understanding the consumption and storage instructions on the label.

All of these situations could lead to unintentional overmedication, which could be followed by patient discomfort or anxiety, increased hospital visits, or other adverse negative health effects.

Recommendations

We introduce the following recommendations to provide mitigation of the unintended negative impacts discussed above. We have separated them into two categories: Youth Use & Patient Understanding.

YOUTH USE:

1. Require Certified Child-Resistant Packaging -

Packaging for Cannabis-infused Edibles should adhere to Title 16 of the Code of Federal Regulations Part 1700 of the Poison Prevention Packaging Act of 1970 (PPPA). This packaging should be opaque, re-closable and non-attractive to children. Here are a few options of Certified Child Resistant Edibles Packaging Products:







2. Implement Accurate and Proper Labeling Requirements.

As proposed by the Working Group, labeling requirements should included information applicable to consumption, such as estimated activation time, serving size, number of servings per container, cannabinoid content per serving, and ingredients. Clear directions for use and storage should be present on the label, as well as a universal warning symbol.





3. The systematic addition of types of edible products beginning with chocolated medicinal pieces.

These could be aesthetically similar to Ex-Lax Medicated Laxative Pieces, a medicinal edible product that is non-appealing to children currently offered in our pharmaceutical market.



PATIENT UNDERSTANDING:

4. Mandatory Consultation with an edibles safety specialist.

All patients who purchase Cannabis-infused edibles should be required to have a mandatory consultation with a Cannabis-infused edibles specialist before they leave the dispensary premises. This consultation should encompass the directions for use and safety of storage of their purchased edible product(s). (Not the dosage that is recommended for them, as the latter should be discussed with their Doctor or APRN)

- 5. Specify a maximum milligram/container content for edibles.
- 6. Educational material should be provided to all patients regarding consumption of edibles.

Thank you for this opportunity.

HB-2097

Submitted on: 2/3/2020 7:23:21 AM

Testimony for HLT on 2/4/2020 8:30:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
Brian Murphy	PATIENTS WITHOUT TIME	Oppose	No

Comments:

PATIENTS WITHOUT TIME begrudgingly SUPPORT HB2097,

which Authorizes dispensaries to advertise, and promote their closed monopoly system, and to "remediate" any batch of inferior cannabis that failed testing for quality. Edibles should be available because **after TWENTY YEARS of WAITING** - cannabis Patients need legal access to safe, standardized edibles, but not purchased from an unjust, over-priced corporate monopoly.

Cannabis should be legalized, and regulated like any other Hawaii businesses!

For the last two decades, Hawaii has been enforcing laws UNEQUALLY upon cannabis consumers, sending some to jail for cannabis crimes, while selling other citizens, (and visiting tourists), a "stay out of jail" card, from the "criminal activity" of consuming cannabis!

HAWAII LAWS VIOLATE CANNABIS CONSUMER'S RIGHT TO EQUAL JUSTICE!

Cannabis consumers have been persecuted and prosecuted for generations, now Hawaii's cannabis patients are being abused for profits. **Meanwhile, the opioid crisis and alcohol crisis in Hawaii continues to worsen, while citizens die.**

Hawaii's PAY-TO-PAY, vertically-integrated, seed-to-sale, medical cannabis monopoly, is operated like a mafia "protection from prosecution" racket, instead of a compassionate health care program.

Poor patients have been priced out of the system for 20 years! While anyone with money can buy a certification, no matter what their actual physical condition, rendering any medical research completely unreliable.

Hawaii needs a real medical cannabis program, AND an adult use program; two separate programs, not the "DUAL-Use" closed-program, as discussed in legislative meetings, and outlined in SB 686 SD1, both of which give Hawaii's entire adult-use market to the dispensary monopoly.

All citizens should have the right to grow their own cannabis strains.

Hawaii's adult-use market should be legalized just as it has been operating for generations; which is thousands of small cannabis entrepreneurs, growing, processing, packaging and delivering world-famous brands of Hawaiian cannabis, and **the cannabis industry should be regulated like any other Hawaii businesses.**

Hawaii's cannabis industry should legalize the thousands of local growers that support their families, and communities by growing cannabis. Not handed over to a small group of big corporations, under the "plantation-mentality" that has destroyed Hawaii's sustainability.

Brian Murphy, Director
PATIENTS WITHOUT TIME

HAWAI'I CANNABIS INDUSTRY ASSOCIATION

February 4, 2020

TO: Representative John M. Mizuno, Chair Health

Representative Bertrand Kobayashi, Vice Chair Health

Members of the House Committee on Health

FR: Teri Freitas Gorman, 2020 Chair, Hawai'i Cannabis Industry Association (HCIA)

Re: HB2097 RELATING TO MEDICAL CANNABIS. - SUPPORT

RELATING TO MEDICAL CANNABIS.

