WRITTEN TESTIMONY OF
THE DEPARTMENT OF THE ATTORNEY GENERAL
TWENTY-NINTH LEGISLATURE, 2017

ON THE FOLLOWING MEASURE:
H.B. NO. 1488, H.D. 1, S.D. 1, RELATING TO MEDICAL MARIJUANA.

BEFORE THE:

SENATE COMMITTEES ON JUDICIARY AND LABOR AND ON WAYS AND MEANS

DATE: Thursday, March 30, 2017 **TIME:** 9:50 a.m.

LOCATION: State Capitol, Room 211

TESTIFIER(S): **WRITTEN TESTIMONY ONLY.**
(For more information, contact Tara K.C.S. Molnar, Deputy Attorney General, at 587-3050)

Chairs Keith-Agaran and Tokuda and Members of the Committees:

The Department of the Attorney General provides comments on this bill.

This measure would amend the definition of "debilitating medical condition" in section 329-121, Hawaii Revised Statutes (HRS), to include lupus, epilepsy, multiple sclerosis, arthritis, and autism as conditions that qualify for the legal use of medical marijuana (page 5, lines 18-19). The bill would also amend section 329D-6, HRS, to enable the Department of Health (DOH) to implement an alternate tracking system that would allow qualified patients to purchase marijuana or manufactured marijuana products from a licensed dispensary on a temporary basis if the DOH's computerized tracking system is not functioning properly or at all (page 15, line 1, through page 16, line 2).

The proposed wording on page 5, lines 18-19, raises concerns, because without a scientific or other basis to indicate that the use of marijuana helps to treat or provide relief to people who have the additional proposed conditions, the proposed expansion may appear to move the State closer to deregulation of marijuana, a schedule I controlled substance under federal law. Adding these new conditions without adequate justification could increase the risk of diversion and could be viewed by the new federal administration as contrary to the goal of having a robust regulatory scheme for the

medical use of marijuana in Hawaii. In order to maintain the robust regulatory scheme required by the U.S. Department of Justice (DOJ) Memorandum for All United States Attorneys dated August 29, 2013 (the Cole memo), we suggest that if the Committees decide to pass this bill, they add a section of findings that would provide a basis for the use of marijuana for the additional conditions.

The proposed wording on page 15, line 1, through page 16, line 2, raises concerns, because it does not require that the alternate tracking system provide a means for actually tracking the sale of marijuana or manufactured marijuana products in real time if the DOH's computer tracking system is not working properly, and may allow qualified patients to purchase marijuana or manufactured marijuana products in excess of statutory limits, which could increase the risk of possible diversion of marijuana and manufactured marijuana products. In order to maintain the robust regulatory scheme required by the Cole memo, we respectfully suggest that the wording creating an alternate tracking system be deleted. If the Committees are inclined to provide a backup system, we recommend that this measure include a requirement that the backup system include a means of tracking the sale of marijuana or manufactured marijuana products in as close to real time as possible through some other means. The Department of the Attorney General respectfully recommends that, if the Committees move this measure forward, they amend the bill as suggested.

the Drug Policy Action Group
A sister organization of the Drug Policy Forum of Hawai'i
PO Box 83, Honolulu, HI 96810 ~ (808) 518-3213

Hawaii's Voice for Sensible, Compassionate, and Just Drug Policy

TO: SENATE COMMITTEE ON JUDICIARY & LABOR & WAYS & MEANS

FROM: PAMELA LICHTY, M.P.H., PRESIDENT

DATE: March 30, 2017, 9:50 a.m., Room 211

RE: H.B. 1488 HD1, SD1 RELATING TO MEDICAL MARIJUANA – **IN STRONG SUPPORT**

Good morning, Chairs Keith-Agaran and Tokuda and members of the Committees. My name is Pam Lichty and I'm President of the Drug Policy Action Group (DPAG), the government affairs arm of the Drug Policy Forum of Hawai'i.

We strongly support this measure, the omnibus bill to improve Hawaii's medical cannabis program. We are especially pleased by Senate Draft 1 which has addressed many of the concerns in earlier drafts.

We do think the bill could be improved even more by some small changes. While we applaud the provision that permits DOH to assess the need for additional dispensaries, we don't believe any artificial delays or deadlines are useful or necessary. Although it is implied here that small amounts of cannabis may be transported interisland by patients or caregivers, we would like to see this spelled out (as it is in HB 836.)

It would also be a fine addition if registered patients were given employment protections (as in HB 1010). And while we're pleased to see the sunset date for caregivers extended, we would prefer to see it eliminated entirely to meet the needs of patients who for various reasons will be unable to utilize the dispensaries (e.g. lack of transportation, high cost.)

In summary, we are **extremely** pleased to see this bill is moving and applaud its timeliness as the dispensaries gear up for their openings. Thank you hearing this measure today; we urge you to pass it out to the full Senate for a vote. Mahalo for the opportunity to testify.

ON THE FOLLOWING MEASURE:

HB1488, HD1, SD1 RELATING TO MEDICAL MARIJUANA

BEFORE THE: SENATE COMMITTEES ON JUDICIARY AND LABOR & WAYS AND MEANS
DATE: Thursday, March 30, 2017 TIME: 9:50 A.M.

LOCATION: State Capitol, Conference Room 211

TESTIFIER: Christopher Garth, Executive Director

Honorable Chairs Keith-Agaran and Tokuda and members of the Committees:

The Hawai‘i Dispensary Alliance submits the following testimony in **OPPOSITION** to **HB1488, HD1, SD1 RELATING TO MEDICAL MARIJUANA**, which Amends the definition of "adequate supply" of marijuana to include seven marijuana seedlings. Amends the definition of "debilitating medical condition" to include lupus, epilepsy, multiple sclerosis, arthritis, and autism as conditions that qualify for the legal use of medical marijuana. Amends the definition of the term "transport" to allow qualified patients and primary caregivers to transport up to one gram of medical marijuana for laboratory testing under certain conditions. Limits each location used to cultivate marijuana to use by five qualifying patients. Authorizes primary caregivers to cultivate marijuana for qualifying patients until December 31, 2020. Adds considerations for establishing marijuana testing standards and selecting additional dispensary licensees. Allows DOH to consider whether existing dispensary licensees shall be allowed to increase plant count, increase the number of production centers, or increase the number of retail dispensing locations. Requires retention of video security recordings of production centers and dispensaries for 45 days. Extends civil service exemptions and interim rulemaking authority to 2020. Authorizes an alternate medical marijuana dispensary tracking system for use when the DOH computer tracking system in nonfunctional and requires DOH to report to the legislative oversight working group.

The Hawai‘i Dispensary Alliance is a patient-centric organization that aims to appropriately introduce the legitimate cannabis industry to the state of Hawai‘i. Our membership is drawn from patients and caregivers, dispensaries, manufacturers, producers, and ancillary businesses who shape the physical and intellectual cannabis space, as well as those who generally support the value of a legal right to cannabis-based medicine. The Alliance has established itself as a consistent voice in the conversation for greater patient access to safe and quality cannabis resources. It is from this perspective that we **OPPOSE HB1488, HD1, SD1.**

Specific and strong objections to this measure are based on:

- SECTION 5: Delay DOH assessment for additional MMJ licenses - **OPPOSE**

SECTION 5. Section 329D-2, Hawai‘i Revised Statutes, is amended to read as follows: "(j) Notwithstanding subsection (d), the department shall determine whether, based on the qualifying patient need, additional dispensary licenses shall be offered to qualified applicants in the State after October 1, [~~2017;~~] 2018;…" A delay of this magnitude is unacceptable as it directly

encourages the continuation of limited access to vital medicine for Hawai‘i’s already large certified patient population. This measure should rather encourage DOH to move to realize the ratio of 500 patients to 1 dispensary currently enshrined in Act 241.

This measure was constructed to be a vehicle to encourage DOH to provide greater patient access as the first three lines of page 2 of this very bill clearly state: “`The legislature also finds that the delay in implementing the medical marijuana dispensing system is affecting patient access to medical marijuana.`”

If this is the case, why then are we entertaining the idea of creating further legislative delay? Your body should instead stick to the current timeline and even create an encouraging tone that suggests DOH create a protocol to introduce additional licenses should one or any of the current or future licensees fail or have their license revoked. Preparation for a worst-case scenario through appropriate expansion of the dispensary program would ensure continued and lawful access to all patient populations spread across our island state. Additional licensees will contribute to a greater marketplace for patients in Hawai‘i by providing affordable access to more diversified and consistent medical products. The availability of more medicine ultimately will lead to less expensive medicine, which in turn helps to significantly erode the feasibility of a secondary or black market economy. Costs for testing products will be shared by a larger number of players further reducing costs and medicine prices. Patient counts will continue to increase as access to medicine improves – up to approximately double the current number of patients – based on the experience of medical programs in other states. Public education and familiarity with this form of medication will improve and the mania and stigma surrounding the industry will erode as more people see a healthy, and safe, medical industry.

