U.S. Hemp Roundtable

502.319.2358 | 100 M Street, S.E., Suite 600, Washington, DC 20003 | info@hempsupporter.com

Chair Mizuno, Vice-Chair Kobayashi, and members of the House Committee on Health. Thank you for the opportunity to provide testimony **in opposition** to HB 2096, HD1 RELATING TO HEALTH. The measure would regulate cannabidiol under the department of health to be consistent with the Hawaii Food, Drug, and Cosmetic Act under chapter 328, Hawaii Revised Statutes, including mirroring certain provisions of the medical cannabis dispensary system under chapter 329D, Hawaii Revised Statutes; and allow licensees under the industrial hemp pilot program to market their products to the consumer market in a manner that is regulated and tested for safety, purity, and potency.

The U.S. Hemp Roundtable is a coalition of leading companies and organizations committed to safe hemp and CBD products. We proudly represent the industry's major national grassroots organizations, and are leading the way forward for hemp and CBD products through education and action. We do not view industrial hemp derived products as medication and believe that the most effective way to realize the potential of the industrial hemp market and allow for safe and regulated CBD products in the market is to establish the right conditions for the market to flourish. Unfortunately, HB 2096, HD1 would:

- prohibit the manufacture, sale, or distribution of any CBD derived products from any source unless approved by the Department of Health or obtained through the recommendation of a physician or advanced practice registered nurse
- Require labelling to be similar to prescribed medication
- Limit the manufacture and distribution of CBD products to approved medical marijuana dispensaries in the state

The proposed HD1 essentially treats CBD similar to medical marijuana in the State of Hawaii, does not provide the necessary framework to establish a viable hemp/cannabidiol industry and, would continue to maintain the current unregulated market being fulfilled through on-line sales and unregulated marketplaces. For these reasons the U.S. Hemp Roundtable would recommend the bill be amended to mirror the language in HB 2102 RELATING TO HEMP PRODUCTS.

Thank you for the opportunity to testify.

February 3, 2020

To: Representative John Mizuno, Chair
Representative Bertrand Kobayashi, Vice Chair
Members of the House Committee on Health

Fr: Margaret Cole, Partner, Pan Pacific Ventures, LP

Re: TESTIMONY IN **SUPPORT** OF HOUSE BILL 2096 HD1

HB 2096 HD1 RELATING TO HEALTH

Pan Pacific Ventures, LP (PPV) is a partnership formed in Hawai`i in 1986 to invest in early stage enterprises on behalf of the Cole family. Over the past 34 years PPV has served as lead investor and often the principal manager for companies in multiple sectors, including organic agriculture, human nutrition, food processing, software development, health information systems and biotechnology.

On March 29, 2019, PPV was awarded license no. R1-01-19-015 by the Hawai'i Department of Agriculture (HDOA) to grow hemp on up to 10 acres under the industrial hemp pilot program administered by HDOA.

PPV **supports** House Bill 2096 HD1, which would subject all products containing cannabidiol to rigorous regulation by the Hawai`i Department of Health and allow businesses with industrial hemp licenses issued by the HDOA to market quality-assured products derived from their hemp oleoresins.

As a state-licensed hemp producer dedicated to the production of quality-assured, hemp-derived medicinal products made in Hawai`i, PPV strongly supports the key provisions contained within HB 2096 HD1, which would help to foster the development of an economically viable hemp industry in Hawai`i while *putting in place rigorous public health protections.*

Over the last few years, there has been an explosion in the availability of over-the-counter CBD products, to the point that they can now be found at just about any gas station convenience store in Hawai`i. Its widespread availability has undoubtedly led some consumers to believe that – apart from having a long list of miraculous health benefits – CBD is a perfectly safe substance to swallow, inhale, or apply to your skin. Yet on its CBD Consumer Advisory page[1], the Food and Drug Administration cites numerous potential health risks associated with the consumption of CBD, including but not limited to liver toxicity[2], drug-drug interactions[3], and reproductive

[1] https://www.fda.gov/consumers/consumer-updates/what-you-need-know-and-what-were-working-find-out-

[2] '***Liver Injury:*** During its review of the marketing application for Epidiolex — a purified form of CBD that the FDA approved in 2018 for use in the treatment of two rare and severe seizure disorders — the FDA identified certain safety

toxicity[4]. Furthermore, there have been numerous credible reports of mislabeled and contaminated CBD products.[5]

By subjecting products containing CBD to strict regulatory oversight by the Hawai`i Department of Health in a manner consistent with the Hawai`i Food Drug and Cosmetic Act under Chapter 328, HB2096 HD1 will rightly ensure the public is properly educated about, and protected from, the potential negative health effects of unregulated and untested CBD products.