Allows for a process to remediate any batch of cannabis that fails laboratory testing standards so long as any final product passes all such laboratory standards. Authorizes licensed retail dispensaries to sell edible cannabis products, under certain conditions, and circulate, sponsor, and promote educational and scientific information and events related to cannabis.

The Hawai'i Cannabis Industry Association (HCIA), formerly known as the Hawai'i Educational Association for Licensed Therapeutic Healthcare (HEALTH), represents all eight of the state's licensed medical cannabis dispensaries plus associate members. The provisions of HB2097 ensure i) registered patients have access to an adequate, affordable supply of manufactured medical cannabis products; ii) provides patients with a wider selection of safety-assured products for those who choose not to inhale cannabis for personal or health reasons; and iii) benefits registered and prospective cannabis patients by allowing dispensaries to disseminate scientific and educational information to increase awareness of the potential therapeutic benefits of quality-assured medical cannabis.

FLOWER REMEDIATION: "Consider processes that allow any batch of product that fails testing standards to be remediated and manufactured so long as any final product passes testing standards."

This provision reflects widespread industry practice while upholding the Department of Health's foundational principles of product safety, patient safety, and public safety. In accordance with these principles, Hawai'i's testing standards have been among the most stringent in the industry, requiring comprehensive testing for flowers and manufactured products. In fact, Hawai'i testing standards have led the industry, especially with regard to the most dangerous pathogens.

For example, it wasn't until September 15, 2019 that Colorado mandated that cannabis plant material that failed yeast and mold testing, and is remediated through extraction to produce cannabis concentrates, must be retested for mycotoxins prior to sale.¹ In fact, Hawai'i's threshold for failure due to the presence of mycotoxins is zero. Regulations of the Hawai'i Department of Health have always mandated a full battery of lab tests for manufactured cannabis products prior to sale.²

¹ Colorado Revised Statues (C.R.S) 44-11-202 (3)(a)(I) & 44-12-202(3)(a)(IV)

² Hawai'i Administrative Rules §11-850-85: Laboratory Standards & Testing

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Prevention is the best way to halt biological contamination in cannabis, so Hawai'i's medical cannabis licensees use measures such as dehumidification, air filtration and biological controls.

According to Michael Covington, chief operating officer for Steep Hill Hawai'i, when cannabis flowers fail mandated testing in Hawai'i, its due to the detection of "biological organisms," including mold, yeast and bacteria. Pesticide residues are very rarely detected, as Hawai'i's licensed growers tend not to use pesticides.³

The biological and chemical contaminents that can trigger dried cannabis flowers to fail Hawai'i's testing standards can often be safely rectified using industry standard processes, such as supercritcal CO2 extraction and processing methods common in the food industry. Bottom line: remediated products available to patients at state-licensed medical cannabis dispensaries have passed a full battery of stingent lab tests administered by independent labs regulated by the State Laboratory Division at Hawai'i DOH.

CANNABIS-INFUSED EDIBLE PRODUCTS: Hawai'i's medical cannabis dispensaries began operating nearly two and a half years ago and throughout this time, a common patient question has been "Why do you not offer edibles?"

The medical cannabis dispensary program's current list of approved products includes ingestible products like tinctures, capsules or lozenges, but many patients prefer to consume cannabis in food for medical reasons. Patients with damaged or diseased lungs cannot inhale cannabis; cancer patients coping with severe nausea or loss of appetite often find edibles to be the most palatible method of administration; and many patients with severe chronic pain prefer edibles for longer pain relief enabling them to enjoy sound sleep for 6 to 8 hours.

Banning edible products from regulated dispensaries leaves patients with two risky alternatives: making their own edible products at home or purchasing products on the black market. Home-cooks discover it is nearly impossible to accurately calculate THC potency in homemade cannabinoid-infused foods. This greatly increases the danger of accidental overdose by an adult and homemade edibles are often accessible to children and other unsuspecting adults seeking a snack.

The recent vaping illnesses demonstrated the health hazards of purchasing illicit products from the black market. Plus, THC-infused, gummy bears and candies in colorful packages are much more enticing to children than the plain packaging mandated by Hawai'i's medical cannabis program.