Finally, additional rounds of applicants/applications would translate into the resources needed to fund a sustainable and self-sufficient state regulatory program – unlike the currently underfunded program. Consider that a second round of applications as early as October 2017 could yield $115,000 at a minimum (23 applicants X $5,000 application fee, though this number will likely be much larger as the number of applicants will greatly exceed the number of available licenses), and $1,725,000 annually in licensing fees (23 licensees X $75,000 licensing fee). This is not to mention the benefits for the state’s economy in general that would result from the creation of dozens of new, local businesses and their need to erect new buildings and hire hundreds of local workers. This is all potential funding that the Department and the State will not have access to if this bill passes.

Dollar valuations and funding considerations aside, this bill should address the needs of the patients that the program is intended to benefit – yet it is actively detrimental to their interests. SECTION 5 of HB1488, HD1, SD1 make no provisions for continued patient access to quality medicine throughout the eminent period of stagnation that the underfunded DOH program will surely endure as it vets additional licensees at some indeterminate time in the future.

For all of the foregoing reasons, the Hawai‘i Dispensary Alliance **OPPOSES** the language of this measure and recommends that **HB1488, HD1**, **SD1** be **DEFERRED**.

Thank you very much for the opportunity to provide testimony on this measure.

HAWAII EDUCATIONAL ASSOCIATION FOR LICENSED THERAPEUTIC HEALTHCARE

To: Senator Gilbert Keith-Agaran, Chair Judiciary and Labor
Senator Jill Tokuda, Chair, Ways and Means
Members of the Joint Senate Committees of Judiciary and Labor and Ways and Means

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

Re: Testimony - **Support House Bill (HB) 1488, House Draft 1 (HD) 1, Senate Draft (SD) 1**

RELATING TO MEDICAL MARIJUANA

Amends the definition of "adequate supply" of marijuana to include seven marijuana seedlings. Amends the definition of "debilitating medical condition" to include lupus, epilepsy, multiple sclerosis, arthritis, and autism as conditions that qualify for the legal use of medical marijuana. Amends the definition of the term "transport" to allow qualified patients and primary caregivers to transport up to one gram of medical marijuana for laboratory testing under certain conditions. Limits each location used to cultivate marijuana to use by five qualifying patients. Authorizes primary caregivers to cultivate marijuana for qualifying patients until December 31, 2020. Adds considerations for establishing marijuana testing standards and selecting additional dispensary licensees. Allows DOH to consider whether existing dispensary licensees shall be allowed to increase plant count, increase the number of production centers, or increase the number of retail dispensing locations. Requires retention of video security recordings of production centers and dispensaries for 45 days. Extends civil service exemptions and interim rulemaking authority to 2020. Authorizes an alternate medical marijuana dispensary tracking system for use when the DOH computer tracking system in nonfunctional and requires DOH to report to the legislative oversight working group. Effective 7/1/2050.

Dear Chairs Keith-Agaran and Tokuda, Vice-Chairs Rhoads and Dela Cruz, and Members of the Committee:

HEALTH is a recently formed trade association made up of the eight (8) licensed medical marijuana dispensaries under Haw. Rev. Stat. (HRS) Chapter 329D. HEALTH's members are all committed to ensuring the goals of patient safety, product safety and public safety.

HEALTH **supports** HB1488, HD1, SD1 as it addresses several of the issues facing our emerging industry, or helps to promote patient access, or helps to ease Dept. of Health's administrative burdens.

I. <u>ADMINISTRATIVE ISSUES</u>

Much of the bills need to extend certain deadlines under the original law, Act 241, Session Laws of Hawaii 2015, is because recent delays have precluded licensed dispensaries from moving forward. While licenses were awarded somewhat timely, shortly after the April 15, 2016 deadline, the law's allowance for retail dispensing of medical marijuana on July 15, 2016 will likely be about 1 year late. While four (4) dispensaries have been issued a notice to proceed on cultivation of medical marijuana, there will have several months before such plants are ready for harvest, production and then retail sale. HEALTH therefore **supports** all of the extended deadlines in the bill.

We also support the language in the bill dealing with the DOH's authority to provide for new licensees or for additional plants or facilities to existing licensees. HEALTH supports the language that was placed in HB1488 HD1, SD1 which allows for an increase in plant count or number of facility locations so long as there is a similar demonstration to provide a need in an underserved or rural geographic area. As the licensees have gone through an extensive and rigorous review and inspection, and are under strict monitoring guidelines to ensure compliance, we support increasing the plant count or allowing new facilities as prudent approach to providing patient access in underserved or rural areas.

II. NEW CONDITIONS

We **strongly support** the addition of certain conditions to qualify for the legal use of medical marijuana. Attached, is a list of the state's that allow medical marijuana and the qualifying conditions. See https://www.leafly.com/news/health/qualifying-conditions-for-medical-marijuana-by-state

While we note that the range of conditions vary state to state with some more restrictive, some broader, than Hawaii, we think it is important to note that Hawaii was one of the first states to authorize the use of medical marijuana program in 2000. Yet, since that time, the list of conditions remained the same until 2015's Act 241 added "post-traumatic stress disorder."

However, we believe that there is an abundance of evidence to demonstrate and substantiate the medicinal benefits of medical marijuana for certain conditions, including those in this bill.

As with any other medication, a patient has the opportunity to try the product and see if it produces positive results, and weigh that against any negative side-effects. In close collaboration with their physician who provided the certification, they can then make their own decision whether to continue or discontinue the use of medical marijuana.

III. TESTING FOR QUALIFIED PATIENTS AND CAREGIVERS

This language allows qualified patients and caregivers to test their marijuana or marijuana products at certified labs and allows for transport in limited circumstances. HEALTH supports this provision as we believe it will help eliminate barriers for qualified patients and caregivers and additional approaches that will help cultivate a competitive and stable laboratory marketplace.

IV. TRACKING SYSTEM

HEALTH **strongly support** HB1488's approach to create an alternative access and tracking system in the remote and hopefully unlikely event that the DOH's tracking system goes down or is inoperable. HEALTH will continue to work with DOH on an approach to ensure compliance with the computer tracking program on a reasonable timetable. However, HEALTH understands that there have been such difficulties in other states with tracking systems, and so we believe that it is important to learn from their experiences.

We recognize that the computer tracking system serves an important role in upholding and ensuring product, patient and public safety, but HEALTH also believes that this must be balanced against the patients' need to receive their medicine. It is our understanding that the alternative access system in this bill mirrors systems in other states like Connecticut, Washington, Illinois, Maine, Nevada, New Jersey, Rhode Island and Vermont where a patient is allowed to designate a dispensary to provide access to the products, which again, is only necessary IF THE SYSTEM GOES DOWN. If that even never occurs, this process never becomes necessary. Unfortunately, given our experiences thus far with the delays in the implementation of the DOH's tracking system, HEALTH supports having prudent proactive approach enacted now, through a pre-determined alternative system to track marijuana product sales. This will allow qualified patients to be able to continue to have their supply of medical marijuana uninterrupted during any shutdown of the initial system with a process that still has the necessary safeguards, and has worked in other states.

Based on the testimony in the prior committee, we understand that the Department of the Attorney General (AG) has concerns over this provision asserting that this alternative process could be viewed as undermining a "rigorous" regulatory system to track medical marijuana contrary to the U.S.

Department of Justice (DOJ) Memorandum for All United States Attorneys dated August 29, 2013 ("Cole memo"). [1]

The Cole memo provides guidance for state law enforcement to set certain broad parameters of public safety where it lessens the likelihood of federal prosecution. The Cole memo states "jurisdictions that have . . . also implemented strong and effective regulatory and enforcement systems . . . is less likely to threaten the federal priorities."

However, these are broad guidelines and there is no specific requirement for a "real-time" tracking system or one that prevents the state from enacting an alternative remedial solution in the event that the state tracking system is inoperable. Dispensaries must have their own tracking systems and are ultimately held liable to ensure that no qualified patient receives marijuana in excess of the statutory limits. Any dispensary that fails to have such safeguards in place, potentially may lose their license, or be subject to criminal penalties.

We therefore **support** the approach taken in HB1488 HD1, SD1 which permits but does not mandate an alternative tracking and access system. We believe this should help ameliorate the DOH's and the AG's concern since it would only be a possible, but already authorized approach for them to implement in the event the computer tracking system is inoperable.

V. LABORATORY TESTING

HEALTH **supports** the language to have the standards established in the interim rules for laboratory testing, be revised to ensure that there are some considerations of the implicated costs of the extensive testing that is mandated in no other jurisdiction.