Current Hawai`i hemp law prohibits the movement of hemp resin or flowering tops from a licensed hemp grow area, thereby preventing hemp farmers from deriving any financial return from their hemp crops – even when they pass mandatory compliance testing for THC levels below .3% on a dry weight basis. HB 2096 HD1 would rightly fix this problem by allowing the movement of compliant resin or flowering tops to a licensed medical cannabis dispensary production center's approved manufacturing facility for processing into consumer products.

We note however, while HB 2096 HD1 allows businesses with dispensary licenses issued under HRS 329D to serve as processors of industrial hemp oleoresin, the measure does not specify a process by which other entities may become licensed to process industrial hemp oleoresins. We urge your committee to consider adding a provision that would allow hemp licensees to obtain hemp processing licenses via a process administered by the Hawai`i Department of Health.

Respectfully,

Margaret Cole

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risks, including the potential for liver injury. This serious risk can be managed when an FDA-approved CBD drug product is taken under medical supervision, but it is less clear how it might be managed when CBD is used far more widely, without medical supervision, and not in accordance with FDA-approved labeling. Although this risk was increased when taken with other drugs that impact the liver, signs of liver injury were seen also in patients not on those drugs.'

[3] '***Drug Interactions:*** Information from studies of the FDA-approved CBD drug Epidiolex show that there is a risk of CBD impacting other medicines you take – or that other medicines you take could impact the dose of CBD that can safely be used. Taking CBD with other medications may increase or decrease the effects of the other medications. This may lead to an increased chance of adverse effects from, or decreased effectiveness of, the other medications.'

[4] '***Male Reproductive Toxicity:*** Studies in laboratory animals showed male reproductive toxicity, including in the male offspring of CBD-treated pregnant females. The changes seen include decrease in testicular size, inhibition of sperm growth and development, and decreased circulating testosterone, among others. Because these findings were only seen in animals, it is not yet clear what these findings mean for human patients and the impact it could have on men (or the male children of pregnant women) who take CBD. For instance, these findings raise the concern that CBD could negatively affect a man's fertility. Further testing and evaluation are needed to better understand this potential risk.'

[5]For Example, see:
https://news.vcu.edu/article/Vape_CBD_The_eliquid_might_contain_some_unexpected_ingredients

Pan Pacific Ventures, LP
PO Box 1149
Kula, HI 96790

Pan Pacific Ventures, LP
PO Box 1149
Kula, HI 96790

HB-2096
Submitted on: 2/1/2020 4:29:49 PM
Testimony for HLT on 2/4/2020 8:30:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
Mariner Revell	Individual	Support	No

Comments:

I strongly support SB2096. All Cannabidiol products should be tested and clearly labeled.

HB-2096
Submitted on: 2/2/2020 4:07:04 PM
Testimony for HLT on 2/4/2020 8:30:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
Shannon Rudolph	Individual	Support	No

Comments:

Support

DAVID Y. IGE
Governor

JOSH GREEN
Lt. Governor

PHYLLIS SHIMABUKURO-GEISER
Chairperson, Board of Agriculture
MORRIS ATTA
Deputy to the Chairperson

State of Hawaii
DEPARTMENT OF AGRICULTURE
1428 South King Street
Honolulu, Hawaii 96814-2512
Phone: (808) 973-9600 FAX: (808) 973-9613

TESTIMONY OF PHYLLIS SHIMABUKURO- GEISER CHAIRPERSON, BOARD OF AGRICULTURE

BEFORE THE HOUSE COMMITTEE ON HEALTH

February 4, 2020

8:30 A.M.

CONFERENCE ROOM 329

HOUSE BILL NO. 2096 HD1 PROPOSED DRAFT RELATING TO HEALTH

Chairperson Mizuno and Members of the Committee:

Thank you for the opportunity to testify on House Bill 2096 HD1 Proposed Draft which mandates regulation of cannabidiol under the Department of Health, and allows licensees in the Hawaii Industrial Hemp Pilot Program to transport harvested hemp to licensed medical cannabis dispensary production centers for processing. The Department of Agriculture recognizes that allowing transportation of harvested hemp for processing is beneficial to its licensees, but respectfully defers to the Department of Health pertaining to the substance and merits of the measure.