Currently, edible products are approved for medical cannabis patients in Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida (pending regulations), Illinois, Maine, Maryland, Massachussets, Michigan, Nevada, Ohio, Oregon, Rhode Island, Vermont, and Washington. These states

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³ Hawai'i lab rejects more than 20% of medical marijuana tested, *Marijuana Business Daily*, October 12, 2018

HAWAI'I CANNABIS INDUSTRY ASSOCIATION

have successfully passed laws and regulations that ensure product safety while effectively barring minors from accessing cannabinoid-infused products and preventing accidental overdose by adults.

We believe this bill contains industry best practices for dispensing edible cannabis products for medical use including:

- Edible products must undergo and pass all laboratory tests;
- A mandatory warning on the label that states: "WARNING: CONTAINS CANNABIS FOR MEDICAL USE. THIS IS NOT FOOD. KEEP OUT OF REACH OF CHILDREN";
- Labels must contain a list of all ingredients;
- Ensuring that the words "candy" or "candies" or "gummy" or "gummies" do not appear on product packaging; and
- Be regulated and approved by the Department of Health's Office of Medical Cannabis Control & Regulation as a medical cannabis manufactured product.

Removing the existing legislative restriction on licensed dispensaries for cannabis-infused edibles will ultimately allow the DOH to exercise its reguatory authority to approve or refuse any cannabis product available in a state-licensed dispensary.

AMEND ADVERTISING RESTRICTIONS TO ALLOW PROMOTION OF PUBLIC EDUCATION

With the passage of HB 321 in 2015 the legislature intended to offer education as part of the medical cannabis program. "HRS §329D-26 (a) provides for a continuing education and trainining program...for community partner agencies, physicians and other healthcare providers, patients, and caregivers, law enforcement agencies, law and policy makers, and the general public." The DOH has been able to educate other agencies, but public education is a huge task best shared among stakeholders.

The association believes that Hawai'i's citizens would benefit from a more thorough understanding of the risks and benefits of medical cannabis usage. Current legislation prevents licensees from promoting or advertising scientific or medical information or events produced for educational purposes. This bill amends current law to allow dispensaries to promote educational events while limiting the purpose to ensure such activity does not promote only commercial interests. We believe this amendment will help dispensaries to replace misinformation and stigma with a more accurate and balanced view of medical cannabis based upon scientific and medical evidence.

Mahalo for the opportunity to testify on behalf of the state's eight medical cannabis licensees and for your consideration to move this bill forward on behalf of the state's 27,152 registed medical cannabis patients.



95-595 Kanamee Street, #326 Mililani, Hawaii 96789-1431 (815) 310-0808 hawaii@outlook.com www.ryanozawa.com

@hawaii OУ► in ⊕ ≥ t ▲ 🏻 🚵

January 31, 2020

Aloha e Rep. John M. Mizuno, Chair, Rep. Bertrand Kobayashi, Vice Chair, and members of the Committee on Health:

I am writing to express my **support** of HB 2097 as it relates to medical cannabis.

My interest in this issue is more than intellectual. Someone very close to me is a Metastatic Breast Cancer (MBC, or Stage 4) patient. Cancer has invaded her bones, and threatens her organs, and she lives with chronic pain. Yet she remains a committed and loving mother of three, a hardworking retail employee, and a first-class wife.

She does benefit from excellent industrial healthcare that provides for powerful daily painkillers – painkillers that bring relief, but that also make headlines every day for their dangerous and sometimes addictive properties. And for all the relief they provide, I can speak firsthand to the chemical and emotional turmoil that this dependence creates.

The one thing that has helped reduce this dependence, and brought additional relief, is the state's nascent medical marijuana program. We are glad to be able to patronize professional and well-regulated facilities for additional help in this lifelong battle. But it is time to take the next step, and that is to allow an additional and more convenient delivery method.

It's frustrating that delivery is currently limited to smoking, vaping, and tinctures, options that range from unhealthy to unappealing and certainly don't help with cancer-related nausea. Edibles are safe, unoffensive, and with the rules stipulated in HB 2097, well regulated.

HB 2097 also provides an opportunity for the medical cannabis industry to be more active in the community in education and outreach, efforts that I am confident will yield positive results for everyone.

Thank you for your consideration.

<u>HB-2097</u> Submitted on: 2/3/2020 10:03:33 AM

Testimony for HLT on 2/4/2020 8:30:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
Tai Cheng	Individual	Support	Yes

Comments:

HB-2097

Submitted on: 2/3/2020 12:01:52 PM

Testimony for HLT on 2/4/2020 8:30:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
Joshua Siefman	Individual	Support	No

Comments:

I support HB 2097, edibles needs to be allowed to be sold by dispensaries this will help further overall progress towards cannabis legalization. Many patients that are unable to smoke have edible cannabis as their only option. Some of these patients are not able to make edibles at home, they need more options.