Hawaii Administrative Rules (Interim Rules) Section 11-850-85, Laboratory standards and testing, requires testing of the tetrahydrocannabinol and cannabinol levels, and sets testing for levels for certain contaminants like metals, microbiologial impurities, moisture. But, the Interim Rules just require testing for:

> (B) Pesticides regulated by the U.S. Environmental Protection Agency: 1.0 ppm (part per million)

There are hundreds of pesticides registered with and regulated by the EPA under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA), which dates back

[1] https://www.justice.gov/iso/opa/resources/305201382913275685746 7.pdf

to 1947. Scientific and agriculture advances have obviously made certain pesticides obsolete in use and production, and while it may be possible to test for every pesticide basically ever known, there seems to be little basis to do so.

While HEALTH supports ensuring product and patient safety, such testing must be done with reasonable tolerance levels and scope. Other states with years of experience, like State of Oregon have implemented testing standards that are appropriate, practical and evidence-based. HEALTH believes that the State Department of Agriculture, which regulates are restricted use pesticides (RUPs) and is knowledgeable about which pesticides are more commonly used for pests in Hawaii, could provide insight, guidance and assistance. But, that could only be done if there is a mechanism alternative to testing "all pesticides" is provided for.

HEALTH supports finding a more balanced approach to testing because we are concerned that unreasonably strict and expansive testing standards will lead to unnecessarily high production costs which will result in unaffordable medical marijuana for patient use.

HEALTH's members are hopeful that in lieu of a legislative change, we can find some resolution via discussions with the DOH about the laboratory testing standards. This discussions are supposed to be scheduled shortly and so we hope to be able to report back favorable results.

However, there is one additional issue which we think does merit further consideration, and that is the administrative rules requirements for
Under HAR 11-850-85(j):

> A dispensary licensee shall destroy a batch that does not conform to the testing set forth in subsection (c) as indicated by the certificate of analysis.

HEALTH asserts that a dispensary should have an opportunity to cure a failed batch, or have the opportunity to re-configure the product for another use that can then be tested to meet the standards. This is an issue which we shall also be discussing with the DOH.

VI. VIDEO STORAGE

HEALTH **supports** changing the requirement for video storage periods since the current administrative rules on the requirements for video storage are extremely large, and it is our understanding that 365 days is over and beyond the requirements of any other jurisdiction which more commonly are at 30-45 days.

Attached, is a chart that shows the current requirements in AZ, NV, OR, CO, AK, WA, NY, IL, and Hawaii. We are unaware of any issues or problems with the 30-45 days in terms of criminal prosecution or any other needs for law enforcement.

The current 365-day requirement of stored video data, will not only likely affect the resolution quality of the video capable of being stored, more importantly, it will lead likely to significant infrastructure and administrative expenses increasing production costs and therefore, affecting patients' affordability.

Under the Department of Health's *Interim* Administrative Rules, Section 11-850-41(b): "[a] dispensary licensee shall retain for a minimum of one year all security recordings." The rules spell out the requirements for such security recordings under Section 11-850-51, including:

- Professionally installation
- 24-hour continuous video monitoring and recoding of all dispensary facilities
- back-up capability
- clearly displayed with time/date
- internet protocol compatible
- minimum resolution for a clear and certain identification of persons to include any area where products are produced, moved, stored, sold, packed/unpacked into containers for transport, surveillance storage areas, exists/entrances to indoor and outdoor locations
- secured in a lockbox, cabinet or closet to minimize access to tampering or theft

The required computerized tracking system in the law and rules will already ensure that marijuana and marijuana products are detailed and monitored from every seed to sale, or even possible disposal. Together with the video surveillance system referenced above, these safeguards will provide much needed security and safety at the dispensary facilities.

Therefore, we support changing the requirement for the duration of storage to 45 days since that mirrors that of other jurisdictions, and we are unaware of any issues or concerns arising out of this more common video storage duration requirement.

March 28, 2017

TO: Senator Gilbert S.C. Keith-Agaran, Chair, Committee on Judiciary and Labor
Senator Karl Rhoads, Vice Chair, Committee on Judiciary and Labor
Senator Jill Tokuda, Chair, Ways and Means Committee
Senator Donovan M. Dela Cruz, Vice Chair, Ways and Means Committee
Members of the Joint Committees of Judiciary and Labor & Ways and Means

FROM: Gregory Park, MD, Co-founder & Chief Compliance Officer, Maui Grown Therapies

Re: Testimony - **Support House Bill (HB) 1488, House Draft 1 (HD) 1, Senate Draft (SD)**

RELATING TO MEDICAL MARIJUANA
Amends the definition of "adequate supply" of marijuana to include seven marijuana seedlings. Amends the definition of "debilitating medical condition" to include lupus, epilepsy, multiple sclerosis, arthritis, and autism as conditions that qualify for the legal use of medical marijuana. Amends the definition of the term "transport" to allow qualified patients and primary caregivers to transport up to one gram of medical marijuana for laboratory testing under certain conditions. Limits each location used to cultivate marijuana to use by five qualifying patients. Authorizes primary caregivers to cultivate marijuana for qualifying patients until December 31, 2020. Adds considerations for establishing marijuana testing standards and selecting additional dispensary licensees. Allows DOH to consider whether existing dispensary licensees shall be allowed to increase plant count, increase the number of production centers, or increase the number of retail dispensing locations. Requires retention of video security recordings of production centers and dispensaries for 45 days. Extends civil service exemptions and interim rulemaking authority to 2020. Authorizes an alternate medical marijuana dispensary tracking system for use when the DOH computer tracking system in nonfunctional and requires DOH to report to the legislative oversight working group. Effective 7/1/2050.

Dear Chairs Keith-Agaran and Tokuda, Vice-Chairs Rhoads and Dela Cruz, and Members of the Committee:

Maui Wellness Group, DBA Maui Grown Therapies **supports** HB1488, HD1, SD1 because it helps to mitigate many of the challenges facing the emerging medical cannabis dispensary industry but more importantly, because it helps to ensure patient access to medicinal cannabis and helps to alleviate some of the Department of Health's administrative.

I. ADMINISTRATIVE ISSUES

We **support** the extension of deadlines for caregivers to ensure patients have adequate access to medical cannabis while dispensaries prepare for sales. Lengthy delays have prevented licensed dispensaries from opening in 2016 as originally envisioned. Even if the process proceeds smoothly from hereon, it is unlikely the first dispensaries will be operating before late

summer. The compassionate response is to extend certain deadlines under the original law, Act 241, Session Laws of Hawai'i 2015.

Furthermore, we **strongly support** DOH's request for greater flexibility in meeting patient demand in underserved areas in a timely manner by allowing existing licensees the ability to increase the number of retail dispensaries. We suggest the option to establish additional dispensaries be made available to licensees who have demonstrated a very high level of product safety and patient education at their initial dispensary locations. This will ensure only proven performers will the earn the privilege of expeditiously serving patients in new locations.

II. NEW CONDITIONS

We **strongly support** the addition of certain conditions such as lupus, epilepsy, multiple sclerosis, arthritis, and autism to qualify for the legal use of medical cannabis. As a physician, I have personally witnessed the medical benefits of cannabis in several of my patients, accompanied by an improved quality of life. In addition, there is an abundance of emerging peer-reviewed research that indicates cannabis is a highly effective therapy for multiple conditions and symptoms with no serious side effects.

III. LAB TESTING FOR QUALIFIED PATIENTS AND CAREGIVERS

This language allows qualified patients and caregivers to test their cannabis or derivative products at certified labs and allows for transport in limited circumstances. Our company **supports** this provision because it will enable qualified patients and caregivers to test their own products for composition and purity. The provision will also help to support a competitive and sustainable laboratory marketplace.

IV. TRACKING SYSTEM

We **strongly support** HB1488's provision to create an alternative access and tracking system in the unlikely event that the DOH's tracking system goes down or is inoperable. Other states have experienced temporary service disruptions in their tracking systems and Hawai'i can benefit from their experience by proactively planning for a contingency procedure.

The seed-to-sale tracking system helps to ensure product, patient and public safety, but we should also consider the personal difficulties that patients will face if they are unable to obtain their cannabis therapy when needed. As an oncologist, I have seen the distressing side effects of chemotherapy and the immediate relief that cannabis can provide to a suffering patient.

Other states provide for alternative access systems in the event of an inventory tracking system outage. Should DOH's tracking system fail, and a technical solution is not enacted in a timely manner, our patients will suffer the burden of this delay.

We **support** the approach taken in HB1488 HD1, SD1 that allows, but does not mandate, an alternative tracking and access system *only* in the event of an inventory software tracking system failure.

