SB2718

Measure Title: RELATING TO CANNABIS FOR MEDICAL USE.

Medical Cannabis; Telehealth; Background Checks;

Packaging; Law Enforcement; Medical Cannabis Registry

and Regulation Special Fund; Reciprocity; Written Certification; Manufactured Cannabis Products

Amends the reciprocity program, subject to certain safeguards, reporting and transparency requirements, and payment of a visiting patient certifying fee. Extends the maximum period of validity of a qualifying patient's written certification of a debilitating medical condition.

Allows a bona fide physician-patient or advanced practice registered nurse-patient relationship to be established via telehealth. Adds certain devices that provide safe pulmonary administration to the list of medical cannabis products that may be manufactured and distributed. Increases the tetrahydrocannabinol limit

per pack or container of certain manufactured cannabis

products. Exempts from the background check

requirement employees of a dispensary or

subcontracted production center or retail dispensing location without direct access, contact, or exposure to

any cannabis or manufactured cannabis product. Conditions the department of health's mandatory

disclosure of information and documents of dispensaries

and production centers, for purposes of verifying qualifying patient information, only upon receipt of a

legally authorized subpoena.

Companion: <u>HB2729</u>

Package: None

Report Title:

Description:

Current Referral: CPH/PSM, JDC/WAM

Introducer(s): BAKER (Introduced by request of another party)



STATE OF HAWAII DEPARTMENT OF HEALTH

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

Testimony COMMENTING on S.B. 2718 RELATING TO CANNABIS FOR MEDICAL USE

SENATOR ROSALYN H. BAKER, CHAIR SENATE COMMITTEE ON COMMERCE, CONSUMER PROTECTION, AND HEALTH

SENATOR CLARENCE K. NISHIHARA, CHAIR SENATE COMMITTEE ON PUBLIC SAFETY, INTERGOVERNMENTAL, AND MILITARY AFFAIRS

Hearing Date: Tuesday, February 6, 2018 Room Number: 229

- 1 **Fiscal Implications:** None determined.
- 2 **Department Testimony:** Thank you for the opportunity to COMMENT on this bill. The
- 3 Department SUPPORTS some provisions with clarifications, definitions, and recommended
- 4 language changes and OPPOSES other provisions.
- 5 In summary, the bill:
- 6 1. Allows but does not require the Department to accept written certifications of
- 7 debilitating medical condition for up to 3 years if the condition is chronic in
- 8 nature;
- 9 2. Defines bona fide patient-provider relationship as including a relationship
- 10 established via telehealth;
- 11 3. Adds vaping instruments as an allowed product;
- 4. Increases milligrams of products sold in multiple dose packs to 1,000 ml;
- 5. Exempts certain persons from background check requirements;

Provides a provision for reciprocity where the dispensary verifies the out-of-state

(OOS) patient qualifications; and

7. Requires disclosure of dispensary information to law enforcement only upon receipt of a subpoena.

Regarding accepting medical certifications for up to three (3) years, the department supports the intent of this provision with the understanding that the department will likely take a more cautious approach based on standard medical practices and recognizing that the language gives the department the authority to accept multi-year certifications but does not require it.

Standard medical practice normally requires annual visits to physicians or APRNs to continue receiving ongoing prescriptions for chronic conditions. This ensures the medical condition is in fact ongoing and determines whether specific medication or medication dosing needs to be changed. Medical cannabis was authorized by the Legislature for medical purposes and its continued access should be consistent with other medical practices. Otherwise, the department could be accepting certification for medical use of cannabis for a time period that exceeds the debilitating condition.

Regarding patient-provider relationships, the bill seeks to redefine bona fide patient-provider relationship as including a relationship established via telehealth. The Department supports the use of telemedicine to be consistent with its support for telemedicine in the medical community and especially in rural areas with physician/APRN shortages. However, the bill defines "telehealth" by cross-referencing to Section 453-1.3(j), HRS, and that creates an inconsistency with Section 453-1.3(c), HRS, which requires an in-person consultation to

- establish a physician-patient relationship. The department could SUPPORT this provision as
- 2 long as the legislature addresses the above inconsistency.

Regarding adding devices that provide safe pulmonary administration to the list of allowed manufactured products, the Department requests the Legislature define "safe pulmonary administration" and "sub-combustion temperature" and amends the bill language to ensure against the use of vaping devices for vaping or smoking of tobacco or tobacco products.

The Department offers an amendment as follows to ensure against the use of devices for consumption of tobacco consistent with the Department's anti-smoking policy (amended language is <u>underlined</u>): "Devices which provide safe pulmonary administration, provided that the <u>device is distributed solely for use with single use, disposable, pre-filled and tamper-resistant sealed containers that do not contain nicotine or other tobacco related products and is used to <u>aerosolize and deliver cannabis orally, the</u> heating element of the device is made of inert materials such as glass, ceramic, or stainless steel, and not of plastic or rubber, and there is a temperature control on the device to ensure a sub-combustion temperature." Dispensaries would be required to provide signage and packaging inserts consistent with the above and Department inspections will determine compliance.</u>

Also, inserting the language on devices that provide safe pulmonary administration in this section of the current statute would require the dispensaries to manufacture the devices. The Legislature should clarify whether the intent is to require dispensaries to manufacture the devices they sell or if they could buy manufactured devices and sell them.

Regarding multi-dose packs, the Department SUPPORTS this as cost beneficial to dispensaries and patients as long as dispensing limits are not exceeded. Department inspections will determine compliance.

Regarding exemptions from background checks, the Department recognizes that dispensaries will continue to be required to log-in and -out persons who access the properties whether the person is required to have a background check or not, and written logs can be verified during Department inspections. However, as long as cannabis remains a Schedule I controlled substance and remains illegal under federal law, background checks should remain a requirement as part of the state's robust regulatory requirements.

Regarding reciprocity, the Department OPPOSES the proposed system. This system would place dispensaries in a conflict of interest position of self-validating patients to whom they would sell products. Other questions are unanswered by the bill, namely: 1. Would this simply allow an individual to purchase medical cannabis from a dispensary, or would it provide the state's legal protection for an out-of-state individual to possess and use cannabis?; 2. Do out-of-state individuals have to meet the state definition of qualifying patient including a debilitating medical condition recognized by the state?; and 3. Would the reciprocity proposed in this bill require changes to other state statute?

A reciprocity program for medical cannabis is complex and requires the discipline of more independent and objective verification processes.

One final comment on reciprocity is that reciprocity at this time could also jeopardize Hawaii patients' access to medical cannabis. Only half of the dispensaries have begun to sell medical cannabis products, and the Department continues to be responsive to dispensaries'

- 1 requests to conduct inspections when they are ready for the next phase of cultivation or
- 2 manufacture or retail sales, and the Department has also been responsive to dispensaries' requests
- 3 for increased plant counts. We have seen news stories that local dispensaries have run out of
- 4 retail product. The Department's focus continues to be on improving access of local medical
- 5 cannabis for local patients. Creating this or any other reciprocity program at this immediate
- 6 point in time could strain the availability of medical cannabis for local patients.
- Regarding disclosure of information to law enforcement, the Department OPPOSES this
- 8 provision as problematic in the event law enforcement needs to take immediate action.
- 9 Requiring subpoena could slow down law enforcement, jeopardize criminal investigations, and
- invite more rigorous enforcement of federal and state criminal laws.
- Finally, the Department respectfully requests that the exempt status of the dispensary
- licensing supervisor position and inspector positions be made permanent to aid in the
- Department's recruitment and retention efforts. Without permanence, the exempt status requires
- the positions to be renewed annually and makes it difficult for qualified persons in other
- permanent positions to want to apply.
- In summary and in closing, the Department SUPPORTS THE INTENT on parts of this
- bill as long as clarifications, definitions, and language changes are made, and OPPOSES other
- parts of the bill as potentially diminishing the state's robust regulatory processes, potentially
- inviting federal law enforcement intervention, and risking access to medical cannabis by
- 20 Hawaii's local patients.
- Thank you for the opportunity to testify on this bill.



ON THE FOLLOWING MEASURE:

S.B. NO. 2718, RELATING TO CANNABIS FOR MEDICAL USE.

BEFORE THE:

SENATE COMMITTEES ON COMMERCE, CONSUMER PROTECTION, AND HEALTH AND ON PUBLIC SAFETY, INTERGOVERNMENTAL, AND MILITARY AFFAIRS

DATE: Tuesday, February 6, 2018 **TIME:** 12:45 p.m.

LOCATION: State Capitol, Room 229

TESTIFIER(S): Russell A. Suzuki, Acting Attorney General, or

Jill T. Nagamine, Deputy Attorney General

Chairs Baker and Nishihara and Members of the Committees:

The Department of the Attorney General provides the following comments on this bill, including our comments in opposition to sections 7, 8, and 9.

This bill would (1) amend the funding sources of the medical cannabis registry and regulation special fund to include fees derived from the certification of patients visiting Hawaii; (2) amend the definition of "written certification" in section 329-121, Hawaii Revised Statutes (HRS), to authorize the Department of Health (DOH) to allow a certification to be valid for up to three years for those patients whose certifier states their debilitating medical condition is chronic in nature; (3) amend section 329-126, HRS, to allow a bona fide physician-patient relationship or advanced practice registered nursepatient relationship to be established via telehealth; (4) amend section 329D-10, HRS, to add certain types of pulmonary administration devices to the types of medical cannabis products that may be manufactured and distributed; (5) amend section 329D-11 to increase the allowable potency of manufactured cannabis products that are sold in packages of multiple doses and containers of oils from 100 milligrams of tetrahydrocannabinol (THC) to 1000 milligrams of THC; (6) amend section 329D-12, HRS, to exclude some dispensary employees and others from background check requirements under certain conditions; (7) amend section 329D-13, HRS, to delete the authority of the DOH to establish a registration process for qualifying patients from other

states and replace it with a method for dispensaries to determine whether a person from out-of-state qualifies as a patient, and to establish purchase limits for out-of-state qualifying patients; and (8) amend section 329D-20, HRS, to prohibit the DOH from disclosing information, documents, and other records in its possession to any state, federal, or county agency engaged in a criminal investigation or prosecution of violations of laws related to the operations or activities of a medical cannabis dispensary unless that agency obtains and provides a subpoena.