BRUCE S. ANDERSON, Ph.D.

DAVID Y. IGE



P. O. Box 3378 Honolulu, HI 96801-3378 doh.testimony@doh.hawaii.gov

Testimony COMMENTING on H.B. 2097 RELATING TO MEDICAL CANNABIS

REPRESENTATIVE JOHN M. MIZUNO, CHAIR HOUSE COMMITTEE ON HEALTH

Hearing Date: Tuesday, February 4, 2020 Room Number: 329

- 1 **Fiscal Implications:** Cannot be determined at this time.
- 2 **Department Testimony:** The Department of Health (DOH) appreciates the opportunity to offer
- 3 COMMENTS on the following proposals:
- 4 (1) Allowing for the remediation of cannabis products;
- 5 (2) Authorizing dispensaries to sell edible cannabis products under certain conditions; and
- 6 (3) Allowing dispensaries to circulate, sponsor, and promote educational and scientific
- 7 information and events related to cannabis.
- 8 Allow us to address each one separately.
- 9 (1) Remediation DOH offers COMMENTS and proposes alternate language.
- In 2015, the Hawaii Legislature established a regulated statewide dispensary system to
- ensure safe and legal access to medical cannabis for qualifying patients. In doing so, the
- Legislature authorized DOH to "establish and enforce standards for laboratory-based testing of
- cannabis and manufactured cannabis products for content, contamination, and consistency." In
- 2017, the Legislature amended the requirements for laboratory standards and testing to ensure
- product and patient safety at reasonable tolerance levels with reasonable cost implications,

- 1 providing that DOH "[r]eview and take guidance from the testing programs and standards
- 2 utilized in other jurisdictions," and "[c]onsider the impact of the standards on the retail cost of
- 3 the product to qualifying patient."

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- 4 Cannabis plants, like other living things, are likely to be naturally contaminated with
- 5 microorganisms, some of which pose a risk to patient safety. This is why DOH requires every
- 6 batch of cannabis flower and manufactured product to meet laboratory standards for bacteria,
- yeast, and mold, as well as other contaminants before being allowed to be sold. All final products
- 8 that fail even one standard are destroyed and cannot be sold.

While regulatory decisions should be based on scientific evidence, the fact remains that although scientific knowledge about cannabis is rapidly evolving, it remains limited. In such cases, decision-making should be based on a reasonable balance of risk analysis, a scientifically-based process of evaluating hazards, the likelihood of exposure to those hazards, and an estimate of the resulting public health impact. Given the potential impact to patients of destroying whole batches of cannabis flower (e.g., cost and the unavailability of products) when methods already in use by other industries, such as pasteurization and concentrated ozone¹, are available to address microbial contamination, it is reasonable to allow the remediation of cannabis under certain circumstances. It does not make sense to regulate based on potential risks that are not evidence-based. If this were the case, there would be no medical use of cannabis.

¹ Prabha, Vithu & Barma, Deb & Singh, Ranjit & Madan, Aditya. (2015). Ozone Technology in Food Processing: A Review. Trends in Biosciences 0974-8. 6. 4031-4047, commenting that ozone is effective against various kinds of microorganisms; decomposes rapidly to produce oxygen, leaving no residues, and is used in water treatment, sanitising, washing and disinfection of equipment, odour removal, and fruit, vegetable, meat and seafood processing; and that ozone treatment retains the sensory, nutritional and physicochemical characteristics of food.

1 To keep abreast of standards used in other jurisdictions, as charged by the Legislature, Hawaii's dispensary program actively participates in a national regulators' workgroup comprised 2 of the administrators, laboratorians, environmental health scientists, enforcement, medical, and 3 legal advisors of the 33 states and District of Columbia with legalized medical use. This 4 workgroup meets twice a year in-person and has monthly conference calls. The cannabis industry 5 is not a part of this workgroup. 75% of participating states explicitly allow for remediation in 6 7 limited circumstances, e.g., only for failed flower material and only for failed microbial standards, but not manufactured products, and not for failed pesticides and heavy metals. The 8 practice of other jurisidictions also helps to inform the viewpoint that it is reasonable to allow 9 10 remediation of cannabis under certain circumstances. Should the committee be inclined to allow this amendment to move forward, DOH 11 requests that any remediation of medical cannabis or manufactured medical cannabis products be 12 subject to DOH review and approval, provided that any final product must pass all required 13 quality assurance standards to be dispensed. This will allow DOH to properly assess each request 14 15 and make a determination based appropriately on current scientific knowledge. This will also allow DOH to monitor the scope and volume of testing failures to promptly identify issues that 16 could jeopardize patient safety. And, it will also allow DOH to more readily and appropriately 17 respond to industry and technology innovations. 18 DOH offers the following alternate language (underlined) for the proposed 19 amendment under SECTION 3, amending subsection (a) of section 329D-8, HRS, to allow 20 21 for remediation (page 3, lines 4-7):

"(4) Consider requests from a licensed medical cannabis dispensary to allow the remediation of a batch of medical cannabis or manufactured medical cannabis product, provided that any such batch of medical cannabis or manufactured medical cannabis product approved for remediation shall meet all required laboratory standards to be dispensed."