V. LABORATORY TESTING

Our company **supports** methodical review of the standards established in the interim rules for laboratory testing to ensure considerations of the implicated costs that would result from the extensive testing that is mandated in no other jurisdiction.

We fully understand and support mandatory lab testing to guarantee product and public safety. However, we also believe that Hawai ʻi can learn from other states with successful medical cannabis programs such as Oregon, which has established a lab testing regimen that balances the imperatives of patient & product safety. Oregon's standards are evidence-based and designed to be practicable for labs, which the existing Hawai'i rules are not. Ultimately, the cost of superfluous testing for "all pesticides" will be passed on to the patient, many of whom are already struggling with significant medical expenses.

We understand the reluctance to address this issue with legislation and we continue to work with the DOH to find a mutually agreeable solution. We also request further consideration of HAR 11-850-85(j) that states:

"A dispensary licensee shall destroy a batch that does not conform to the testing set forth in subsection (c) as indicated by the certificate of analysis."

We believe that a dispensary should have the opportunity to ameliorate a failed batch or retain an ability to re-configure the product for another use that can then be tested to meet the standards. This is an issue that we will continue to discuss with the DOH.

VI. VIDEO STORAGE

Although Maui Grown Therapies has the capability to meet the current requirements for video storage, we **support** changing the length of time from 365 days to a more reasonable 45-day period. No other jurisdiction requires video storage for one year. In the event of a security breach, video records are typically secured within 24-48 hours following the incident. Overlong storage requirement for video data is cumbersome, costly and unnecessary.

We appreciate your consideration of the provisions in HB1488 HD1, SD1.

Respectfully submitted,

Gregory Park, MD

From: mailinglist@capitol.hawaii.gov
To: JDLTestimony
Cc:
Subject: *Submitted testimony for HB1488 on Mar 30, 2017 09:50AM*
Date: Tuesday, March 28, 2017 10:04:32 PM

HB1488
Submitted on: 3/28/2017
Testimony for JDL/WAM on Mar 30, 2017 09:50AM in Conference Room 211

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

Comments:

Please note that testimony submitted less than 24 hours prior to the hearing, improperly identified, or directed to the incorrect office, may not be posted online or distributed to the committee prior to the convening of the public hearing.

Do not reply to this email. This inbox is not monitored. For assistance please email webmaster@capitol.hawaii.gov

Senate Committee on Judiciary and Labor
Senator Keith-Agaran (Chair), Senator Rhoads (Co-chair)
Senate Committee on Ways and Means
Senator Tokuda (Chair), Senator Dela Cruz (Co-chair)

Re: HB1488 HD1 SD1 - Relating to Medical Marijuana

From: Clifton Otto, MD (Support with changes)

Public decision making: 03-30-17 9:50AM in conference room 211.

(1) Amend the definition of "adequate supply":
What is the definition of a marijuana plant ? Of a seedling ?
Dispensaries have a plant definition, but patients do not.
Let's help our patients be compliant, not put them at risk of being subjected to random interpretation of the law.

(2) Amend the definition of "debilitating medical condition":
AMYOTROPHIC LATERAL SCLEROSIS (ALS)
PARKINSON'S DISEASE
ALZHEIMER'S DISEASE

(3) Amend the definition of the term "transport":
How can the intra-state transportation of medicine be restricted ?
That 's like saying you can't drive from LA to San Francisco with your medicine.
Let the DEA enforce the transportation of controlled substances through federal air space if they are so inclined.
BTW, one gram is not enough to perform all the required testing on even just one sample.
And where is the provision that allows patients to "transport" products from a Dispensary to their home ?

Section 4(a)(2):
Rather than try to infringe upon a patient's right to privacy, a better approach to controlling patient cultivation would be to hurry up and issue additional small scale Dispensary licenses based on horizontal production integration.
Time to stand up for the state-accepted medical use of marijuana in Hawaii.

From: mailinglist@capitol.hawaii.gov
To: JDLTestimony
Cc:
Subject: *Submitted testimony for HB1488 on Mar 30, 2017 09:50AM*
Date: Tuesday, March 28, 2017 8:57:27 AM

HB1488
Submitted on: 3/28/2017
Testimony for JDL/WAM on Mar 30, 2017 09:50AM in Conference Room 211

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

Comments:

Please note that testimony submitted less than 24 hours prior to the hearing, improperly identified, or directed to the incorrect office, may not be posted online or distributed to the committee prior to the convening of the public hearing.

Do not reply to this email. This inbox is not monitored. For assistance please email webmaster@capitol.hawaii.gov

From: Lynn Robinson-Onderko
To: JDLTestimony
Subject: Support for HB1488 HD1 SD1
Date: Wednesday, March 29, 2017 7:38:56 AM

Aloha Chair,
My name is Lynn Robinson-Onderko. I am a resident of Ewa Beach. I am writing in strong support for HB 1488 HD1 SD1. Please vote in favor of this measure so that patients with these debilitating diseases can get the medicine they need.
Mahalo for your time and attention. Lynn Robinson-Onderko

From: mailinglist@capitol.hawaii.gov
To: JDLTestimony
Cc: g
Subject: Submitted testimony for HB1488 on Mar 30, 2017 09:50AM
Date: Wednesday, March 29, 2017 9:53:40 AM

HB1488
Submitted on: 3/29/2017
Testimony for JDL/WAM on Mar 30, 2017 09:50AM in Conference Room 211

Submitted By	Organization	Testifier Position	Present at Hearing
Maddy Lum	Individual	Comments Only	No

Comments: To Whom It May Concern: Comments regarding HB1488, HD1, SD1. Your committees' consideration of laboratory testing protocol for dispensaries and patients medical cannabis should ideally include language that allows employees of certified laboratories to pickup, receive, and transport cannabis and cannabis products from dispensaries and patients. An amendment to DOH Administrative rules §11-850-36 could provide an answer to some of the confusion that has been brought up in recent public forums. Thank you for this opportunity. Respectfully, Madeline C. Lum

Please note that testimony submitted less than 24 hours prior to the hearing, improperly identified, or directed to the incorrect office, may not be posted online or distributed to the committee prior to the convening of the public hearing.

Do not reply to this email. This inbox is not monitored. For assistance please email webmaster@capitol.hawaii.gov

From: mailinglist@capitol.hawaii.gov
To: JDLTestimony
Cc:
Subject: *Submitted testimony for HB1488 on Mar 30, 2017 09:50AM*
Date: Sunday, March 26, 2017 2:06:40 PM

HB1488
Submitted on: 3/26/2017
Testimony for JDL/WAM on Mar 30, 2017 09:50AM in Conference Room 211

Submitted By	Organization	Testifier Position	Present at Hearing
Marilyn Mick	Individual	Support	No

Comments:

Please note that testimony submitted less than 24 hours prior to the hearing, improperly identified, or directed to the incorrect office, may not be posted online or distributed to the committee prior to the convening of the public hearing.

Do not reply to this email. This inbox is not monitored. For assistance please email webmaster@capitol.hawaii.gov

Ronald Cannarella

Honolulu, HI 96822

TESTIMONY before the Senate Ways and Means Committee and Senate Judiciary and Labor

TESTIMONY ON:
H.B. NO. 1488, HD1 SD1. RELATING TO MEDICAL MARIJUANA

DATE: Thursday, March 30, 2017 TIME: 9:30 a.m.
LOCATION: State Capitol, Room 211

Chairs Tokuda and Gill-Agaran and Members of Ways and Means Committee
and Judiciary and Labor

I am submitting this testimony in support of HB1488 HD1 SD1 on behalf of myself, a medical cannabis patient.

Today I am going to address only item number eight for this bill “Amend requirements for laboratory standards and testing to ensure product and patient safety at reasonable tolerance levels with reasonable cost implications.”

SUMMARY
Having reviewed previous versions of HB1488, I believe that the objective of item 8 was to address the problem of detecting pesticides in our medical Cannabis products, and to set tolerances for the tests to measure THC and CDBs. I am not qualified to speak to the protocols for THC and CDBs. But it seems to me that since Hawaii has no pesticide laws or regulations specific to use on Cannabis for human consumption, that the larger conversation would be; “How can we assure the consumer that our Cannabis supply is free from unsafe levels of pesticides”.

So I have reframed the question in a format that may be useful to Ways and Means and Judiciary committees.

I want to be as specific as possible, without submitting a textbook on toxicology, but that contains enough material here for your staff people to work with as soon as they can get to it, if that is the wish of the committees.

In light of all of the problems that Oregon, Washington and Colorado are having with high levels of pesticides in their Cannabis supplies, both patients and providers alike would be well served by addressing the issue of pesticides on Cannabis during this legislative session, before this first commercial crop is brought to market.