Comments on Section 4 (page 4, line 20, through page 6, line 7)

This section would amend section 329-126, HRS, to allow a bona fide physician-patient relationship or advanced practice registered nurse-patient relationship to be established via telehealth. For this section to apply as intended, the word "subsection" at page 6, line 4, should be changed to "section." Additionally, the definition of "telehealth" is cross-referenced to section 453-1.3(j), HRS, and that creates an inconsistency with section 453-1.3(c), HRS, which provides "For the purposes of prescribing opiates or medical cannabis, a physician-patient relationship shall only be established after an in-person consultation between the prescribing physician and the patient." If the committees are inclined to advance this section, we recommend that these inconsistencies be resolved.

Comments on Section 5 (page 6, line 8, through page 7, line 10)

This section would amend section 329D-10, HRS, to allow for the production of "[d]evices that provide safe pulmonary administration," which have a temperature control "to ensure a sub-combustion temperature" (page 7, lines 4 through 9). These terms are not defined. If the committees are inclined to allow for the production of these devices, we suggest they define the terms "safe pulmonary administration" and "sub-combustion temperature," in order to clarify the type of devices that may be manufactured.

Comments on Section 7 (page 8, line 1, through page 9, line 10)

This section would exempt employees of a medical cannabis dispensary, subcontracted production center, or retail dispensing location, as well as "[a]ny other person approved for access and entry by the department," from complying with the

Testimony of the Department of the Attorney General Twenty-Ninth Legislature, 2018 Page 3 of 4

background check requirements in section 329D-12, HRS, when the employee or person "will have no direct access, contact, or exposure to any cannabis or manufactured cannabis product, and the person (not an employee) is "accompanied at all times on the premises by an authorized employee of the dispensary" (page 8, line 8, through page 9, line 5). While the section limits the exemption to individuals who will not have "direct access, contact, or exposure to any cannabis or manufactured cannabis product," in practice, the DOH does not have the resources to ensure that the individuals who use the exemption maintain distance from cannabis. Because cannabis is a Schedule I controlled substance and still illegal under federal law, we recommended that this section be deleted from the measure so as to prevent unauthorized access, contact, or exposure to any cannabis or manufactured cannabis product.

Comments on Section 8 (page 9, line 11, through page 11, line 8)

This section would amend section 329D-13, HRS, to delete the authority of the DOH to establish a registration process for qualifying patients from other states and replace it with a method for dispensaries to determine whether a person from out-of-state qualifies as a patient, and to establish purchase limits for out-of-state qualifying patients. It would impose requirements on dispensaries to verify and copy all documents presented by the out-of-state patient and enter information about the patient into the computer tracking system to ensure compliance with dispensing limits provided for out-of-state qualifying patients. The dispensaries would be required to make reasonable good faith efforts to verify whether the visitor's photo identification and medical cannabis card or written certification has not expired, and that the certifying physician's license is in good standing within the applicable jurisdiction.

It is unclear what would constitute reasonable good faith efforts, but it is unlikely that dispensaries would be able to reliably verify the validity of a person's medical cannabis card without accessibility to a computerized database, such as the DOH's medical cannabis registry. Currently, there is no means for dispensaries to access out-of-state registry data, so assigning the heavy responsibility of determining who is entitled to the medical use of cannabis to a dispensary will create a risk of diversion of cannabis to people who are not entitled to have it, and that, in turn, may create a risk to

Testimony of the Department of the Attorney General Twenty-Ninth Legislature, 2018
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the State of federal intervention to enforce laws against controlled substances. We recommend that this section of the bill be deleted in order to allow a more cautious and reliable approach to reciprocity.

Comments on Section 9 (page 11, line 9, through page 12, line 2)

This section would amend section 329D-20, HRS, to prohibit the DOH from disclosing information, documents, and other records regarding medical cannabis dispensaries and production centers to any state, federal, or county agency engaged in a criminal investigation or prosecution of violations of laws related to the operations or activities of a medical cannabis dispensary unless that agency obtains and provides a subpoena. By requiring a subpoena for all disclosures of records pertaining to the operations or activities of a medical cannabis dispensary, without exception, this section would impede both the DOH and law enforcement from doing their jobs. If in the process of monitoring the activities of licensed dispensaries, the DOH was to suspect that illegal activity was occurring, the DOH would need the ability to openly share information with law enforcement for the purpose of preventing illegal activity, but this section would prevent that. Similarly, sometimes exigent circumstances require law enforcement to act guickly without taking the time to get a subpoena, but the proposed amendment would not allow any exceptions for emergency situations. We recommend that this section of the bill be deleted to prevent interference with DOH's monitoring activities of licensed dispensaries and with the duties of law enforcement.

Thank you for considering our comments.



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

TO: Senate Committee on Commerce, Consumer Protection and Public Health

FROM: Carl Bergquist, Executive Director HEARING DATE: 6 February 2018, 12:45PM

RE: SB2718, RELATING TO CANNABIS FOR MEDICAL USE, SUPPORT/COMMENTS

Dear Chair Baker, Vice Chair Tokuda, Committee Members:

The Drug Policy Forum of Hawai'i (DPFHI) <u>supports</u> this measure to reform the medical cannabis registry and dispensary programs that are administered by the Hawai'i Department of Health (DOH). Among the provisions are several that would directly benefit *current* registered patients as well as help encourage *prospective* patients to register with the state. While these reforms are essential, there are additional provisions that are detailed in other bills before the legislature. Many of those provisions were recommended to the legislature by a majority of the Act 230 Legislative Oversight Working Group.

We particularly support the following provisions in this bill:

- longer valid certification periods for patients (up to 3 years in cases of chronic conditions);
 and
- allowing telehealth certification by expanding the definition of what constitutes a "bona fide" relationship between the patient and his/her health care professional; and
- allowing the sale of certain new devices for easier ingestion of medicine; and
- increasing of the tetrahydrocannabinol (THC) limit per pack or container of certain dispensary products; and
- the outlining of a reciprocity system for out of state patients, which will ultimately also benefit Hawaii's patients when they travel.

In addition, we want to make the committee aware of key provisions in the other main omnibus bill, <u>SB2248</u>, which has a double referral to CPH/JDC/LBR & WAM. The instant bill would be improved by incorporating the following from SB2248, or stand-alone bills like e.g. <u>SB168</u> (repealing

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unnecessary felony penalties related to dispensaries) and <u>SB2220</u> (prohibiting discrimination of registered patients by employers):

- End of prohibition on interisland transportation for patients/caregivers; and
- Protections for using medical cannabis, not including smoking, in places of public accommodation such as a cafe or restaurant; and
- Making it easier for incapacitated or bedridden patients to get the necessary identification in order to become a medical cannabis patient; and
- Adding "substance use disorder" as a qualifying condition; and
- Amending the definition of "prescription drugs" to include state approved medical cannabis for purposes of workers compensation.

Thank you for the opportunity to testify.

HAWAII EDUCATIONAL ASSOCIATION FOR LICENSED THERAPEUTIC HEALTHCARE

To: Senator Rosalyn Baker, Chair Consumer Protection and Health (CPH)
Senator Clarence Nishihara, Chair Public Safety, Intergovernmental and Military
Affairs (PSM)

Senator Jill Tokuda, Vice-Chair Chair Consumer Protection and Health (CPH) Senator Glenn Wakai, Vice-Chair Public Safety, Intergovernmental and Military Affairs (PSM)

Members of the Joint Senate Committee

Fr: Blake Oshiro, Esq. on behalf of the HEALTH Assn.

Re: Testimony In Strong Support on Senate Bill (SB) 2718
RELATING TO CANNABIS FOR MEDICAL USE

Dear Chairs Baker and Nishihara, Vice-Chairs Tokuda and Wakai, and Members of the Committee:

HEALTH is the trade association made up of the eight (8) licensed medical cannabis dispensaries under Haw. Rev. Stat. (HRS) Chapter 329D. We **support SB2718** as an important bill for the dispensary industry in order to enhance the medical cannabis dispensary program with additional patient access, product controls and safety, and provide improvements to the administration of the program.

(1) Reciprocity program

The current law, Haw. Rev. Statutes (HRS) 329D-13, provided for a start date of January 1, 2018 for a program where patients from other states would be able to legally purchase medical cannabis from dispensaries. Unfortunately, that program has yet to be implemented.

As such, the bill proposes to allow for these out-of-state patients to obtain medical cannabis similar to the way in which Nevada ran its reciprocity program. By keep the purchase limit low (basically half of what a Hawaii resident is able to obtain), this should help to minimize the concern about an out-of-state patient obtaining a large quantify of product. All purchases are to be logged into the state's tracking system, and dispensaries would be held accountable for any improper or invalid sale.

(2) Extend possible validity of a qualifying patient's written certification from 1 to 3 years

The current law authorizes a qualified patient's written certification to be valid for up to one year. However, because most, if not all, of the qualifying conditions under HRS 329-121 are chronic debilitating diseases and conditions by definition, these conditions will likely be with the patient for a significant and ongoing time. While their condition could be approached with many different types of treatment, the underlying condition

will likely still remain with the patient, and we believe that medical cannabis should always remain as part of, it not an option for, their ongoing treatment.

(3) Telehealth relationship

We believe that telehealth can be especially helpful for patients in rural communities and/or patients suffering from severe debilitating conditions that make even a physical face-to-face appointment or traditional patient-provider interaction relationship difficult. Therefore, this change will be especially helpful for patient access and for monitoring of a patient's use of medical cannabis.