(2) Edibles – DOH offers COMMENTS and proposes alternate language.

DOH's overwhelming concern related to edible cannabis products ("edibles") is ensuring patient and product safety. As demonstrated by the recent nationwide outbreak of vaping-related lung illnesses, the addition of a single ingredient to a product can result in significant morbidity and mortality among previously healthy individuals, and medical cannabis patients are certified as having a debilitating medical condition. "Edibles" can comprise a myriad of products from confections to baked goods to savory items to beverages. To ensure product safety, any approval for edible products should be made on a case-by-case basis and based on a thorough assessment which considers good manufacturing practices, dosing, serving size and homogeneity, labelling and packaging, food safety training of employees, and of course, laboratory testing, among other things.² Towards this end, over half of state cannabis programs require the pre-approval of all products, including requirements or limits related to ingredients or flavorings. One-third of medical-use only states explicitly prohibit edibles. Hawaii is not alone.

When dispensary facilities first began opening in 2017 and the types of manufactured

² Nat'l Environmental Hlth Assn. (March 2018). Food Safety Guidance for Cannabis-Infused Products. Retrieved from https://www.neha.org/sites/default/files/eh-topics/food-safety/Food-Safety-Guidance-Cannabis-Infused-Products.pdf.

- products were limited, the program focused heavily on security concerns related to the 2013 Cole
- 2 Memorandum.³ However, in 2019, to prepare for potential expansion of the types of authorized
- 3 products, the dispensary program augmented its attention to quality control, health, safety, and
- 4 sanitation standards by incorporating the elements of section 11-850-75, HAR, into routine
- 5 inspections. In 2019, the program conducted 151 facility inspections, over 100 of which were
- 6 unannounced. The only inspections that are scheduled are record reviews and inspections
- 7 pertaining to approvals for new facilities. Also in 2019, DOH administratively re-assigned
- 8 environmental health support functions for the dispensary program from the DOH Food Safety
- 9 Program (formerly the Sanitation Branch) to the DOH Food and Drug Program to align with its
- 10 role of ensuring that food, drugs, cosmetics, medical devices and related consumer products are
- 11 safe.
- Another major DOH reservation related to edibles remains the risk of accidental
- poisoning of children. Studies continue to show that changes in laws which made edible products
- more accessible to children have resulted in increased child exposures.^{4, 5, 6, 7, 8} Adult over-
- 15 intoxications from overconsumption due to failed appreciation of the delayed effects of edibles

³ Memorandum for All United States Attorneys: Guidance Regarding Federal Marijuana Enforcement, Office of the Deputy Attorney General (August 29, 2013).

⁴ Wang GS, Roosevelt G, Heard K. Pediatric Marijuana Exposures in a Medical Marijuana State. JAMA Pediatr. 2013;167(7):630–633. doi:10.1001/jamapediatrics.2013.140

⁵ Wang, George S. et al. Association of Unintentional Pediatric Exposures With Decriminalization of Marijuana in the United States. Annals of Emergency Medicine, Volume 63, Issue 6, 684 - 689

⁶ Wang GS, Le Lait M, Deakyne SJ, Bronstein AC, Bajaj L, Roosevelt G. Unintentional Pediatric Exposures to Marijuana in Colorado, 2009-2015. JAMA Pediatr. 2016;170(9):e160971. doi:10.1001/jamapediatrics.2016.0971

⁷ Dazhe Cao, Sahaphume Srisuma, Alvin C. Bronstein & Christopher O. Hoyte (2016) Characterization of edible marijuana product exposures reported to United States poison centers, Clinical Toxicology, 54:9, 840-846, DOI: 10.1080/15563650.2016.1209761

⁸ Whitehill JM, Harrington C, Lang CJ, Chary M, Bhutta WA, Burns MM. Incidence of Pediatric Cannabis Exposure Among Children and Teenagers Aged 0 to 19 Years Before and After Medical Marijuana Legalization in Massachusetts. JAMA Netw Open. 2019;2(8):e199456. doi:10.1001/jamanetworkopen.2019.9456.