Thank you for the opportunity to testify on this measure.

To: Rep. John M. Mizuno, Chair
Rep. Bertrand Kobayashi, Vice Chair
Members of the Health Committee

Fr: Jaclyn L. Moore, Pharm D.

TESTIMONY IN SUPPORT OF HOUSE BILL 2096

Requires cannabidiol products sold in the State to be tested by an independent testing laboratory for contaminants unsafe for human consumption and THC levels. Requires the packaging on all cannabidiol products to contain information concerning THC levels and other product safety requirements.

As a pharmacist, I am submitting testimony today **in support of HB2096** which establishes minimum laboratory testing and labeling requirements for cannabidiol products consistent with the 2018 Farm Bill.

Labeling accuracy for CBD product ingredients, and potency is critical when assessing potential drug interactions for patients consuming CBD products and other medications. CBD is a known inhibitor of certain liver enzymes (CYP 2C19, 2C9, 3A4) that are responsible for metabolizing external substances such as pharmaceutical and over-the-counter medications. Medications with narrow therapeutic windows, such as warfarin, are metabolized by this same sub group of enzymes that CBD inhibits, the combination of which could potentially result in adverse drug reactions, therapeutic failure, or toxicity. However, drug interactions can be effectively managed if the proper information is available to patients and their healthcare providers.

According to a May 15, 2019 ABC report which accessed the largest test results and analysis on CBD products in market, 70 percent of the 240 top-selling hemp-derived CBD products were "highly contaminated" with lead, glyphosphate (Round-up), BPA, arsenic, pesticides, and toxic mold. When assessed for "truth in labeling" some products had no CBD whatsoever, and others contained 5-6 times more CBD than claimed.

Another research study analyzed 84 products from 31 different companies. The results: 42 percent of products were under-labeled for CBD; only 31% were labeled accurately; and THC was detected in 18 of the 84 products. *Marcel O. Bonn-Miller, PhD et al, 2017*

With the wide availability of unregulated CBD on the market with an unknown pedigree, this bill establishes the framework needed to provide consumers with the peace of mind that what people are consuming, in some cases as medicine, is tested and accurate with the information provided on the label, and has undergone extensive lab testing for pesticides, microbials, and heavy metals.

Aloha,

Jaclyn L. Moore, Pharm.D.

HB-2096
Submitted on: 2/3/2020 10:29:48 AM
Testimony for HLT on 2/4/2020 8:30:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
dillon rellez	irie hawaii	Support	No

Comments:

I support this bill because it's good to regulate cannabidiol by people who research about the outcomes of the products we consume. We should continue to check each and every product that we come in contact with! Thank you for your time.

HB-2096
Submitted on: 2/3/2020 12:01:20 PM
Testimony for HLT on 2/4/2020 8:30:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
Linda Revell	Individual	Support	No

Comments:

HB-2096
Submitted on: 2/3/2020 12:33:58 PM
Testimony for HLT on 2/4/2020 8:30:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
HANALEI BENN	Irie Hawaii	Support	No

Comments:

Highly Support Bill HB2096. Just what I have personally tried and studied about Cannabidiol I believe It should be introduced and regulated by Hawaii Food and drug Act so others can experience the advantage it may have on you in a safe and Tested products. Curtain products i have tried has changed my daily life style in a very positive and active way. Having this act could help others experience something that could better you and your life style

HB-2096
Submitted on: 2/3/2020 12:52:16 PM
Testimony for HLT on 2/4/2020 8:30:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
Hoku	Individual	Support	No

Comments:

HB-2096
Submitted on: 2/3/2020 1:01:18 PM
Testimony for HLT on 2/4/2020 8:30:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
DOC	irie Hawaii	Support	No

Comments:

HB-2096
Submitted on: 2/3/2020 1:14:58 PM
Testimony for HLT on 2/4/2020 8:30:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
VALENTINO MIRANDA-KEPA	Individual	Support	No

Comments:

DAVID Y. IGE
GOVERNOR OF HAWAII

BRUCE S. ANDERSON, Ph.D.
DIRECTOR OF HEALTH

STATE OF HAWAII
DEPARTMENT OF HEALTH
P. O. Box 3378
Honolulu, HI 96801-3378
doh.testimony@doh.hawaii.gov

LATE

Testimony COMMENTING on HB 2096 HD1
RELATING TO HEALTH

REPRESENTATIVE JOHN M. MIZUNO, CHAIR
HOUSE COMMITTEE ON HEALTH
Hearing Date: 2/4/2020 Room Number: 329

Fiscal Implications: This measure may impact the priorities identified in the Governor's Executive Budget Request for the Department of Health's (Department) appropriations and personnel priorities.