(4) Add safe pulmonary administration to the list of medical cannabis products

We support this addition to possible product offerings because of the ability for more precise dosage administration, safe inhalation of certain patients and their conditions, and the possible stigma associated with "smoking" cannabis.

Our research has shown that administration through pulmonary inhalation, can be more effective for certain patients who have a low tolerance for, or resistance to, smoking the cannabis. It is more readily absorbed, and its effects felt more quickly, so that the potential for taking too large a dose, is minimized.

The language ensures that the device's heating element would be made of inert materials, and there is a temperature control, so that there is additional safety against a device becoming unsafe and combustible.

(5) THC limit per pack or container

Because edibles are not an authorized cannabis product, there is little need for any package or container limit. Should that product list ever change, then this provision should likely be revisited.

(6) Clarify background check requirement to those with direct access to cannabis or manufactured cannabis product

The current law requires all employees and any subcontractors to undergo a background check. This requirement seems overbroad, for there are many employees and subcontractors who never come in contact with, or have any access to, cannabis product. The bill does NOT seek to change the department's authority to approve these individuals having access to the premises. As such, we think that providing the DOH with authority to indicate when a background check should be conducted on any individual that does not have access to product, is reasonable.

(7) DOH's disclosure of information via a legally authorized subpoena

With the changes and uncertainties of the current federal administration, along with even recent examples of local law enforcement using patient information for purposes unrelated to cannabis possession where the Honolulu Police Department had initially

required gun-owners with medical cannabis card to surrender their legally held guns, we are concerned with the existing law's low threshold for law enforcement to obtain any information "upon request." While we can understand the need for law enforcement to verify that a person is a valid and qualifying patient under the law, and perhaps even to verify where that person may have obtained their cannabis or cannabis product, any other disclosure of personal health information, should only be disclosed via a lawful process, like a subpoena.

Thank you for your consideration.



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Testimony of Aloha Green Holdings Inc.
SUPPORTS OF SB 2718, RELATING TO CANNABIS MEDICAL USE
Before the Senate Consumer Protection and Health and Public Safety and Military
February 6, 2018

SB 2718 fixes operational issues with State of Hawaii Medical Cannabis Dispensary Program ("Cannabis Program"), including establishing a framework for medical patient reciprocity, improvements to alleviate the labor requirements at the DOH Patient Registry Program, provide clarification on acceptable medical devices needed to accurate dosing, and logistical fixes.

Aloha Green **SUPPORTS SB 2718** because SB 2718 provides solutions to challenges not previously contemplated at the inception of the Cannabis Program.

Tai Cheng COO Aloha Green Holdings Inc.



ON THE FOLLOWING MEASURE:

SB2718, RELATING TO CANNABIS FOR MEDICAL USE

BEFORE THE:

COMMITTEE ON COMMERCE, CONSUMER PROTECTION, AND HEALTH

DATE: Tuesday, February 6 TIME: 12:45PM

LOCATION: Conference Room 229

TESTIFIER: Brian Goldstein, CEO, Noa Botanicals

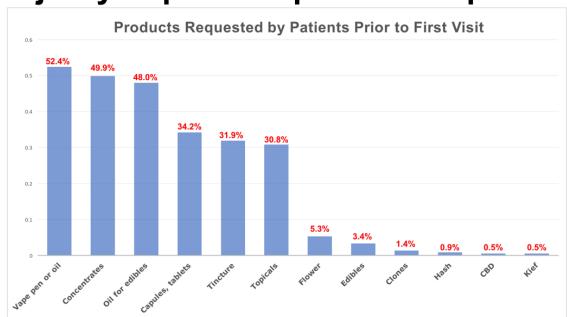
POSITION: SUPPORT WITH COMMENTS

Chair Baker, Vice Chair Tokuda and Members of the Committee:

Noa Botanicals is a licensed medical marijuana dispensary in the City and County of Honolulu.

Hundreds of our patients have been asking that we sell cannabis oil in pre-filled cartridges. It is the number one request that we receive.

Majority of patients prefer to vaporize



Survey data of 565 pre-registrations "What products are you interested in purchasing"

NO OTHER STATE IN THE NATION PROHIBITS MEDICAL CANNABIS DISPENSARIES FROM SELLING PRE-FILLED VAPING CARTRIDGES.

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A survey of our patients before their visit (via a pre-registration form) shows that over 52% of Hawaii patients are interested in vaping cannabis oil. Since we are not allowed to sell pre-filled cartridge, we sell cannabis oil in dispensing syringes. It is then up to the patient to purchase an appropriate tool for vaporizing the cannabis oil and for filling the cartridge. This increases patient cost and complexity and can place undue stress on oftentimes fragile patients.

Vaporizing cannabis is a safe delivery system. Not just safer but safe. This is demonstrated in the peer reviewed, clinical study (attached) *Vaporization as a Smokeless Cannabis Delivery System: A Pilot Study*. According to this study "CO levels were reduced with vaporization. No adverse events occurred. Vaporization of cannabis is a safe and effective mode of delivery of THC."

This bill also limits background check requirements to those individuals that have direct contact with cannabis plants.

This section is important for several reasons;

- REDUCE INDSUTRY STIGMA AND INCREASE ACCESS TO BANKING SERVICES - The medical cannabis industry in Hawaii lacks access to banking services, cash transport and vaulting services, has limited access to insurance services, and needs additional MDs and APRNs willing to certify patients. A critical tool that dispensaries can use to reduce stigma and educate bank and insurance executives, MDs and APRNs is to have them visit our facilities and see that we are professionally run companies. Numerous bank executives have expressed interest in visiting our facility, but none are willing to go through the time and trouble to get fingerprinted and go through the background check process.
- REDUCE PATIENT COSTS Current rules require that every person that enters
 a dispensary or production facility be fingerprinted and background checked. This
 include cleaning people, electricians, HVAC repair persons, etc. This requirement
 limits the pool of available people and as a result increases costs.

This bill modifies the reciprocity system to one that is workable and does not require DOH rulemaking. In 2015 the legislature determined that Hawaii dispensaries should begin accepting qualifying patients from outside of Hawaii beginning January 1, 2018 (reciprocity system). Unfortunately, DOH never issued the necessary rules to implement

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a reciprocity system. The reciprocity system described in this bill limits purchases and provides a framework for a safe and fair system for accepting out-of-state patients.

Medical cannabis dispensaries in Hawaii have very high operating costs due, in part, to the stringent requirements of the Hawaii medical cannabis program. Currently, the number of qualifying patients in Hawaii is relatively small and growing at a slow pace. This can result in medical cannabis product costs that are higher than they would otherwise. The best way to reduce product costs is to increase demand for medical cannabis. A well-run reciprocity program will provide additional revenues to the state and decrease product costs to Hawaii patients.

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nature publishing group ARTICLES

Vaporization as a Smokeless Cannabis Delivery System: A Pilot Study

DI Abrams^{1,2,3}, HP Vizoso^{1,3}, SB Shade^{1,3}, C Jay^{4,5}, ME Kelly^{1,2,3} and NL Benowitz^{3,6}

Although cannabis may have potential therapeutic value, inhalation of a combustion product is an undesirable delivery system. The aim of the study was to investigate vaporization using the Volcano device as an alternative means of delivery of inhaled *Cannabis sativa*. Eighteen healthy inpatient subjects enrolled to compare the delivery of cannabinoids by vaporization to marijuana smoked in a standard cigarette. One strength (1.7, 3.4, or 6.8% tetrahydrocannabinol (THC)) and delivery system was randomly assigned for each of the 6 study days. Plasma concentrations of Δ -9-THC, expired carbon monoxide (CO), physiologic and neuropsychologic effects were the main outcome measures. Peak plasma concentrations and 6-h area under the plasma concentration–time curve of THC were similar. CO levels were reduced with vaporization. No adverse events occurred. Vaporization of cannabis is a safe and effective mode of delivery of THC. Further trials of clinical effectiveness of cannabis could utilize vaporization as a smokeless delivery system.

The Institute of Medicine (10 m) report on Marijuana as Medicine published in 1999 concluded that "scientific data indicate the potential therapeutic value of cannabinoid drugs, primarily THC, for pain relief, control of nausea and vomiting, appetite stimulation; smoked marijuana, however is a crude THC delivery system that also delivers harmful substances". The report recommended that clinical trials of cannabinoid drugs for symptom management should be conducted with the goal of developing rapid onset, reliable, and safe delivery systems. While acknowledging therapeutic potential, the IOM report stressed that cannabis is not a completely benign substance, but a powerful drug with a variety of effects, but "except for the harms associated with smoking, the adverse effects are within the range of those tolerated for other medications." The report comments that "because of the health risks associated with smoking, smoked cannabis should generally not be recommended for longterm medical use. Nonetheless, for certain patients, such as the terminally ill or those with debilitating symptoms, the long-term risks are not of great concern." The Institute of Medicine sends a clear message suggesting that smoking is not a desirable delivery system for the potential therapeutic effects of cannabis.

Cannabis vaporization is a technology for delivering inhaled tetrahydrocannabinol (THC) and other cannabinoids while reducing toxic byproducts of smoked cannabis primarily caused by combustion.^{2,3} By heating cannabis to a temperature between 180 and 200°C, it is possible to vaporize the cannabinoids that reside on the trichomes on the surface of cannabis flowers and leaves, while avoiding combustion (which occurs at 230°C and above) and attendant smoke toxins. Vaporization is a relatively new technology. Various vaporizer designs are currently under development. The feasibility of vaporization of THC has been demonstrated in a series of laboratory studies involving different vaporizer designs.² An electric vaporizer was shown to release substantial amounts of the THC while producing no measurable amounts of the benzene, toluene, and naphthalene, which are generated when marijuana is smoked. Reductions in carbon monoxide (CO) and tar generation were also observed under vaporization compared to smoking. Although no measurements were made of other smoke toxins, it is quite possible that the vaporizer eliminated or substantially reduced the polycyclic aromatic hydrocarbons and other combustion-generated toxins commonly found in cannabis smoke, as they form at the higher temperatures of pyrolysis.