also remain of concern. The consequences of unintentional exposure in children and adult			
intoxications must be considered when proposing to authorize edibles.			
Should the committee be inclined to allow this amendment to move forward, DOH			
requests authority to pre-approve all manufactured cannabis products, including edibles, as well			
as the authority to establish and modify, as appropriate, requirements or limits to ingredients,			
flavorings, or additives, product packaging and labelling, employee training, and requirements			
for patient education on safe usage and safe storage.			
$ DOH \ offers \ the \ following \ alternate \ language \ (\underline{underlined}) \ for \ the \ proposed $			
amendment under SECTION 4, amending section 329D-10, HRS, to authorize edibles			
(page 6, lines 1-21; page 7, lines 1-4):			
"(c) As used in this section, "edible cannabis products" means manufactured cannabis			
products intended for gastrointestinal administration of any cannabinoid extracted from			
the cannabis plant and regulated as manufactured cannabis products and not as "food" as			
defined and regulated in chapter 328.			
(d) Provided further, that any medical cannabis products manufactured pursuant to this			
chapter shall be regulated and approved by the department and meet all requirements of			
rules adopted pursuant to this chapter."			
(3) Education – DOH offers COMMENTS and proposes alternate language.			
Preventing youth use is a key objective of Hawaii's medical cannabis program and			
exposure to advertising has been shown to significantly impact youth perception of cannabis. A			
2018 RAND Corporation study found that the proportion of adolescents in Southern California			

who reported viewing medical marijuana advertising increased sharply from 25% in 2010 to

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- 1 70% by 2017 and that higher average exposure to advertising was associated with higher average
- 2 use. ⁹ Accordingly, at least two-thirds of state cannabis programs have some form of restriction
- 3 on advertising including prohibitions on event sponsorship, radio, television, and print media,
- 4 and branded apparel; over half have restrictions specific to youth appeal. Despite these concerns,
- 5 DOH supports the circulation of science- and evidence-based educational information. DOH
- 6 opposes the circulation of materials that would otherwise be construed as advertising or self-
- 7 serving by the medical cannabis industry.

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- Should the committee be inclined to allow this amendment to move forward, DOH requests adequate controls to prevent youth exposure, ensure safe access to medical cannabis retail locations, and prevent broad advertising,
- DOH offers the following alternate language (underlined) for the proposed amendment under SECTION 5, amending section 329D-11, HRS, to allow dissemination of educational materials and event sponsorship (page 9, lines 10-14):
 - "(d) The department is authorized to allow dispensaries to provide, disseminate, and publish educational and scientific materials relating to medical cannabis and its approved products, and sponsor events about medical cannabis."
- 17 Thank you for the opportunity to testify on this measure.

⁹ D'Amico Elizabeth J. et al. Planting the seed for marijuana use: Changes in exposure to medical marijuana advertising and subsequent adolescent marijuana use, congnitions, and consequences over seven years. Drug and Alcohol Dependence, Volume 188, 2018, 385-391. doi.org/10.1016/j.drugalcdep.2018.03.031.

Testimony in OPPOSITION of HB 2097

Submitted by: Peter Oshiro Resident of Mililani.



Aloha Chair Mizuno, Vice Chair Kobayashi and Members of the House Committee on Health,

Mahalo for allowing me to testify.

I am testifying as a private citizen and my testimony has not been approved or endorsed by the DOH.

I stand in Strong Opposition to HB 2097 for the following reasons:

- 1) There are no scientific or medical studies to date, which concludes that the practice of "remediating" cannabis/cannabis products that have failed mold/yeast product standards is safe. Please keep in mind that many 329 card-holders are immuno-compromised due to disease or the treatment of adverse medical conditions.
 - a) Would you allow restaurants to remediate unwholesome, "moldy" food by washing it off, cooking it off, or dipping it in a chemical that removes the mold?!
- 2) Disturbingly, the DOH has allowed industry to do exactly that beginning around the Fall of 2017. No dispensaries were ever inspected under HAR §11-850-75 Quality control, health, safety, and sanitation standards prior to opening. That is the only section of the existing rule that addresses public health controls over the industry to prevent adulteration of cannabis products which may have been produced under insanitary conditions. You all would be surprised if I told you that as of today, the DOH had not made even ONE unannounced inspection, with an employee that would have the skills necessary to inspect a cookie shop, much less a cannabis extraction operation that produces edibles, vape pens, etc). There are no properly trained individuals to inspect qualified individual (trained to enforce HAR 11-50, Food Safety Code) of any dispensary to enforce the section of the rule that is supposed to protect the health of 329 card holders. The only

routine inspections of the dispensaries being done, were to ONLY address diversion of cannabis and not sanitary conditions or sanitary techniques being used by industry to manufacture and package cannabis/cannabis products. The DOH has knowingly allowed industry to violate HAR §11-850-85 (c) which clearly prohibits the dispensing of ANY product that have not met standards designed to protect public health from high levels of pesticides, yeast, mold, bacteria and various other contaminants.