Department Testimony: The Department appreciates the opportunity to provide comments on this measure.

In part, the bill requires the Department create rules for laboratory-based testing of cannabidiol (CBD) and cannabidiol products for content, contamination, and consistency including microbiological impurities and heavy metals that mirror the medical cannabis dispensary program under HRS 329D.

Bill further requires the Department establish labeling requirements for CBD containing products. The Department has concerns over the proposed labeling language that would require all CBD products be labeled as medications. Labeling a product as a medication, in HRS 328, could create confusion and possible conflict with other parts of HRS 328 that regulate drugs that have been FDA approved for prescription only or over-the-counter use. With the exception of the FDA-approved drug Epidiolex™, all other hemp-derived products containing CBD are not approved drugs. We find the phrase "For medical use only" and reference to the product as "medication" misleading as it appears to promote the product as a drug when it is not.

The Department would also like to note that the bill, as written, would appear to only regulate hemp products containing CBD. The market is currently evolving and shifting focus to products that do not include CBD, but rather other cannabinoids, like CBG and CBN. The Department recommends any language seeking to better regulate hemp derived products not be restricted to products that only contain the cannabinoid CBD.

The Department agrees that rules should be written to allow for hemp derived products to be better regulated in the State. However, if the intent is to have the Department regulate hemp products, we respectfully recommend language from HB2278 be incorporated into this measure. In part, HB2278 seeks to amend HRS 328 by allowing the Department to promulgate interim rules that establish a registration process for hemp processing facilities in the State. Rulemaking authority would include, but not limited to, establishing manufacturing standards, laboratory testing requirements, and proper labeling of hemp derived products, including those that may not include CBD but other emerging cannabinoids.

The Department would like to request that proposed amendments to HRS 329D-9 found in Section 5d (pg. 17, line 9) include a provision granting DOH the authority to approve requests made by licensees before including any CBD product, made outside their facility, into their manufactured cannabis products.

Offered Amendments: None

Thank you for the opportunity to testify on this measure.

LATE

HB-2096
Submitted on: 2/3/2020 6:46:16 PM
Testimony for HLT on 2/4/2020 8:30:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
Eric Heaukulani	Individual	Support	No

Comments:

LATE

HB-2096
Submitted on: 2/3/2020 7:33:09 PM
Testimony for HLT on 2/4/2020 8:30:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
pua	Individual	Support	No

Comments:

LATE

HB-2096
Submitted on: 2/3/2020 8:34:30 PM
Testimony for HLT on 2/4/2020 8:30:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
natalea mikami	Individual	Support	No

Comments:

LATE

HB-2096
Submitted on: 2/3/2020 9:06:27 PM
Testimony for HLT on 2/4/2020 8:30:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
Alayna Revell	Individual	Support	No

Comments:

I am in favor of this bill.

the Drug Policy Forum of hawai'i

LATE

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

COMMENTS ON HB 2096

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) would like to offer comments on HB 2096, related to cannabidiol (CBD) products. DPFH was 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. DPFH actively participated in the Act 230 (2016) Medical Cannabis Legislative Oversight Working Group.

CBD should not be confined to the limitations of Hawai'i's current medical cannabis regulatory landscape. DPFH supports broad access to tested, accurately labeled CBD products. As the federal government remains mired in its own kinetic lethargy, Hawai'i consumers should have the option to choose those products they feel may be beneficial to them.

The original version of this bill afforded Hawai'i retailers broader discretion to offer tested, accurately labeled products. It is preferable to the HD1 version, which would operationally foreclose the availability of commercial CBD products for many months, if not longer, in this state.

Unduly restrictive labeling requirements that are not found elsewhere on more established CBD products like those offered by NuLeaf Naturals and Barlean's will effectively—and unnecessarily—shut them out of Hawai'i's relatively small market. There are also local suppliers who are now providing tested, accurately products, including Hawaiian Choice, Hawaii Cannabis Care, and Mana Artisan Botanics. These suppliers, who provide many with gainful employment, should be provided a workable, fair, and otherwise sensible regulatory framework.