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A recent evaluation of the Volcano waporizer device used herbal cannabis or pure cannabinoid ethanolic solution preparations to test the efficacy and reproducibility of THC delivery into the balloon receptacle. Cannabinoids were measured in the THC-containing materials before and after vaporization, and in the vapor that was generated by the device and collected within the balloon. The results validated the Volcano vaporizer as an efficient and reproducible mode of delivery of Δ -9-THC. On average, 54% of the applied dose of THC was recovered in the balloon receptacle.

This study investigated vaporization using the Volcano[®] device compared to smoked cannabis. This is the first pharmacokinetic and pharmacodynamic evaluation conducted in humans to determine whether the Volcano[®] may be an appropriate system for use in clinical effectiveness studies.

RESULTS

Baseline characteristics of study subjects

A total of 68 patients were screened for eligibility between August 2004 and May 2005. Of these, 47 were not enrolled (33 patients were unavailable to commit to a 6-day hospitalization, 10 patients were excluded as a result of their medical history or concurrent illness, and four patients were excluded because of active substance abuse). Twenty-one patients were randomly assigned; however, three patients did not complete the intervention of the study phase (one patient for non-adherence to the General Clinical Research Center (GCRC) rules of comportment, one patient for acute influenza, and one patient withdrew consent), leaving 18 total patients for analysis.

Participants were predominately men (83%), Caucasian (72%), with some college education (94%). All of the participants were active marijuana users (median 5–6, range 3–10 marijuana cigarettes in the past 30 days). None had used the Volcano[®] device, although one participant had previously experienced vaporized marijuana using a similar device.

Primary outcome measure

The mean and 95% confidence intervals (CIs) for the plasma concentrations of THC at each time point for each strength of THC using both vaporization and smoking are presented in **Figure 1**. The vaporizer resulted in higher plasma concentrations of THC compared to smoked marijuana at 30 and 60 min at each strength (**Table 1**). The two modalities were not significantly different from one another at any of the three strengths in the 6-h area under the plasma THC concentration—time curve (AUC), or for the peak THC plasma concentrations measured at 2 min.

There was evidence of decreasing bioavailability and/or titration of THC intake with increasing strength of THC. The plasma THC AUC derived from the vaporizer normalized for the THC strength was highest at 1.7% THC (27.1 ng h/ml/%) and was progressively lower at higher THC strengths (3.4% THC: 20.5 ng h/ml/% and 6.8% THC: 14.3 ng h/ml/%; **Table 1**), suggesting higher bioavailability and/or more intensive puffing at lower THC potency. This decline was

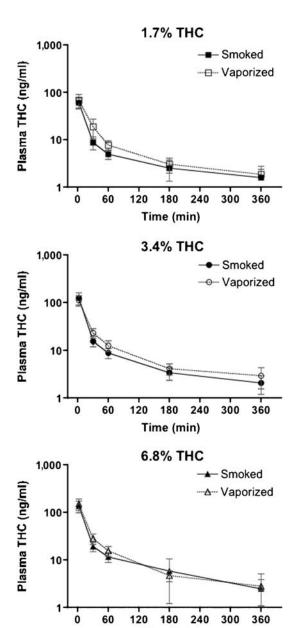


Figure 1 Plasma THC using vaporizer and smoked cannabis by THC strength (mean and 90% CI).

Time (min)

statistically significant (ratio: 0.87; 95% CI: 0.84, 0.90; P < 0.001 per 1% increase in THC strength) and did not appear to differ between vaporization and smoking (ratio for interaction: 0.92; 95% CI: 0.79, 1.05; P = 0.25) in a mixed model which included fixed effects for randomization, a linear term for THC strength, and a term for the interaction between these effects.

There was also evidence of titration of intake of THC with increasing THC strength based on puffing behavior. The number of puffs taken using smoked marijuana remained stable with increasing strength THC (mean puffs, 95% CI: 6.1 (4.8, 7.3), 5.9 (4.9, 6.8), and 6.4 (5.3, 7.6) for 1.7, 3.4, and 6.8% THC, respectively; mixed model analysis ratio: 1.01; 95% CI: 0.96, 1.05; $P\!=\!0.81$). The number of puffs taken

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Table 1 THC pharmacokinetics for vaporized cannabis and ratio of vaporized vs smoked cannabis^{a,b}

			Vaporizer		Vapo	Vaporizer/smoked ratio		
THC, % outcome measure	Mean	95% CI	Minimum	Maximum	Odds ratio	95% CI*	<i>P</i> -value	
1.7%								
AUC ₀₋₆	46.00	34.89, 57.11	15.59	98.08	1.26	0.94, 1.68	0.12	
$C_{\text{max}} (=C_2)$	68.95	46.99, 90.91	6.00	186.20	1.01	0.65, 1.58	0.97	
C ₃₀	18.94	10.57, 27.32	4.90	79.90	1.95	1.37, 2.80	0.001	
C ₆₀	7.56	6.02, 9.50	3.70	16.50	1.56	1.26, 1.93	0.001	
C ₁₈₀	3.05	1.99. 4.00	0.10	9.40	1.31	0.83, 2.06	0.25	
C ₃₆₀	1.87	0.97, 2.77	0.20	8.20	1.17	0.82, 1.66	0.38	
Puffs	10.06	8.81, 11.30	7.00	17.00	1.71	1.47, 2.00	0.001	
AUC/THC %	27.06	20.52, 33.60	9.17	57.69	1.26	0.94, 1.68	0.12	
3.4%								
AUC ₀₋₆	69.76	52.91, 86.62	22.30	140.44	0.99	0.81, 1.21	0.95	
$C_{\text{max}} (=C_2)$	112.45	84.55, 140.65	36.70	201.10	1.07	0.64, 1.80	0.80	
C ₃₀	23.04	17.74, 28.35	28.35	43.20	1.50	1.29, 1.73	0.001	
C ₆₀	12.58	9.46, 15.70	3.30	24.20	1.41	1.11, 1.79	0.006	
C ₁₈₀	4.14	3.05, 5.24	1.40	10.10	1.24	1.06, 1.46	0.008	
C ₃₆₀	2.94	1.55, 4.34	0.60	12.90	1.34	1.03, 1.75	0.03	
Puffs	9.17	8.23, 10.10	4.00	13.00	1.58	1.36, 1.84	0.001	
AUC/THC %	20.52	15.56, 25.48	6.56	41.31	0.99	0.81, 1.21	0.95	
6.8%								
AUC ₀₋₆	96.79	67.51, 126.06	18.98	278.20	1.22	0.98, 1.54	0.08	
$C_{\text{max}} (=C_2)$	187.12	100.65, 273.59	22.50	813.20	1.19	0.86, 1.65	0.30	
C ₃₀	28.80	22.19, 35.41	9.20	50.00	1.45	1.16, 1.82	0.001	
C ₆₀	15.99	12.41, 19.58	4.60	29.40	1.38	1.13, 1.69	0.002	
C ₁₈₀	4.81	3.65, 5.96	1.10	9.20	1.15	0.88, 1.52	0.31	
C ₃₆₀	2.99	0.79, 5.20	0	19.50	0.88	0.53, 1.45	0.62	
Puffs	8.55	7.72, 9.40	5.00	11.00	1.43	1.11, 1.85	0.006	
AUC/THC %	14.23	9.93, 18.54	2.79	40.91	1.22	0.98, 1.54	0.08	

AUC, area under the curve; CI, confidence interval; THC, tetrahydrocannabinol. a AUCs in ng h/ml; C_{max} values in ng/ml. b Analysis conducted using mixed models to adjust for day of observation.

using vaporized marijuana tended to decrease with increasing strength of THC, but the trend was not significant (mean puffs, 95% CI: 10.1 (8.8, 11.3), 9.2 (8.2, 10.1), and 8.6 (7.7, 9.4) for 1.7, 3.4, and 6.8% THC, respectively; mixed model ratio: 0.97; 0.92, 1.01; P = 0.17).

Secondary outcome measures

The levels of exhaled CO increased very little after vaporization; mean = -1.9 p.p.m.; 95% CI: -4.4, 0.6 for 1.7% THC; mean = -1.8 p.p.m.; 95% CI: -3.7, 0.7 for 3.4% THC; and mean = -0.5 p.p.m.; 95% CI: -1.9, 0.9 for 6.8% THC), whereas there was a substantial increase after smoking marijuana (mean = 15.5 p.p.m.; 95% CI: 11.0, 20.1 for 1.7% THC; mean = 11.9 p.p.m.; 95% CI: 6.8, 17.1 for 3.4% THC; mean = 7.0 p.p.m.; 95% CI: 4.0, 10.0 for 6.8% THC) (**Figure 2**). This difference was statistically significant

(P<0.001) at each THC strength. The increase in CO (AUC for CO) decreased during smoking (P=0.003 for trend), but not vaporization (P=0.25) with increasing THC strength. The expired CO AUC per puff is an indicator of how much smoke is inhaled per puff for the smoked marijuana. The CO AUC per puff decreased progressively (1.7% THC: [mean, 95% CI]: 2.8 (2.2, 3.3); 3.4% THC: 2.1 (1.1, 3.0); 6.8% THC: 1.2 (0.6, 1.9); P<0.001 for trend), consistent with taking smaller puffs with increasing THC content in the marijuana.

Subjective and safety observations

Self-reported high did not differ during vaporization compared to smoking overall (6-h AUC) or at any observation after consumption of cannabis (**Figure 3**). Self-reported high did increase significantly during both vaporization and smoking with increasing strength of THC (P<0.001).