- 3) For good reason, this proposal does not set a maximum level of how much mold or yeast that would be allowed in order for the adulterated cannabis product to be remediated. Under this proposal, cannabis products that that have unlimited amounts of mold or yeast would be allowed to be further processed for ingestion or inhaling after being "remediated".
 - a) Common sense would dictate that there should be a point where the cannabis has so much mold and yeast that it must be destroyed. It is curious that the point at which the product must be destroyed has already been determined by the DOH and codified in the current rule.
 - b) Trace elements of the dead mold and yeast colonies will be concentrated in any extracted product, and even though the "remediated" product may pass the testing for mold and yeast after being "remediated", there are no studies that show that the trace elements or by- products of mold and yeast colonies that were exposed to varying "remediation techniques" produce no long or short term maladies. Can you imagine "vaping" these unknown compounds into the lungs of unsuspecting 329 cared holders. Or spraying these into your mouth or consuming pills made from adulterated source product.
 - c) I can already hear proponents of this measure state that some other states allow this practice. This is especially apparent in "recreational" States that have already succumbed to "Regulatory Capture", including Hawaii, whereby industry has influenced regulatory to do an about face to their rules under the guise of losing or going out of business which in turn affects the coffers of government tax take from the industry.

- d) Because the DOH refused to do any regulatory lab testing, we already have an unholy alliance whereby we rely on results that are paid for by industry. There is absolutely a place for third-party lab testing (to ensure QC of a product for industry), but if you want unbiased, uninfluenced lab results, the DOH must collect and test regulatory samples at a determined frequency to keep the system above board. Shopping for labs is a frequent practice in States that allow 3rd party testing as the sole regulatory source.
- 4) There is already scant research regarding the safety of any cannabis/cannabis product, why on earth would we intentionally add the unknown variable of remediating adulterated product that is intended to be used by persons treating various medical conditions?!
- 5) We really need to talk about vape products being produced at the dispensaries and how ill equipped the DOH is to regulate this industry.
 - a) In June of 2019, I sent an email to all DOH Administrators involved in regulating medical cannabis, warning them that some dispensaries were actually adding unknown, imported, un-approved ingredients to vape pens in direct violation of HAR. In September of 2019 we began hearing nation-wide concerns that persons were dying or becoming gravely ill from what appeared to be tainted, unregulated THC vape pens. In October of 2019, I have it on good word that someone from the DOH contacted the dispensaries warning them that the DOH would be "cracking down" on adulterated vape products being sold. So instead of taking clear regulatory action, or formally notifying industry to cease and desist from selling vape cartridges with illegal additives, the mixed message left industry to resort to a "Fire Sale" of vape products with unapproved ingredients. Cartridges that normally sold for \$45-\$60 for 0.5 gm were being sold for as low as \$6 each in unlimited quantities "while supplies last". This allowed industry to literally flood the 329 card holder market with illegal vape pens. 329 Card holders were not told that these pens contained ingredients that were not approved by the DOH.

This is exactly the definition of and what "Regulatory Capture" looks like in real life.

For over three decades, I have worked as a professional environmental law enforcer, where we sample and analyze products for violations of MCL's in food, milk, and shellfish, and take swift enforcement action with set protocols to remedy any sampling violations. If you want to ensure that industry follows the rule of law, you must give industry "crystal clear" instruction and consistent interpretations of the laws. It is critical that the regulatory program conduct unannounced inspections for the sole purpose of ensuring compliance with the law. If the dispensaries were at least inspected with the same vigor and frequency as a food establishment, food safety specialist would have easily identified illegal sourced products on the shelf. But to do this, you actually have to do inspections!!

The regulatory agency must be completely transparent to both the public and regulated industry in order to influence industry behavior, and not sweep major problems under the rug while boasting that the DOH has one of the strictest Med Cann programs in the Nation. This statement, which has been repeated ad nauseam to cover up DOH's ineptness, is no more than a bald faced lie when not even one inspection has been done at a dispensary for the purpose of enforcing HAR §11-850-75, Quality control, health, safety and sanitation standards.