Because “You only have one chance to make a first impression.”

Hawaii is fortunate to be able to benefit from the experience of three medical marijuana states, Oregon, Washington and Colorado.

Contamination of Cannabis with high levels of harmful pesticides is turning out to be a much bigger problem than most people imagined. With the advent of testing labs, it seems that everywhere they look, the more they find. A few examples:

Roger Voelker, who is the scientific director of OG Analytical, a marijuana testing laboratory in Oregon, began to notice that a high percentage of Cannabis products he was examining were contaminated with pesticides that were not covered by Oregon’s Cannabis pesticide rules. From Oct. 15 to Dec. 31, 2016 more than half of the 154 concentrates, or oils that Voelker tested were tainted. (Source: The Oregonian: Marijuana - A special report. June 11, 2015. Accessed online March 29, 2017 at http://www.oregonlive.com/marijuana-legalization/pesticides/)

In 2016 a Berkeley laboratory found that 84% of the medical Cannabis samples contained large amounts of pesticides. “Problem of Cannabis Consumers” by Alicia Lozano in LA Weekly, March 27, 2016.

I found at least 10 different examples of this same problem. It seems that the more people look, the more they find. Just finding this stuff out is already a big side benefit of these state Cannabis industries.

A common thread running through all of these reports, is;
1. The states all regretfully neglected to develop regulations for pesticide use on Cannabis before the magnitude of the problem became known, and
2. When Cannabis products are recalled, it puts stress on everyone involved - growers, regulators, and most importantly, patients.

Example 1. In 2015 the State of Oregon instructed growers to quit using pesticides on their Cannabis. This move only frustrated growers who had become accustomed to using pesticides. Moreover, by banning pesticides at this late date did not solve the

problem as more growers turned a blind eye to some of the practices taking place in their greenhouses.

Example 2. Steve Wagner, who oversees the Oregon state medical marijuana dispensary program, said the Oregon Health Authority lacks the power to regulate medical marijuana producers or labs. Without it, he said, there is little the agency can do. (Source: The Oregonian: Marijuana - A special report. June 11, 2015. Accessed online March 29, 2017 at http://www.oregonlive.com/marijuana-legalization/pesticides/)

So, clearly it is in everyone's best interest to keep pesticides out of the Cannabis supply to begin with, and in order to do that, the states need the regulatory tools to manage pesticides.

But there's a Catch 22.

A brief review of Pesticides 101:

The Federal Insecticide Fungicide and Rodenticide Act (FIFRA) is the federal law that governs pesticide use in the United States, and the EPA is the main federal agency charged with implementing the law. All pesticides sold and used in the United States must be registered with the EPA. FIFRA sets forth how the EPA evaluates all pesticide in terms of toxicity, method of application, and route of exposure.

When a pesticide is brought to market, EPA requires an enormous amount of data before that product can be sold. During this Registration Process EPA informs a prospective registrant on the different number of studies required to develop the toxicological profile for the ingredient. The EPA then compiles all of the information about how a pesticide can he used, including on which crops it can be used on, and under which environmental conditions. All of that information is then used to create the label for that pesticide.

The "label" in this sense is much more than what you see on a bottle if mosquito repellant. A typical label for a common agricultural pesticide is usually from 25 to 30 pages. Single space. No pictures. Dense.

"THE LABEL IS THE LAW" Everyone using a pesticide is legally required to follow what is on the label. No exceptions. And more than that, for those pesticides that are labeled as "Restricted Use" Pesticides application of a pesticide can only be done under the supervision of a certified pesticide applicator.

Certification is not difficult or expensive. But it is crucial that the applicator knows how to read a label, how to mix, apply and clean up a pesticide, and how to avoid human exposure or exposure to non-target species.

FIFRA and EPA both act at the federal level. EPA scientists respond to many incidents where unacceptably high levels of pesticides are found in the food supply, water supplies and the environment in general. In mounting a pesticide response, state and local partners play a very active role as well.

Each state has its own pesticide law and set of regulations that are at least as stringent as the FIFRA rule.

If a state identifies a unique situation that calls for a specific pesticide in an “off-label” use, then the state may petition EPA for a Special Local Need (SLN) registration. The application for a SLN has a lot of the same information that is required for the federal registration use.

That is the fully legal way to go about regulating pesticides on cannabis. But developing a SLN permitted use is no small thing. It can take years, only to get denied. It is expensive. And the SLN must be requested by the registrant for that pesticide. Many times it is not worth their while to devote resources for a niche market.

All of what I have described so far is more clearly spelled out in a letter with appendix that was prepared by EPA at the request of the State of Colorado, specifically with respect to pesticides on Cannabis. (“Special Local Needs Registration for pesticide uses for legal marijuana production in Colorado” From Jack E. Housenger (EPA) to Mitchell Yergert (Colorado Dept. of Agriculture), May 19 2015.)

Shortly thereafter,on November 12, 2015 the governor issued Executive Order D2015-015. That EO directed state agencies to address the problems caused by contaminated Cannabis. Unfortunately for Colorado the problems caused by adulterated Cannabis were only going to get worse.

The next step was when the Colorado Dept.of Agriculture developed the background document; “Factual and Policy Issues Related to the Use of Pesticides in Colorado” (Undated, Attached) and the Colorado Department of Agriculture Pesticide Applicators’ Act, Rules and Regulations. (March 30, 2016, Attached)

Note how simple the pesticide act is - a mere two pages. Note, there are no quantities or label uses in the Act. These are handled by regulations pursuant to the Act.

Finally, Colorado and Oregon have also produced their lists of pesticides that can be used on Cannabis in their states. The lists contain several hundred pesticides. (Too long for inclusion here). The states have also begun to develop lists of pesticides that should not be used.

To that end, I have included a copy of Colorado's Department of Agriculture Pesticide Applicators' Act. Effective March 30, 2017. Simple two page document, but one that would not only give our consumers greater peace of mind, it also provides guidance to an industry that is just figuring out its best practices. Hopefully, growers will be able to select for those traits suited to our growing conditions, diseases and pests, and consumer demand.

My final point is that Cannabis will soon be one of Hawaii's most valuable crops, and it should be treated as so by State government. Hopefully, the Department of Agriculture and UH College of Tropical Agriculture and Human Resources (CTAHR) are being consulted as this industry grows.

CONCLUSION
"You only have one opportunity to make a first impression."

This is a once in a lifetime opportunity for Hawaii to develop a world class medical Cannabis industry, and that we can all get ahead of the problem with unregulated pesticides, and well, regulate them. And whatever one may think about the use of pesticides on marijuana, if the legislature lays out their policy, then growers will know what pesticides they have at their disposal. Moreover, all of the people who consume Hawaiian Cannabis will have confidence that their product is safe.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Mr. Mitchell Yergert, Director
Division of Plant Industry
Colorado Department of Agriculture
305 Interlocken Parkway
Broomfield, Colorado 80021

MAY 19 2015

Subject: Special Local Needs Registration for pesticide uses for legal marijuana production in Colorado

Dear Mr. Yergert:

Thank you for your inquiry regarding the utilization of Special Local Need (SLN) registrations of pesticides under FIFRA section 24(c) for use on cannabis. As you are aware, EPA's regulations, 40 CFR 162.152(a)(4), state that any SLN registration must be in accord with the purposes of FIFRA, which authorizes the registration of a pesticide only on a finding that it will not lead to "unreasonable adverse effects on the environment." In order to facilitate this finding, EPA strongly encourages a State to pursue SLN authorizations only where a federally registered pesticide is approved for use(s) similar to the manner in which the SLN pesticide would be used. EPA expects that a showing of such similarity would provide the best support for making the necessary determinations. Given our understanding of how cannabis is cultivated and the intended way cannabis plant materials may be consumed by humans, we anticipate that a federally registered pesticide would be regarded as having similar use patterns if the federally registered pesticide is approved for use:

1. on food (in order to have a complete toxicity database to evaluate the potential toxicity of acute, short-term, intermediate, and chronic exposure);
2. on tobacco (in order to have a pyrolysis study to determine the breakdown products formed when the treated plant material is burned);
3. by the same type(s) of application methods (in order to assess the exposure of workers who mix, load, and apply the pesticides);
4. on crops with agronomic characteristics similar to cannabis (in order to adequately protect workers reentering areas following application of the pesticide); and
5. in the same kind of structure (e.g., greenhouses/shadehouses) or on the same kind of site (e.g., outdoor dryland site) as the proposed SLN use (in order to ensure that workers handling the pesticide are adequately protected when applying the pesticide – for example, ensuring that the adequate personal protective equipment is required – and that the environmental fate and effects of the SLN use are adequately understood and that any appropriate measures are in place to protect non-target organisms and water resources).