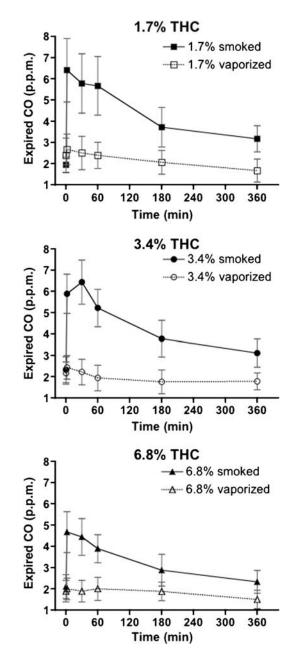


Figure 2 Expired CO at each time point for each mode of administration and THC strength (mean and 95% CI).

Although blinded with regard to dose, eight participants selected the day they received 3.4% THC (seven vaporized, one smoked) as their most preferred treatment day; four participants selected the day they received 6.8% THC via vaporization, and six participants had no treatment day preference. Overall, vaporization was the preferred method of administration by 14 participants, smoking was preferred by two, and two reported no preference. During the course of the study, no adverse events were reported.

DISCUSSION

Our study provides novel data on the absorption of THC from marijuana inhaled via the Volcano® vaporizer system

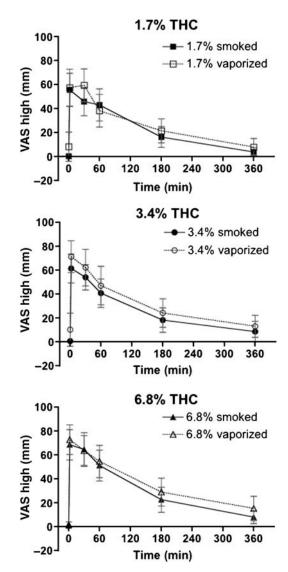


Figure 3 Self-reported "high" at each time point for each mode of administration and THC concentration (mean and 95% CI).

compared to smoking marijuana cigarettes. We found that THC levels were generally similar over 6 h for the two types of delivery. The vaporizer was associated with higher plasma THC concentrations at 30 min and 1 h compared to smoking at each THC strength, suggesting that absorption was faster with the vaporizer.

Bioequivalence criteria developed for drugs require that the CIs for the ratios of AUC for the test and reference products be between 80 and 125% to be judged bioequivalent.⁵ Using these criteria, we were not able to establish the bioequivalence of vaporization and smoking of marijuana. A much larger study would be needed to establish bioequivalence in this setting.

Of interest was that the systemic dose of THC, as estimated by the plasma AUC, normalized for the THC content of the cannabis, varied with THC strength. The dose of THC normalized for concentration of THC in the cannabis was greater at lower compared to higher THC strengths, both

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for vaporized and smoked cannabis. This observation suggests either dose-dependant bioavailability or self-titration of THC intake. Self-titration of drug intake means that smokers adapt their smoking behavior to obtain desired levels of THC from the particular delivery system, taking more puffs and/or inhaling more efficiently at lower compared to higher THC strengths. Supporting the idea of titration was the trend to take more puffs at lower THC concentrations of vaporized marijuana and the higher CO per puff at lower THC concentrations of smoked marijuana. The phenomenon of self-titration of psychoactive drug intake from an inhaled delivery system is well documented for nicotine from cigarette smoking,⁶ but to our knowledge has not been previously reported for marijuana.

Whereas smoking marijuana increased CO levels as expected for inhalation of a combustion product, there was little if any increase in CO after inhalation of THC from the vaporizer. This indicates little or no exposure to gaseous combustion toxins. Combustion products are harmful to health and reflect a major concern about the use of marijuana cigarettes for medical therapy as expressed by the Institute of Medicine. Although we did not measure other combustion products such as polycyclic aromatic hydrocarbons and oxidant gases, the observation of little or no CO exposure suggests little or no exposure to these other compounds. The vaporizer was well tolerated, with no reported adverse effects. Most subjects preferred the vaporizer compared to marijuana smoking, supporting its potential for medical therapy. Thus, the Volcano[®] is an acceptable system and may provide a safer way to deliver THC than smoking marijuana cigarettes.

In summary, we provide data indicating that the availability of THC delivered by the Volcano[®] vaporizer is comparable to that of marijuana cigarettes. Vaporization of marijuana does not result in exposure to combustion gases, and therefore is expected to be much safer than smoking marijuana cigarettes. The vaporizer was well tolerated and preferred by most subjects compared to marijuana cigarettes. The Volcano[®] device is an effective and apparently safe vehicle for THC delivery, and warrants further investigation in clinical trials of cannabis for medicinal purposes.

METHODS

Study patients. Participants were healthy adults between the ages of 21 and 45 years who were current cannabis users and had smoked cannabis within the past 30 days but in an amount totaling less than 10 cannabis cigarettes or the equivalent. Subjects with active substance abuse (e.g., recurrent or continuous drug and/or alcohol use) or diagnosed with marijuana dependence as defined in DSM-IV code no. 304.30. were excluded. Subjects were required to abstain from smoking cannabis for 48 h before their admission into the GCRC at San Francisco General Hospital (SFGH). The study was approved by the Institutional Review Board at the University of California San Francisco, the Research Advisory Panel of California, the Drug Enforcement Administration, the Food and Drug Administration, and the National Institute on Drug Abuse. Written informed consent was obtained from all patients. The trial was monitored by an independent Data Safety Monitoring Board (DSMB) established by the University of California Center for Medicinal Cannabis Research.

Study medication. The National Institute on Drug Abuse provided pre-rolled cannabis cigarettes, weighing on average 0.9 g and containing 1.7, 3.4, and 6.8% Δ -9-THC, respectively. The cigarettes were kept in a locked and alarmed freezer until they were dispensed to a locked freezer in the San Francisco General Hospital General Clinical Research Center where the in-patient study was conducted. The cigarettes were bisected; one half to be smoked and the contents of the other half to be vaporized. The half cigarettes were rehydrated in a humidifier overnight before their use. Patients were housed in a room with a fan ventilating to the outside. Research staff monitored patients during smoking sessions, weighed the cannabis cigarettes immediately before and after they were administered to patients, and returned all leftover material to the pharmacy. To maximize standardization of inhaled doses, patients followed the Foltin uniform puff procedure where inhalation for 5s is followed by a 10 s breath hold, then exhalation; the entire process is repeated after 45 s. Study participants smoked or vaporized cannabis once a day. Subjects were instructed to continue puffing until they exhausted smoke or vapor from the delivery device or until they had inhaled as much as they could tolerate.

The vaporizer device. The Volcano® vaporizer was obtained from Storz & Bickel GmbH & Company (Tuttlingen, Germany) and was employed according to the manual provided. The device works as a vaporizer that evaporates the active substances or aromas from plant material by using a hot airflow (Figure 4). Cannabis placed in the filling chamber is heated by the device to 190°C. The vaporized compounds are collected in the inflatable, detachable bag fitted with a mouthpiece and a one-way valve that allows the vapor to remain in the balloon until inhalation. It required two to three balloon inflations to vaporize each half cigarette. Subjects also followed the Foltin puff procedure when inhaling the vaporization product.

Study design and procedures. The study was a 6-day "proof of concept" pilot study to investigate the delivery of cannabinoids by way of vaporization of cannabis compared to cannabis smoked in a standard cigarette. The in-patient setting permitted us to measure plasma THC concentration over time and to rigorously assess the primary and secondary outcome variables in a controlled clinical environment.

Screening visit. Once a subject for the protocol had been identified, details of the study were carefully discussed and the subject was asked to read and sign a consent form. Subjects were asked questions about their medical history including psychiatric illness and substance abuse. Subjects were asked to abstain from smoking or ingesting cannabis 48 h before their hospitalization based on our prior studies which indicated that after 24 h of abstinence, plasma THC concentrations are sufficiently low so that the concentration-time curve could be determined after the experimental exposure. 8

GCRC in-patient hospitalization (days 1-6). Subjects inhaled three strengths of cannabis (1.7, 3.4, and 6.8% THC) as smoked cigarettes and three as vaporized cannabis using the Volcano device. Half of one cigarette was inhaled via one of the two delivery systems on each of the 6 in-patient GCRC days. The uniform puff procedure described above was utilized to attempt to standardize inhalation. Blood was drawn at 2, 30, 60, 180, and 360 min after smoking on each of the 6 inhalation days to measure the concentrations of THC. Expired CO was measured using the Ecolyzer before inhalation, and 2, 30, 60, 180, and 360 min after inhalation.

Subjects rated the subjective "high" they experienced using a 100 mm visual analog scale anchored by "none" and "highest ever". On day 5 before discharge, subjects were asked to choose which inpatient day they preferred. Subjects were asked to rate their preferences from 1 to 5 with 1 indicating very satisfied and 5 indicating very dissatisfied.

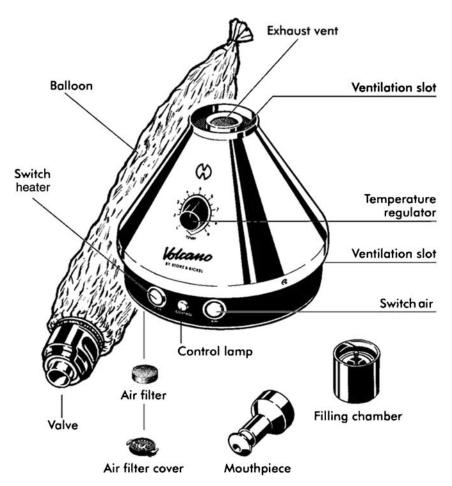


Figure 4 Volcano® apparatus.