Having to give and prepare this testimony is very difficult as I am extremely disturbed at how I truly believe the DOH is endangering the health and safety of the State's 329 Card holders. I am more disturbed by the years of sweat and the very steep knowledge curve that my program has gained in assessing the safety and practices of the cannabis industry which apparently resulted in my program being recently removed from any aspect of interfacing with this industry to protect public health. Appearances allude to the DOH attempting to cover up past egregious actions by replacing my program's involvement with regulating this industry. It is odd that the Food Safety Branch even recently participated in the 2019 legislatures' PIG regarding edible cannabis products to assist the legislature in regulating this industry. We chaired the manufacturing of cannabis edibles sub-committee.

Our program has been removed from regulating this industry and has been replaced with a neophyte program with no track record of any accomplishments

or abilities and no applied knowledge of how medical cannabis is processed. This is the same Food and Drug Branch that was abolished in 2012 due to major performance issues and resurrected in early 2019.

I can only surmise that the DOH was afraid that my program would take the necessary action to reverse wrongdoings of the past and give the DOH another black eye.

Mahalo for the opportunity to testify and please take the time to read all of the materials sent. It should be very enlightening and frightening at the same time.





Dedicated to safe, responsible, humane and effective drug policies since 1993

TESTIMONY IN SUPPORT OF HB 2097

TO: Chair Mizuno, Vice Chair Kobayashi & House Health Committee Members

FROM: Nikos Leverenz

DPFH Board President

DATE: February 4, 2020 (8:30 AM)

Drug Policy Forum of Hawai'i (DPFH) supports HB 2097, which authorizes licensed retail dispensaries to produce and sell cannabis-infused edible products.

DPFH actively participated in the Act 230 (2016) Medical Cannabis Legislative Oversight Working Group, which addressed, among other concerns, the facilitation of cannabis-infused edible products.

DPFH was also instrumental in the passage of Act 228 (2000), authorizing the acquisition, possession, and use of medical cannabis, and Act 241 (2015), authorizing the establishment and regulation of medical cannabis dispensaries.

Many cannabis consumers prefer edibles over flower and other products currently offered by dispensaries. DPFH strongly supports efforts to facilitate the production, distribution, and sale of edibles, which have been offered by medical cannabis dispensaries and adult-use retail establishments in other states for many years. For example, cannabis-infused edible products were widely available in most storefront patient collectives in California well over a decade ago.

DPFH also supports prospective efforts to involve other businesses in the production of cannabis-infused edibles. Continued vertical integration inhibits the variety of available products—to the detriment of consumers and those persons who could be otherwise employed in Hawai'i's emerging cannabis economy.

Thank you for the opportunity to testify on this measure.



HB-2097

Submitted on: 2/4/2020 6:59:17 AM

Testimony for HLT on 2/4/2020 8:30:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
Mary Whispering Wind	Individual	Oppose	No

Comments:

I **OPPOSE** HB2097,

which Authorizes dispensaries to advertise, and promote their closed monopoly system, and to "remediate" any batch of inferior cannabis that failed testing for quality. Edibles should be available because **after TWENTY YEARS of WAITING** - cannabis Patients need legal access to edibles, but not purchased from an unjust, over-priced corporate monopoly.

Cannabis should be legalized, and regulated like any other Hawaii businesses!

For the last two decades, Hawaii has been enforcing laws UNEQUALLY upon cannabis consumers, sending some to jail for cannabis crimes, while selling other citizens, (and visiting tourists), a "stay out of jail" card, from the "criminal activity" of consuming cannabis!

HAWAII LAWS VIOLATE CANNABIS CONSUMER'S RIGHT TO EQUAL JUSTICE!

Cannabis consumers have been persecuted and prosecuted for generations, now Hawaii's cannabis patients are being abused for profits. **Meanwhile, the opioid crisis and alcohol crisis in Hawaii continues to worsen, while citizens die.**

Hawaii's PAY-TO-PAY, vertically-integrated, seed-to-sale, medical cannabis monopoly, is operated like a mafia "protection from prosecution" racket, instead of a compassionate health care program.

Poor patients have been priced out of the system for 20 years! While anyone with money can buy a certification, no matter what their actual physical condition, rendering any medical research completely unreliable.

Hawaii needs a real medical cannabis program, AND an adult use program; two separate programs, not the "DUAL-Use" closed-program, as discussed in legislative

meetings, and outlined in SB 686 SD1, both of which give Hawaii's entire adult-use market to the dispensary monopoly.

All citizens should have the right to grow their own cannabis strains.

Hawaii's adult-use market should be legalized just as it has been operating for generations; which is thousands of small cannabis entrepreneurs, growing, processing, packaging and delivering world-famous brands of Hawaiian cannabis, and **the cannabis industry should be regulated like any other Hawaii businesses.**