In addition, EPA encourages the State to consider pesticides for which the agency's aggregate and cumulative risk assessment indicate that some modest additional exposure would not approach a risk of concern, i.e., that there is "room in the human health risk cup."

If the State decides to pursue a SLN registration for use of a pesticide on cannabis, it could meet its responsibility for showing that a proposed SLN registration would be appropriate by identifying a federally registered pesticide with similar use(s) and relying on the agency's most recent risk assessments showing that the pesticide meets the no "unreasonable adverse effects on the environment" standard. In addition, please be certain that any submission contains the information described in 40 CFR part 162 and characterized at the following website: http://www.epa.gov/opprd001/24c/. Like other SLN registrations, the State would need to submit a full label that describes the use pattern and associated mitigation for protecting human health and the environment.

EPA agrees with the State's assessment that pesticides considered for an SLN use on cannabis should have an appropriate dataset for use in assessing the potential for use of the pesticide and for residues on treated plant material to cause human health and environmental risks. In the event that the State cannot identify a federally registered pesticide with use(s) similar to the proposed SLN use, EPA would expect the requesting State to take responsibility for providing information and analysis to support the SLN registration for cannabis. To aid the State in preparing these assessments, an overview of the human and ecological risk assessment methodologies used by the Office of Pesticide Programs (OPP) is presented in the attachment. OPP is available to provide further guidance or answer any questions as to how to ensure the safety of a use under an SLN on cannabis.

Sincerely,

Jack E. Housenger, Director
Office of Pesticide Programs

Attachment

cc: Mr. John Scott, Pesticides Section Chief, Colorado Department of Agriculture
Ms. Laura Quakenbush, Pesticide Registration Coordinator, Colorado Department of Agriculture
Mr. Eric Johansen, Washington State Department of Agriculture
Ms. Melanie Wood, Division Director, Pesticides Program, EPA Region 8
Ms. Jennifer Schuller, Pesticides Team Leader, EPA Region 8
Ms. Rebecca Perrin, Agriculture Advisor, EPA Region 8
Mr. Ed Kowalski, Division Director, Pesticides Program, EPA Region 10
Ms. Kelly McFadden, Section Chief, Pesticides Program, EPA Region 10

ATTACHMENT

The following sections describe how EPA assesses the risks to human health and the environment resulting from use of pesticides.

I. HUMAN HEALTH ASSESSMENT

OPP evaluates pesticide chemicals prior to registration, and reevaluates older pesticides already on the market, to ensure that they can be used without causing unreasonable adverse effects on the environment. OPP employs the National Research Council's four-step process for human health risk assessment: hazard assessment; exposure assessment; risk characterization; and risk assessment. Details are available at http://www.epa.gov/pesticides/factsheets/riskassess.htm

1. Hazard Assessment

In evaluating toxicity or hazard, OPP reviews toxicity data, typically from studies with laboratory animals, to identify any adverse effects on the test animals. Where available and appropriate, OPP will also take into account studies involving humans, including human epidemiological studies. An extensive battery of toxicological studies are required for full pesticide registration. Toxicology data requirements are described in 40 CFR §158 subpart F http://www.epa.gov/ocspp/pubs/frs/home/guidelin.htm. Toxicology data requirements for a food-use chemical are presented in Table 1.

Once a pesticide's potential hazards are identified, OPP determines a toxicological endpoint of concern for evaluating the risk posed by human exposure to the pesticide. Two critical parts of this evaluation involve identification of a quantitative dose level(s) from these studies to be used in assessing the pesticide's safety to humans, referred to as the Point of Departure (POD), and selection of appropriate uncertainty/safety factors for translating the results of toxicity studies in relatively small groups of animals or humans to the overall human population, including major identifiable subgroups of consumers.

A POD is the dose serving as the 'starting point' in extrapolating a risk to the human population. The POD can be a no observed adverse effect level (NOAEL), the lowest-observed adverse effect level (LOAEL) or an extrapolated benchmark dose (BMD). For details refer to http://www.epa.gov/raf/publications/pdfs/rfd-final.pdf.

For threshold effects, risk assessments are normally conducted using the Reference Dose (RfD) approach. The RfD is calculated by dividing the POD by the appropriate uncertainty/safety factors. OPP's safety/uncertainty factor practice with regard to pesticides was altered to a degree by the Food Quality Protection Act (FQPA). FQPA requires EPA to use an additional safety factor of 10X to protect infants and children, unless EPA determines, based on reliable data, that use of another safety factor would protect infants and children. For pesticides, a Population Adjusted Dose (PAD) is derived by dividing the RfD by the FQPA Safety Factor. For complete details, refer to http://www.epa.gov/pesticides/trac/science/determ.pdf. An example of the toxicity endpoint selection is presented in Table 2.

For compounds causing non-threshold effects, such as carcinogens, an RfD approach is not used. Instead, a cancer risk assessment is conducted which provides an estimate (expressed as a probability) of the excess cancer risk resulting from exposure to a pesticide chemical. http://www.epa.gov/raf/publications/pdfs/

As an unreasonable adverse effects finding is developed for any prospective SLN, EPA encourages you to use the assessment endpoints that have been identified by EPA for that chemical.

2. Dietary Exposure Assessment

Acute, chronic, and cancer dietary exposure and risk assessments are conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID). This software uses 2003-2008 food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). The Agency is in the process of transitioning from the 2003-2008 NHANES/WWEIA consumption data to the 2005-2010 NHANES/WWEIA consumption data. The DEEM model that incorporates the 2005-2010 consumption data can be downloaded from http://www.epa.gov/pesticides/science/deem/

Generally, it would not be expected that the requesting State would have the residue and consumption data needed to perform a quantitative assessment of oral exposure for a SLN on cannabis. In the absence of such data, however, the State could estimate potential dietary exposure by making reasonable assumptions about high end consumption and residue levels. In addition, the State's risk assessment should address, at least qualitatively, why the additional exposure from the use of SLN on cannabis would not result in exposure exceeding the remaining room in the "human health risk cup." We expect that such an assessment will be more straight-forward if the active ingredient being proposed for the SLN registration has ample room in the risk cup for the new use.

3. Occupational and Residential Exposure Assessment

Occupational and residential exposure data requirements are described in 40 CFR part 158 subpart H available at http://www.epa.gov/ocspp/pubs/frs/publications/Test_Guidelines/series875.htm

In general, the data needed for a human health risk assessment for an agricultural crop, outdoor residential use, and a greenhouse use are similar; however, the exposure scenarios assessed may differ. A typical exposure assessment is divided into two parts. The handler assessment addresses potential exposure from the individuals who mix, load, and apply a pesticide, and the post-application assessment addresses the potential exposure of individuals who enter into previously treated areas and engage in activities that bring them into contact with pesticide residues. An overview of the residential human health risk assessment methodology and corresponding data for the various residential handler and post-application scenarios can be found at http://www.epa.gov/pesticides/science/residential-exposure-sop.html.

Occupational handler scenarios are assessed for the dermal and inhalation exposure pathways. (http://www.epa.gov/pesticides/science/handler-exposure-data.html) OPP uses non-chemical specific unit exposures and information from the labels about application type, site, formulation, rates, and personal protective equipment (PPE) to define each scenario. The resulting risk estimates from the handler assessment inform the risk management decisions on whether additional PPE requirements or other mitigation measures are necessary. PPE requirements on the label also fall under the Worker Protection Standard (WPS) related to the acute toxicity of the end-use product.

The occupational post-application scenarios are assessed for the dermal exposure pathway. OPP uses non-chemical specific transfer coefficients to capture the potential dermal exposure from different crop and activity combinations (http://www.epa.gov/opp00001/science/post-app-exposure-data.html).

OPP also uses chemical-specific data to inform the potential pesticide residue that is available on a foliar surface after an application; these data are referred to as dislodgeable foliar residue (DFR) and turf transferable residue (TTR) studies. When these data are not available, OPP currently uses default assumptions of 25% for DFR and 1% and 0.2% for TTR for the liquid and granular formulations, respectively. The post-application risk estimates determine how many days after treatment an individual may safely reenter the treated area for routine post-application activities. The more protective Restricted Entry Interval value is typically required on the labels. In addition, specifically for greenhouse uses, the WPS provides information on proper ventilation requirements to protect workers from post-application inhalation exposure.

If the pesticide proposed for a SLN use has no federally registered indoor uses, the State should specifically address whether handlers applying the pesticide indoors or others who would contact the pesticide treated plants would be adequately protected without additional PPE, and if not, what additional PPE would be needed to prevent unacceptable exposures from the anticipated application and post-application scenarios.

4. Risk Characterization and Risk Assessment

(i) Dietary Exposure Risk Assessment

The State's risk assessment should provide a general characterization of risk for the general population and should take into account both potential acute and chronic exposures.