All adverse events were spontaneously reported by the subject or observed by the study personnel and/or GCRC nursing staff, documented along with any medical intervention, and evaluated according to standardized criteria in terms of severity, frequency, duration, and relationship to study drug. Adverse events were graded using the NIH Division of AIDS table for scoring severity of adult adverse experiences.⁹

Randomization. The order of administration of the six combinations of THC strength and delivery method for the 18 participants was randomized in three 6×6 Latin squares. This ensured balance in the sense that each of the six combinations occurred exactly three times on day 1, exactly three times on day 2, and so on. In addition, the orders were restricted so that the two delivery methods for the same strength always occurred on consecutive days. This was to prevent patients from developing an early preference for one delivery method if it was used with a higher strength cigarette than the other. Randomization was computer-generated, and study drug distribution was managed by a research pharmacist. Subjects and study personnel were blinded to the THC strength.

Statistical analysis. The 18-patient target sample size was based on a standardized effect size to calculate sample size and power for the study. With a sample of 18 subjects, we had an 80% power to detect a true standardized effect size (E/S) of 0.70, using an α of 0.05, where E is the effect size and S is the standard deviation of the paired differences. ^{10,11} This calculation assumes use of a paired t-test using data at a single concentration of THC.

The primary outcome was the within-person ratio for the 6-h area under the curve (AUC_{0-6}) for plasma concentration of THC, comparing the vaporizer with smoking cannabis cigarettes. AUC₀₋₆ was computed using the linear trapezoidal method, assuming zero THC concentration at baseline. This assumption was based on our previous research that observed undetectable plasma concentration of THC 8h after smoking in all subjects.8 For each mode of administration and THC strength, we plotted the mean and 95% CIs of the observed values at each time point. To assess the withinperson ratio comparing vaporization to smoking, each outcome (AUC₀₋₆, C_2 , C_{30} , C_{60} , C_{180} , C_{360} , number of puffs, AUC₀₋₆ per THC percent, and AUC₀₋₆ per puff) was log transformed for analysis using mixed effects models. The overall effect of vaporization compared to smoking for each parameter was assessed by fitting a fixed effect term for randomization (vaporization vs smoking), controlling for strength of THC (indicators for 3.4% THC and 6.8% THC cannabis, relative to 1.7% THC cannabis). Each patient was treated as a random effect. Another model was fit to assess THC strength-specific effects of vaporization compared to smoking. This model included fitting additional fixed effects for the use of the vaporizer at each strength of THC (vaporization at 1.7% THC, vaporization at 3.4% THC, and vaporization at 6.8% THC).

We also assessed the potential presence of order effects due to the study day of observation, as well as potential practice effects due to additional experience using the vaporizer. To assess the presence of order effects, additional variables were added to both the overall and strength-specific models to assess whether day of observation impacted the outcomes, as well as whether there was a difference

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in measurements taken on the first day of the study compared to other study days. In these models, day of observation was treated as a linear variable with and without an additional indicator variable for the first study day. Similarly, to assess the presence of practice effects, additional variables were added to both the overall and strength-specific models to assess whether previous use of the vaporizer impacted the outcomes. These models included either a linear variable for how many days the participant had used the vaporizer or separate indicator variables for each day of vaporizer use.

To explore possible evidence of titration of THC intake and dose-dependent changes in bioavailability, we created additional mixed models for number of puffs and AUC₀₋₆ per THC percent, which included fixed effects, as above, for randomization (vaporization vs smoking), as well as linear terms for strength of THC, and the interaction between randomization and strength of THC. As above, these models included a random effect for each patient. These models assess not only whether the ratio of the number of puffs or the AUC per THC percent differs during vaporization and smoking but also whether the ratio increases or decreases with increasing strength of cannabis, and whether this increase or decrease differs during vaporization compared to smoking.

We compared the observed values for expired CO and self-reported high using similar methods. We plotted the mean and 95% CIs of response measures at each time point for each mode of administration and THC strength. We also fit mixed models for the 6-h AUC for expired CO and self-reported high, as described above, to compare within-person effects using vaporization and smoking. For 6-h AUC for CO, we fit models for the within-person arithmetic difference in effects, because we were unable to fit models for the ratio of effects for 6-h AUC for CO due to the presence of many negative values (and therefore non-valid log transformation of these values) during vaporization. For 6-h AUC for self-reported high, we fit models for the within-person ratios in effects, as above.

All analyses were conducted using SAS 8.2.

ACKNOWLEDGMENTS

We are grateful to our study participants; the General Clinical Research Center nursing staff for their meticulous adherence to protocol; Sheila Huang, PharmD; Peter Bacchetti, PhD, at the UCSF Department of Biostatistics and Epidemiology for his assistance in creating the randomization scheme; and Heather Bentley at the University of California

Center for Medicinal Cannabis Research for her invaluable assistance with regulatory affairs, data quality management, and interaction with the Data Safety Monitoring Board. This work was supported by the University of California Center for Medicinal Cannabis Research and NIH Grant 5-MO1-RR00083.

CONFLICT OF INTEREST

The authors declared no conflict of interest.

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SB-2718

Submitted on: 2/5/2018 10:30:44 PM

Testimony for CPH on 2/6/2018 12:45:00 PM

Submitted By	Organization	Testifier Position	Present at Hearing	
Me Fuimaono-Poe	Malie Cannabis Clinic	Oppose	Yes	

Comments:

Aloha Senators thank you for hearing our testimony today. My name is Me Fuimaono-Poe I am a Family Nurse Practitioner and a Cannabis Clinician. I have over 20 years of clinical experience and I am currently the medical director for the Malie Cannabis Clinic. I am also the provider for a quarter of the patients in the medical cannabis program in Oahu.

In its current form, I do not support Senate Bill 2718 for the following reasons

SECTION 3. Section 329-121

Subsection B

(b) For purposes of this subsection, a bona fide physician-patient relationship or bona fide advanced practice registered nurse-patient relationship may be established via' telehealth, as defined in section 453-1.3(]). I1

I am currently a telehealth provider for HMSA and have been doing Telehealth visits for over 3 years. When doing telehealth, we follow the current state mandate which states

Source: HI Revised Statutes § 329-1.

Treatment recommendations made via telemedicine are appropriate for traditional physician-patient settings that do not include a face-to-face visit, but in which

prescribing is appropriate, including on-call telephone encounters and encounters for which a follow-up visit is arranged.

Issuing a prescription based solely on an online questionnaire is prohibited.

For the safety of the patients, the cannabis clinician should be held to the same standards of all other patient provider relationships.

Source: HI Revised Statutes § 453-1.3.

Newly Passed Legislation (Effective Jan. 1, 2017)

A physician-patient relationship may be established via telehealth if the patient is referred to the telehealth provider by another health care provider who has conducted an in-person consultation and has provided all pertinent patient information to the telehealth provider. This would provide ample protection to our patient population.

I would like to highlight §453-1.3 Practice of telehealth.

opiates or medical marijuana, a physician-patient relationship shall only be established [pursuant to chapter 329.] after an in-person consultation between the prescribing physician and the patient.

I suggest telehealth: Should be available only for follow up once a patient has been seen in the clinic, unless the patient is referred by another provider who forwarded all of the patient's information.

SECTION 5. Section 329D-10,

shall contain more than a total of one [one] thousand milligrams of tetrahydrocannabinol per pack or container.

I would like to know if this will be limited to certain products like vaporizers or topical. I would also like to know the justification of increasing the current limit from 100 to 1,000 essentially making it 10 x's stronger. I agree with the increase if it is limited to vaporizer cartridges and topical preparations, where a single dose is not equal to 1,000 mg. There is no efficacy or safety data available for high doses of THC. The average dose is around 10 mg of THC

3. Section 329D-12, H

or the patient furnishes a written certification from the patient's primary care physician certifying that the patient has a debilitating medical condition;

A medical cannabis dispensary shall make reasonable good faith efforts to verify that the patient's government issued photo identification is valid, the patient's medical cannabis card or written certification has not expired, and the certifying physician's license is in good standing with the applicable jurisdiction.

which shall be valid for a period of no more than six months and may be renewed prior to expiration every six months

- 1. If only a written certification is required what is the plan for fraudulent cards. Will the dispensaries be able to verify the medical licenses of Physicians located in New York?
- 2. I would like to see all out of state patients verified using bio track
- 3. According to http://dbedt.hawaii.gov/visitor/tourism/ Hawaii department of tourism the average length of stay in Hawaii is 9 days I think that temporary cards should be available for a maximum of 4 weeks well over the average length of stay for our visitors. Tourists wishing to stay longer should establish relationships with local clinicians for the safety of our patients and the safety of our patient focused industry.

In closing, we have a medical cannabis program with over 20,000 patients in the state of Hawaii. We have 116 physicians and 18 APRN-RX's in the state providing care to these patients. In a medical model the clinicians should be at the center of care. Providing an environment that promotes medical cannabis use in a safe and responsible manner should be a priority for the state.

Hawaii should be proud of our patient focused program, we have one of the cleanest, and most reliable program in the nation right now and we must protect that legacy.



February 5, 2018

TO: Committee on Commerce, Consumer Protection and Health

Senator Rosalyn H. Baker, Chair, Senator Jill N. Tokuda, Vice Chair Committee on Public Safety, Intergovernmental and Military Affairs Senator Clarence K. Nishihara, Chair, Senator Glenn Wakai, Vice Chair

FROM: Teri Freitas Gorman

RE: Testimony-SUPPORT SENATE BILL (SB) 2718

RELATING TO CANNABIS FOR MEDICAL USE

Aloha e Chairs Baker and Nishihara, Vice-Chairs Nishihara and Wakai and Members of both committees:

My name is Teri Freitas Gorman and I am Director of Community Relations & Patient Affairs for Maui Grown Therapies and a board member of the Hawai'i Educational Association for Licensed Therapeutic Healthcare, the trade association for all state-licensed dispensaries. Mahalo for allowing me to testify in favor of SB 2718.

Maui Grown Therapies made history on August 8, last year when we became Hawai'i's first licensed medical cannabis dispensary. During the past six months we have worked closely with Department of Health (DOH) staff to launch our business as well as our fledgling industry. My executive role puts me in close personal contact with a wide spectrum of Maui's medical cannabis patients.