In short, Hawai'i consumers deserve access tested, accurately labeled CBD products, in alignment with the wide range of products that are functionally available in other states.

DPFH also supports prospective efforts to involve other businesses in the production of cannabis products, as is the case here with those local hemp farmers now awaiting authorization to engage in the marketplace. Continued vertical integration inhibits the variety of available products—to the detriment of consumers and those persons who could be otherwise employed in Hawaiʻi's emerging cannabis economy.

Thank you for the opportunity to testify on this measure.

From: John Calvert <jcalvert@crystal3.com>

Subject: SUPPORT for HB2096 with major amendments

LATE

Aloha Members of the Committee:

My name is John Calvert and I'm a hemp licensee and small farmer in Puna district, Big Island. I am growing CBD hemp using the horticultural method, in a greenhouse.

I support laboratory testing requirements – this makes good sense; however, the marketing and labeling requirements in this bill, as it is currently written, are overreaching and off the mark. Please read my comments below.

Hemp flower extract (containing CBD and other cannabinoids and terpenes) is not a "medical product" or "medication" any more than any other medicinal herb extract that is currently on the market (e.g. chamomile, echinacea, goldenseal, valerian), sold as "herbal supplements." This bill confuses drug-type CBD (e.g. Epidiolex) with hemp flower extract. This is wrong and should be removed from the bill. The bill confuses hemp flower extract with the medical cannabis provided and regulated under the state's medical *marijuana* dispensary system. This is also wrong.

PLEASE – I urge you to not lump together "hemp flower extract" with other types of CBD products, such as **isolates**, which are added to various products including CBD oil, foods, beverages, etc. These are very different substances (i.e. extract vs. isolate), with different properties, and different production processes. The safest product is *pure hemp flower extract*, properly lab tested for purity.

Sec. 328, Prohibitions, gives all the power to the DOH to control the sale of CBD products in Hawaii, which is wrong. The Hawaii DOH should require laboratory testing and basic labeling requirements such as omitting health claims; however the legislation should not enable the DOH to override federal regulations regarding the sale of CBD products derived from hemp. There is in fact a bi-partisan bill in Congress now that addresses the regulation of CBD, H.R. 5587. This bill was proposed by representatives from Kentucky, a state that leads the industry in hemp cultivation and CBD production. Please be aware also that, at the federal level, currently there is no law prohibiting the addition of hemp-derived cannabis to cosmetics, which includes "topicals".

High-quality, hemp-derived CBD oil is not the potentially dangerous "medication" that this bill makes it out to be.

Problems with the labeling requirements in this bill:

1) *"black lettering on a white background"* – this is too restrictive and doesn't resemble anything presently in the CBD oil industry in the U.S. There are plenty of

high-quality, safe, CBD oil products on the market which have attractive packaging and this is as it should be.

2) *"For medical use only"* – this is wrong, as I have stated above. Hemp flower extract is not for "medical use". Millions of Americans are benefiting from high-quality hemp extract that they can easily obtain from a natural food store – for children, for the elderly, and anyone who benefits from the results. This may be seen as a threat to the stakeholders in the "medical cannabis dispensary system;" however, this bill is not about that system, it's about making safe hemp extract available to the people of Hawaii, and legal for producers to sell these products.

3) *"Not for resale or transfer to another person"* – this is too restrictive. Anyone can buy any other herbal extract product currently on the market and give it or sell it to another person. Hemp extract should be treated no differently.

4) *"Includes a listing of the equivalent physical weight of the cannabidiol used to manufacture the amount of the product that is within the packaging"* – this is confusing. The product label should show the amount of cannabidiol in the package and the amount in one dose (e.g. a CBD oil dropper bottle). Some producers will add CBD isolate to the product, while other producers will market the product as a full spectrum hemp extract. The important part is to list the actual amount of cannabidiol (mg) in the bottle and in the dose. THC should be listed as well.

5) *"Is a medication..."* – it is a *medicinal herbal extract*, and if extracted with care, and meeting the lab testing requirements, should be allowed to be added to foods, beverages, cosmetics, and sold as an herbal supplement.

Labeling requirements should include: *Keep out of reach of children. Seek doctor's advice before use if pregnant or nursing, of if you have a medical condition or are taking any medications.*

Thank you for your consideration,

Mahalo,

John Calvert

small farmer in Puna district, Big Island