(ii) Occupational Exposure Risk Assessment

- Occupational Handlers

In this section, the State's risk assessment should identify the occupational handler exposure scenarios based on the proposed use (list representative scenarios only). Briefly describe the data sources used such as an existing EPA risk assessment or, if a new assessment is being conducted, PHED, biomonitoring studies, or chemical specific data. Summarize the risks assessed. If there are no risks at baseline PPE, simply state the lowest Margin of Exposures (MOEs). If there are scenarios with risks of concern at baseline and additional personal protective equipment (PPE) will be needed to

achieve MOEs greater than the level of concern (LOC), summarize the MOEs at different PPE levels. The summary can be in tabular or paragraph form. As noted earlier, we encourage the State to use existing risk assessments to prepare this information.

- Occupational Post-Application

In this section, identify the occupational post application exposure scenarios based on the proposed use in a general manner. Briefly describe the data sources used such as an existing EPA risk assessment or, if a new assessment is being conducted, biomonitoring studies or chemical-specific data. Indicate whether or not dislodgeable foliar residue (DFR) studies are available. Indicate whether or not the most recent transfer coefficients were used to determine post-application exposure and risk. Summarize the scenarios with risks of concern, and provide a summary of the MOEs. Data can be in tabular or text form.

- Inhalation Exposure Assessment

It is OPP's policy to assess risk following short-term exposure to pesticide residues in tobacco products as the chronic health effects from tobacco use are well documented. OPP uses data from a pyrolysis study (Test Guideline 860.1000) and a magnitude of residue study (Test Guideline 860.1500) for this assessment. This assessment assumes: (1) 100% of the inhaled residue is absorbed; (2) the average U.S. smoker smokes 15 cigarettes per day (Pierce, J. P., *et al.* (1989), Tobacco use in 1986 – Methods and Basic Tabulations from Adult Use of Tobacco Survey, U.S. Dept. of Health and Human Services Publication Number OM90-2004, Office on Smoking and Health, Rockville, Maryland); (3) 1 gram of tobacco per cigarette; and (4) male/female body weight of 70/60 Kg. The POD established for short-term exposure is used to derive a MOE for expressing risk via this exposure scenario. If there is no federally registered tobacco use of the proposed SLN pesticide, the State's risk assessment should assess the potential acute risk from inhaling residues from smoking treated plant material; the assessment should use the above assumptions or justify the use of different assumptions.

II. ECOLOGICAL EFFECTS AND ENVIRONMENTAL FATE

In general, the types of data used to support an ecological risk assessment for a SLN pesticide registration should be comparable to the ecological effects and environmental fate data required for a Section 3 pesticide registration (see 40 CFR part158, subpart G and subpart N). Note the data requirements for outdoor terrestrial uses and greenhouse/indoor uses are substantially different in regards to the number and types of studies required for registration. Outdoor terrestrial uses are also subject to the data requirements for pollinators (see Guidance for Assessing Pesticide Risks to Bees). Tables 3 and 4 provide an overview of the data requirements for ecological effects and environmental fate respectively. An overview of the ecological risk assessment framework and supporting documentation can be found at: http://www.epa.gov/oppefed1/ecorisk_ders/.

The ecological risk assessment should consist of a problem formulation, an analysis characterizing the exposure and effects of the chemical stressor and a risk characterization.

1. Problem Formulation

Problem formulation provides the foundation for the ecological risk assessment. It is an iterative process for generating hypotheses concerning whether ecological effects could occur from human activities. The problem formulation articulates the purpose and objectives of the risk assessment and defines the problem and regulatory action. The quality of the assessment depends on rigorous development of the following products of problem formulation: 1) assessment endpoints that reflect management goals and the ecosystem they represent; 2) conceptual model(s) that represents predicted key relationships between stressor(s) and assessment endpoint(s); and 3) a plan for analyzing the risk.

2. Analysis of Exposure and Effects

For a pesticide risk assessment, the exposure characterization describes the potential or actual contact of a pesticide with a plant, animal, or media. The objective is to describe exposure in terms of intensity, space, and time and to describe the exposure pathway(s). A complete picture of how, when, and where exposure occurs or has occurred is developed by evaluating sources and releases of the pesticide, distribution of the pesticide in the environment, and extent and pattern of contact with the pesticide.

For greenhouse/indoor uses there are several factors the State will need to consider. First there is a difference between a greenhouse and a shadehouse. A greenhouse is defined as "operations that produce agricultural plants indoors in an area that is enclosed with nonporous covering and that is large enough to allow a person to enter." Shadehouses are defined as "a roof made of fencing or fabric to provide shade on plants (no walls)." Growing operations in a shadehouses are typically considered an outdoor terrestrial use.

The other factor to consider in the risk assessment for greenhouse/indoor use is the potential for "Down the Drain" release to publically owned treatment works or in some cases direct discharge to the environment. The "Down the Drain" assessment accounts for the normal use of a pesticide in a greenhouse, not the illegal disposal of a pesticide.

An ecological effects characterization describes how toxic a pesticide is to different organisms and/or to other ecological entities (e.g., community), what effects it produces, how the effects relate to the assessment endpoints, and how these effects change with varying levels of pesticide exposure. This characterization is based on a stressor-response profile that describes how toxic a pesticide is to various plants and animals, the cause-and-effect relationships, how fast the organism(s) recovers, relationships between the assessment endpoints and measures of effect, and the uncertainties and assumptions associated with the analysis. The stressor-response profile is the final product of the ecological effects characterization.

3. Risk Characterization

The risk characterization integrates the analyses from the exposure characterization and ecological effects characterization; describes the uncertainties, assumptions, and strengths and limitations of the analyses; and synthesizes the overall conclusion about risk that is used by risk managers in making risk management decisions.

Risk characterization has two major components: risk estimation and risk description. Risk estimation compares exposure and effects data, considers integrated exposure and effects data in context of Levels of Concern (LOCs), and states the potential for risk. The risk description interprets risks based on assessment endpoints. In interpreting the risk, the risk assessor evaluates the lines of evidence supporting or refuting risk estimates in terms of the following factors: adequacy and quality of data; degree and type of uncertainty; and the relationship of evidence to risk assessment questions.

As noted above for the human health risk assessment, EPA encourages the State to consider and use EPA's existing ecological risk assessments, where appropriate, to assess the environmental fate and ecological effects of any proposed SLN on cannabis.

Table 1. Toxicology Data Requirements

The requirements (40 CFR 158.340) for a typical food-use chemical are listed below:

Study Type		Requirement
870.1100	Acute Oral Toxicity	yes
870.1200	Acute Dermal Toxicity	yes
870.1300	Acute Inhalation Toxicity	yes
870.2400	Primary Eye Irritation	yes
870.2500	Primary Dermal Irritation	yes
870.2600	Dermal Sensitization	yes
870.3100	Oral Subchronic (rodent)	yes
870.3150	Oral Subchronic (nonrodent)	yes
870.3200	21-Day Dermal	yes
870.3250	90-Day Dermal	No
870.3465	90-Day Inhalation	**CR**
870.3700a	Developmental Toxicity (rodent)	yes
870.3700b	Developmental Toxicity (nonrodent)	yes
870.3800	Reproduction toxicity	yes
870.4100a	Chronic Toxicity (rodent)	yes
870.4100b	Chronic Toxicity (nonrodent)	yes
870.4200a	Carcinogenicity (rat)	yes
870.4200b	Carcinogenicity (mouse)	yes
870.4300	Combined chronic toxicity/carcinogenicity	yes
870.5100	Mutagenicity—Gene Mutation - bacterial	yes
870.5300	Mutagenicity—Gene Mutation - mammalian	yes
870.5xxx	Mutagenicity—Structural Chromosomal Aberrations	yes
870.5xxx	Mutagenicity—Other Genotoxic Effects	yes
870.6100a	Acute Delayed Neurotoxicity (hen)	no
870.6100b	90-Day Neurotoxicity (hen)	no
870.6200a	Acute Neurotoxicity Screening Battery (rat)	yes
870.6200b	90-Day Neurotoxicity Screening Battery (rat)	yes
870.6300	Develop. Neurotoxicity	**CR**
870.7485	General Metabolism	yes
870.7600	Dermal Penetration	yes
870.7800	Immunotoxicity	yes

CR= Conditionally Required. See footnotes in Part 158 Table.