Since opening, we've seen medical cannabis help a retired plantation worker get through chemotherapy, a wheelchair-bound former professional football player relieved of knee pain, a quadriplegic with frequent muscle spasms who found tinctures help him sleep through the night, and an arthritic grandfather who can use his computer keyboard again. There are some sad stories too. We also received flowers from a widow, grateful that her husband's personality was not muted by narcotics during his final days.

As legislators, it is important for you to understand both the characteristics and character of our patients. Most of them--65 percent--are well over the age of 45. Nearly 50 percent are retirement aged, 55 years or older. Our oldest patient is 93. Our patients come from every community in our county, including Hana, a two and a half-hour drive away, and others who travel from Moloka'i and Lana'i.

Several of our island-born patients live in multi-generational households to help their children and grandchildren cope with Maui's cost of living. Some of our patients get by on fixed incomes while others have retired to Maui with ample means. But they all share conditions that bring them to our dispensary in search of a better quality of life. My testimony today is delivered as patient advocate who understands that our industry must thrive if we are to serve our fellow islanders with cannabis products that are second to none.

Below are our positions on key provisions of SB 2718:

1. Amend the Reciprocity Program

Act 231 provides that qualifying patients, verified as a patient in their home state, may be served by licensed dispensaries beginning January 1, 2018. Maui Grown Therapies started receiving inquiries from hopeful out-of-state patients as soon as we opened our doors. However, both phone and email inquiries have accelerated dramatically last month because some websites are erroneously reporting that reciprocity in Hawai'i began at the start of 2018.

Even though we have information on our homepage explaining the status of reciprocity, we have received 107 email inquiries from out-of-state patients and our staff has answered slightly over 250 telephone phone queries. Approximately 48 percent of inquiries come from California residents and nearly 15 percent have come from Canadian citizens. Although we do not request personal information, many of those inquiring through our website offer medical reasons for their requests. Mentioned most often are cancer/chemotherapy, severe pain, and end-of-life care.

Compassion dictates that Hawai'i develop its medical cannabis reciprocity program without further delay. Pragmatism suggests the program be simple to implement and execute without unnecessary bureaucracy. More than 30 American jurisdictions oversee medical cannabis programs, each with different laws and regulations. To try to design a reciprocity program that synchronizes the unique requirements of each jurisdiction with those of Hawai'i is a recipe for failure.

For this reason, we recommend that any patient with a letter from their licensed healthcare provider be eligible to shop in a Hawai'i-licensed dispensary if their provider is licensed and in good standing in the patient's home state. This allows physicians to determine medical options for their patients. Statelicensed dispensaries can vet and process visitor registrations as the only sanctioned method for them to access medical cannabis while in Hawai'i. Additionally, dispensaries can collect visitor registration fees on behalf of the state to help offset costs of the medical cannabis dispensary program without adding to the financial burden of Hawai'i patients.

Smart business dictates that reciprocity must begin before the end of this year. Licensees have invested millions of dollars based upon statute that promised out-of-state visitors would have access to dispensaries in 2018. As a result of DOH staffing shortages, the rate of growth for registered 329 patients has fallen from 4 percent per month one year ago to 0.55 percent during the last month of 2017. This is an area of concern for all licensees, but even more so for those operating on neighbor islands, serving several small rural communities. When dispensaries serve more patients, including those from out-of-state, prices will come down for Hawai'i patients. In every single jurisdiction, when the sector becomes economically viable, prices to patients inevitably fall. This is especially important for our kūpuna on fixed incomes.

2. Extend the maximum validity of a qualifying patient's written certification

The current requirement for annual renewal for a 329 card does not consider the chronic nature of the vast majority of Hawai'i's qualifying conditions. Annual renewals add both cost and inconvenience for patients, and because of unpredictable registry response times, patients often experience a lapse in treatment.

3. Allow a bona fide physician-patient or advanced practice registered nurse-patient relationship to be established via telehealth

Telemedicine is an especially important option for physicians to certify extremely ill patients including those who cannot leave their homes and/or are receiving hospice care. However, this option is especially needed on the neighbor islands. Maui's largest single employer of physicians is Kaiser Permanente, with 73 MDs on their payroll. These physicians are prevented from certifying patients for

medical use of cannabis and they represent 26.6 percent of all Maui physicians. Additionally, our neighbors on Lana'i and Moloka'i must commute to Maui for many of their medical appointments. Telemedicine would increase their accessibility to MDs and APRNs who understand and support the applications of cannabis therapy to qualifying conditions.

4. Add certain devices that provide safe pulmonary administration to the list of medical cannabis products that may be manufactured and distributed

This provision is crucial for the large number of our patients who do not want to smoke herbal cannabis. Pulmonary administration of cannabinoids provides quick relief for severe pain, nausea and other conditions; effects are typically felt within two minutes of dosage. Ingestible forms of cannabis (tinctures, capsules, etc.) can take up to three hours before patients experience relief.

With DOH permission, Maui Grown Therapies sold pre-filled cartridges intended for use in personal vaporization devices for about four weeks in October of 2017. This position was later reversed and we were required to sell concentrate oils packaged in syringes that forced patients to fill their own cartridges. Our patients were angry about this development and wanted to express their displeasure, so we provided printed postcards for their signature and comment. We are aware of 114 signed postcards that our patients mailed to Department Director Pressler.

Because so many of our older patients live in multigenerational households, they prefer to use vaporization devices to get quick relief without the pungent, tell-tale smell of burning cannabis. Other patients have conditions such as paralysis, arthritis, tremors, or injuries that prevent them from using a syringe to fill a cartridge. This is not only callous it is also discriminatory because it prevents patients with disabilities from using this form of administration.

5. Increase the tetrahydrocannabinol limit per pack or container of certain manufactured cannabis products

As with all packaged products, smaller sizes are always more expensive for consumers than larger sizes. The current limit of 10 mg. per dose and 100 mg. per package for THC does not accomplish much more than increase final cost to patients. Many conditions and symptoms require larger doses of THC for relief so increasing the THC limit for manufactured products is important for our patients both therapeutically and economically.

Me ka ha'a ha'a (humbly yours),

Teri Freitas Gorman

Director of Community Relations & Patient Affairs

<u>SB-2718</u> Submitted on: 2/3/2018 5:55:23 AM

Testimony for CPH on 2/6/2018 12:45:00 PM

Submitted By	Organization	Testifier Position	Present at Hearing	
Kat Culina		Support	No	

Comments:

Submitted on: 2/4/2018 12:06:41 PM

Testimony for CPH on 2/6/2018 12:45:00 PM

Submitted By	Organization	Testifier Position	Present at Hearing
Scott Foster		Support	No

Comments:

Submitted by Scott Foster for Hawai'i Advocates For Consumer Rights

<u>SB-2718</u> Submitted on: 2/4/2018 1:35:32 PM

Testimony for CPH on 2/6/2018 12:45:00 PM

Submitted By		Organization	Testifier Position	Present at Hearing
	Joseph A. Bobich		Support	No

Comments:

<u>SB-2718</u> Submitted on: 2/1/2018 11:55:16 AM Testimony for CPH on 2/6/2018 12:45:00 PM

Submitted By	Organization	Testifier Position	Present at Hearing
Teri Heede		Support	No

Comments:



Gregory K. Yim, M.D. LLC Pediatric Neurology

Kapiolani Medical Center for Women and Children 1319 Punahou Street, Suite 1000 • Honolulu, HI 96826 TEL 808-946-4474 • FAX 808-946-4475 E-mail: Gregyim@aol.com

February 5, 2018

TO: Committee on Commerce, Consumer Protection and Health Senator Rosalyn H. Baker, Chair,

Senator Jill N. Tokuda, Vice Chair

Committee on Public Safety, Intergovernmental and Military Affairs

Senator Clarence K. Nishihara, Chair Senator Glenn Wakai, Vice Chair

FROM: Gregory Yim, MD

RE: Testimony-SUPPORT SENATE BILL (SB) 2718

RELATING TO CANNABIS FOR MEDICAL USE

Dear Chairs Baker and Nishihara, Vice-Chairs Takuda and Wakai and Members of the CPH and PSM Committees:

As a pediatric neurologist, a member of the Act 230 Working Group and the chief medical officer for one of Hawai'i's eight licensed dispensaries, I am very pleased to testify in favor of key provisions in SB 2718.

I first testified before this committee in 2015 at the urging of a parent of one my patients with Dravet syndrome, a severe form of infantile epilepsy. Together we supported the measure that ultimately became Act 241. At that time, we presented anecdotal evidence that cannabis may help, but did not appear to harm kids with this disease. In our case, we observed that cannabis therapy significantly reduced the frequency of seizures without negative side effects.

With the passage of the medical cannabis dispensary law the legislature jumped ahead of the clinical evidence. Like lawmakers in dozens of other states, you voted with patients and their families despite federal classification of cannabis as a Schedule 1 substance. Although this classification has had a chilling effect on research, the scientific evidence is mounting that many conditions can be safely treated with controlled-dose, quality-assured medical cannabis.¹

¹ With regard to Dravet syndrome, results from a double-blind, placebo-controlled study of 120 children found that fewer seizures where experienced by patients taking a daily oral solution of the cannabis compound cannabidiol. Over 14 weeks of treatment, convulsive seizures dropped from a monthly

What follows are my recommendations regarding the key provisions of SB 2718.

1) Amend the reciprocity program - strong support

Act 231 provides that qualifying patients <u>verified as a patient in their home state</u> may be served by licensed dispensaries beginning January 1, 2018 subject to a registration process established by the Department of Health (DOH). The statute further requires that patients be "verified as patients in their home state." To the extent this provision is interpreted as patients <u>verified by their home state</u> (i.e., a government agency) we can expect a complex, costly and ultimately unworkable program. The regulatory agencies, patient credentialing and the qualifying conditions for medical cannabis in the other 28 states, two territories and the District of Columbia are varied and ever changing. No two are alike.

I therefore strongly support the language in section 8 where, as an alternative to presenting a medical cannabis card from their home state, patients can supply a written certification from their primary care physician certifying that the patient may benefit from cannabis therapy. Such a provision honors the sanctity of the physician-patient relationship while minimizing the need for complex interstate compliance management among and between numerous agencies. As for the physician validation process, US states and territories require physicians to hold licenses and ascertaining standing seems straightforward relative to uncovering the latest patient credentialing scheme in 31 separate jurisdictions.

As for administering the visiting patient credentialing process, we know DOH is overwhelmed by staffing challenges in both the patient registry and licensed dispensary programs. However, licensed dispensaries have been cleared by DOH to conduct sales, have been thoroughly vetted, maintain real time records, submit regular reports, are subject to unannounced inspections by multiple agencies, and must reapply annually for license renewals.

Hawai'i's dispensaries are operating in one of the most rigorously regulated medical cannabis programs in country. This proposed process to serve visiting patients will honor the patient-physician relationship, simplify a potentially protracted and complex interstate scheme, and relieve administrative pressure at the DOH.

 Extend the maximum validity of a qualifying patient's written certification – strong support Annual certification for <u>chronic</u> conditions is unnecessary. A longer validation period for chronic or progressive conditions will reduce costs for patients, ease the workload for DOH registry staff and reduce the risk of treatment interruption.

 Allow a bona fide physician-patient or advanced practice registered nurse-patient relationship to be established via telehealth – strong support

A University of Hawai'i study released in September 2017 concluded that the physician shortage in the state is worsening. The university's Physician Workforce Assessment found O'ahu needs 381 physicians; Hawai'i Island is short 196 providers; Maui County has a deficit of 139, and the island of Kaua'i is short 53 doctors. Telemedicine is an efficient way to help bridge this gap. Telemedicine is especially important for house-bound patients including those receiving end-of-life care.

 Add certain devices that provide safe pulmonary administration to the list of medical cannabis products that may be manufactured and distributed – strong support

Multiple peer-reviewed medical and scientific studies² have concluded that vaporization is a safer alternative to smoking that permits rapid relief for patients experiencing acute symptoms. By heating cannabis material to a temperature at which cannabinoids convert vapors but below the point of combustion, vaporization prevents the inhalation of harmful pyrolytic compounds that are produced when cannabis material is combusted³. Many cannabis patients, especially cancer patients, refuse to smoke herbal cannabis but still want the fast onset pulmonary administration provides. Personal vaporization devices made of non-reactive materials are safe for this purpose. Cartridges pre-filled with cannabis extract, which can permit greater ease of administration than cannabis plant material, are especially important for paralyzed or disabled patients and those with rheumatoid arthritis and/or tremors from age-related conditions. In fact, not providing pre-filled cartridges to these patients may be discriminatory for those with disabilities.

 Increase the tetrahydrocannabinol limit per pack or container of certain manufactured cannabis products -strong support

Noted cannabis researcher Donald Abrams, MD documented⁴ how patientdetermined dose titration is not unique to cannabis; he recommends patient-

² See for example Abrams et al (2007): Vaporization as a smokeless delivery system, *Clinical Pharmacology and Therapeutics* 82(5) pg. 572: **'Vaporization is a safe and effective mode of delivery of THC.'**

³ Fischedick et al (2010): Cannabinoid Receptor Binding Activity and Quantitative Analysis of Cannabis Sativa L Smoke and Vapor, Chemical and Pharmaceutical Bulletin: 58(2) pg. 207: 'Quantitative comparison of cannabis smoke and vapor shows that vaporizing cannabis...is a more reliable and safer administration form for the delivery of d9-THC due to the lack of pyrolytic degradation and more efficient d9-THC volatilization.'

⁴ Abrams et al (2010) **Cannabis for chronic neuropathic pain: a randomized controlled trial.** A single inhalation of 25 mg of 9.4% tetrahydrocannabinol herbal cannabis three times daily for five days reduced the intensity of pain, improved sleep and was well tolerated. (International Standard Randomized

determined dosing as preferable given the safety and low toxicity of cannabis. The maximum 100mg/package limit in Hawai'i law was likely modeled after restrictions on edible products in other jurisdictions. Oral ingestion of THC has quite different pharmacokinetics than pulmonary administration because the onset of effects is delayed making dose titration more complicated. An experienced cannabis patient can easily titrate and regulate dose through pulmonary administration to obtain desired effects and minimize any undesirable effects cannabis products.

Optimal THC dosage will vary from patient to patient, but Abrams found that a single inhalation of 25 mg. of 9.4% Delta-9-tetrahydrocannabinol (THC), three times daily for five days effectively reduced the intensity of neuropathic pain, improved sleep and was well tolerated by patients. The current Hawai'i per-dose limit of 10 mg. is insufficient, impractical and adds unnecessary production and packaging expenses that are passed on to patients.

Mahalo for your time and consideration.

Gregory K. Yim, M.D.

SB-2718

Submitted on: 2/6/2018 6:20:33 AM

Testimony for CPH on 2/6/2018 12:45:00 PM

Submitted By	Organization	Testifier Position	Present at Hearing	
Richard Ha		Support	Yes	

Comments:

I am in strong support of SB2717

I am CEO of Lau Ola LLC, one of the 8 medical cannabis liscensees. SB2718 goes a long way toward strengthening product, public and patient safety.

i received a medical cannabis patient 329 card nine months ago. As a senior, I have seen the positive effects of cannabis. My hip/ back pain is now manageable and because of that I started riding a bicycle a month ago. My dependency on alcohol went completely away.

The science basis of cannabis is the Endocannabinoid System(ECS), which keeps the human body in balance. This is why the medical cannabis model is different from straight recreational usage.

Richard Ha

CEO

Lau Ola LLC

Hawaiian Ethos

To: Senator Rosalyn Baker, Chair Consumer Protection and Health (CPH)

Senator Clarence Nishihara, Chair Public Safety, Intergovernmental and Military Affairs (PSM)

Senator Jill Tokua, Vice-Chair CPH Senator Glenn Wakai, Vice-Chair PSM Members of the Joint Senate Committee

Fr: Blake Oshiro, on behalf of Hawaiian Ethos.

Re: Testimony In Strong Support on Senate Bill (SB) 2718

RELATING TO CANNABIS FOR MEDICAL USE

Dear Chairs Baker and Nishihara, Vice-Chairs Tokuda and Wakai, and Members of the Committee:

Hawaiian Ethos is one of the two licensed medical cannabis dispensaries for the island of Hawaii under Haw. Rev. Stat. (HRS) Chapter 329D. We **support SB2718** as an important bill for the dispensary industry. This bill will serve to enhance the medical cannabis dispensary program with additional patient access, product controls and safety, and provide improvements to the administration of the program.

(1) Reciprocity program

The current law, Haw. Rev. Statutes (HRS) 329D-13, provides for a start date of January 1, 2018 for a program where patients from other states would be able to legally purchase medical cannabis from dispensaries. Unfortunately, that program has yet to be implemented. We believe that the bill properly seeks to minimize the concern regarding out-of-state patients obtaining large quantities of product.

(2) Extend possible validity of a qualifying patient's written certification from 1 to 3 years

Almost all of the qualifying conditions under HRS 329-121 are chronic debilitating diseases and conditions by definition, these conditions will likely be with the patient for a significant and ongoing period of time beyond the current one-year validity period of cards. We believe that the current one-year validity period is burdensome to patients as well as the registry program that is responsible for issuing and renewing patient cards.

(3) Telehealth relationship

We believe that telehealth can be especially helpful for patients in rural communities and/or patients suffering from severe debilitating conditions that make even a physical face-to-face appointment or traditional patient-provider interaction relationship difficult. This is of particular importance to Hawaii Island patients whose geographic distribution spans is much larger area than the other islands. Therefore, this change will be especially helpful for patient access and for monitoring of a patient's use of medical cannabis in rural and underserved communities.

(4) Add safe pulmonary administration to the list of medical cannabis products

We support this addition to possible product offerings because of the ability for more precise dosage administration, safe inhalation of certain patients and their conditions, and the possible stigma associated with "smoking" cannabis.

Our research has shown that administration through pulmonary inhalation, can be more effective for certain patients who have a low tolerance for, or resistance to, smoking the cannabis. It is more readily absorbed, and its effects are felt more quickly, so that the potential for taking too large a dose, is minimized.

The bill's language provides proper consumer protections that ensure the device's heating element would be made of inert materials, and there is a temperature control, so that there is additional safety against a device becoming unsafe and combustible.

(5) THC limit per pack or container

Every patient responds to their medicine differently, which depends on a number of varying factors including their specific medical condition, age, endocannabinoid system, to name a few. As such, a wide range dosage options will be required to achieve the desired medical effect.

(6) Clarify background check requirement to those with direct access to cannabis or manufactured cannabis product

The current law requires all employees and any subcontractors to undergo a background check. This requirement seems overbroad, for there are many employees and subcontractors who never come in contact with, or have any access to, cannabis product. The bill does NOT seek to change the department's authority to approve these individuals having access to the premises. As such, we think that providing the DOH with authority to indicate when a background check should be conducted on any individual that does not have access to product, is reasonable.

(7) DOH's disclosure of information via a legally authorized subpoena

With the changes and uncertainties of the current federal administration, along with even recent examples of local law enforcement using patient information for purposes unrelated to cannabis possession where the Honolulu Police Department had initially required gun-owners with medical cannabis card to surrender their legally held guns, we are concerned with the existing law's low threshold for law enforcement to obtain any information "upon request." While we can understand the need for law enforcement to verify that a person is a valid and qualifying patient under the law, and perhaps even to verify where that person may have obtained their cannabis or cannabis product, any other disclosure of personal health information, should only be disclosed via a lawful process, like a subpoena.

Thank you for your consideration.