Table 2. Summary of Points of Departure and Toxicity Endpoints Used in Human Risk Assessment

Summary of Toxicological Doses and Endpoints for [Chemical] for Use in Dietary and Non-Occupational Human Health Risk Assessments				
Exposure/ Scenario	**Point of Departure**	**Uncertainty/FQPA Safety Factors**	**RfD, PAD, Level of Concern for Risk Assessment**	**Study and Toxicological Effects**
Acute Dietary (General Population, including Infants and Children)	NOAEL= [ ] mg/kg/day	UF_A= [ ]x UF_H=[ ]x FQPA SF= [ ]x	Acute RfD = [ ] mg/kg/day aPAD =[ ] mg/kg/day	[insert study name] LOAEL = [ ] mg/kg/day based on [ ]
Acute Dietary (Females 13-49 years of age)	NOAEL = [ ] mg/kg/day	UF_A= [ ]x UF_H=[ ]x FQPA SF= [ ]x	Acute RfD = [ ] mg/kg/day	[insert study name] LOAEL = [ ] mg/kg/day based on [ ]
Chronic Dietary (All Populations)	NOAEL= [ ] mg/kg/day	UF_A= [ ]x UF_H=[ ]x FQPA SF= [ ]x	Chronic RfD = [ ] mg/kg/day cPAD = [ ] mg/kg/day	[insert study name] LOAEL = [ ] mg/kg/day based on [ ]
Incidental Oral Short-Term (1-30 days)	NOAEL= [ ] mg/kg/day	UF_A= [ ]x UF_H=[ ]x	Residential LOC for MOE = [ ]	[insert study name] LOAEL = [ ] mg/kg/day based on [ ]
Incidental Oral Intermediate-Term (1-6 months)	NOAEL= [ ] mg/kg/day	UF_A= [ ]x UF_H=[ ]x FQPA SF= [ ]x	Residential LOC for MOE = [ ]	[insert study name] LOAEL = [ ] mg/kg/day based on [ ]
Dermal Short-Term (1-30 days)	NOAEL= [ ] mg/kg/day	UF_A= [ ]x UF_H=[ ]x FQPA SF= [ ]x	Residential LOC for MOE = [ ]	[insert study name] LOAEL = [ ] mg/kg/day based on [ ]
Dermal Intermediate-Term (1-6 months)	NOAEL= [ ] mg/kg/day	UF_A= [ ]x UF_H=[ ]x FQPA SF= [ ]x	Residential LOC for MOE = [ ]	[insert study name] LOAEL = [ ] mg/kg/day based on [ ]
Inhalation Short-Term (1-30 days)	NOAEL= [ ] mg/kg/day	UF_A= [ ]x UF_H=[ ]x FQPA SF= [ ]x	Residential LOC for MOE = [ ]	[insert study name] LOAEL = [ ] mg/kg/day based on [ ]
Inhalation Intermediate-Term (1-6 months)	NOAEL= [ ] mg/kg/day	UF_A= [ ]x UF_H=[ ]x FQPA SF= [ ]x	Residential LOC for MOE = [ ]	[insert study name] LOAEL = [ ] mg/kg/day based on [ ]

Summary of Toxicological Doses and Endpoints for [Chemical] for Use in Dietary and Non-Occupational Human Health Risk Assessments				
Exposure/ Scenario	**Point of Departure**	**Uncertainty/FQPA Safety Factors**	**RfD, PAD, Level of Concern for Risk Assessment**	**Study and Toxicological Effects**
Cancer (oral, dermal, inhalation)	Classification: This should be consistent with section 4.5.3 and the CARC document.			

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. UF_S = use of a short-term study for long-term risk assessment. UF_{DB} = to account for the absence of key data (i.e., lack of a critical study). FQPA SF = FQPA Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern. N/A = not applicable.

Summary of Toxicological Doses and Endpoints for [*Chemical*] for Use in Occupational Human Health Risk Assessments				
Exposure/ Scenario	**Point of Departure**	**Uncertainty Factors**	**Level of Concern for Risk Assessment**	**Study and Toxicological Effects**
Dermal Short-Term (1-30 days)	NOAEL= [ ] mg/kg/day	UF_A=10x UF_H=10x	Occupational LOC for MOE = [ ]	[insert study name] LOAEL = [ ] mg/kg/day based on [ ]
Dermal Intermediate-Term (1-6 months)	NOAEL= [ ] mg/kg/day	UF_A=10x UF_H=10x	Occupational LOC for MOE = [ ]	[insert study name] LOAEL = [ ] mg/kg/day based on [ ]
Inhalation Short-Term (1-30 days)	NOAEL= [ ] mg/kg/day	UF_A=10x UF_H=10x	Occupational LOC for MOE = [ ]	[insert study name] LOAEL = [ ] mg/kg/day based on [ ]
Inhalation Intermediate-term (1-6 months)	NOAEL= [ ] mg/kg/day	UF_A=10x UF_H=10x	Occupational LOC for MOE = [ ]	[insert study name] LOAEL = [ ] mg/kg/day based on [ ]
Cancer (oral, dermal, inhalation)	Classification: This should be consistent with section 4.5.3 and the CARC document.			

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. UF_S = use of a short-term study for long-term risk assessment. UF_{DB} = to account for the absence of key data (i.e., lack of a critical study). MOE = margin of exposure. LOC = level of concern. N/A = not applicable.

Table 3. Ecotoxicology Studies[1]

Guideline	Study Type	Comments
850.2100	Avian acute oral	Data required for a passerine species and either a waterfowl or upland game species
850.2200	Avian sub-acute dietary	Data required for a waterfowl and upland game species
850.2300	Avian reproduction study	Data required for a waterfowl and upland game species
850.1075	Acute freshwater fish	Data required for a cold water species and a warm water species
850.1075	Acute estuarine/marine fish	
850.1010	Acute freshwater invertebrates	
850.1025 850.1035 850.1045 850.1055	Acute toxicity to estuarine/marine invertebrates	Data required for one mollusk and one invertebrate
850.1300	Chronic freshwater invertebrate	
850.1350	Chronic estuarine/marine invertebrate	Conditionally required depending on exposure and toxicity (see CFR 158 for more details)
850.1400 or 850.1500	Chronic freshwater fish	
850.1400 or 850.1500	Chronic estuarine/marine fish	Conditionally required depending on exposure and toxicity (see CFR 158 for more details)
850.1735	Acute sediment toxicity to freshwater benthic organisms	Conditionally required depending on the physical properties of the chemical and toxicity to non-benthic organisms (see CFR 158 for more details)
850.1740	Acute sediment toxicity to estuarine/marine benthic organisms	Conditionally required if chemical is applied directly to estuarine/marine water bodies or expected to enter them in significant amounts. Also depends depending on the physical properties of the chemical and toxicity to non-benthic organisms (see CFR 158 for more details)
Non-guideline	Chronic sediment toxicity	Conditionally required depending on the physical properties of the chemical and toxicity to non-benthic organisms (see CFR 158 for more details)
850.3020	Acute contact toxicity to honeybee	
OECD 213	Acute oral toxicity to adult honeybee	Pollinator Guidance Document requirement (not in CFR 158)
Non-guideline	Subchronic 10-day toxicity to adult honeybees	Pollinator Guidance Document requirement (not in CFR 158)

[1] With the exception of non-guideline data requirements, the studies listed in this table were compiled from tables in the CFR "Terrestrial and aquatic nontarget organisms data requirements table" in 40 CFR §158.630 and "Nontarget plant protection data requirements table" in 40 CFR §158.660. Please see the CFR for the full tables, all applicable footnotes, and several additional studies which are not typically required but may be required in specific instances.

Guideline	Study Type	Comments
Non-guideline	Acute and chronic larval honeybee toxicity	Pollinator Guidance Document requirement (not in CFR 158)
Non-guideline	Pesticide residues in pollen and nectar	Conditionally required if honeybee concerns are identified from the laboratory tests. Pollinator Guidance Document requirement (not in CFR 158)
850.3040	Field testing for pollinators	Conditionally required if honeybee concerns are identified from the laboratory tests.
850.4100	Seedling emergence	
850.4150	Vegetative vigor	
850.4400	Vascular aquatic plant testing	
850.4500	Non-vascular aquatic plant testing	Testing is required for one freshwater algal species, freshwater diatom, and estuarine/marine diatom
850.4550	Cyanobacteria toxicity	
870.1100	Acute mammalian oral toxicity	
870.3800	Two-generation rat reproduction study	

Table 4. Environmental Fate Studies[2]

Guideline	Study Type	Comments
835.2120	Hydrolysis	
835.2240	Photodegradation in water	
835.2410	Photodegradation in soil	
835.2370	Photodegradation in air	Conditionally required for terrestrial and greenhouse use patterns depending on Henry's law constant and other chemical factors. (See CFR 158 for more details.)
835.4100	Aerobic soil metabolism	
835.4200	Anaerobic soil metabolism	
835.4300	Aerobic aquatic metabolism	
835.4400	Anaerobic aquatic metabolism	
835.1230 835.1240	Leaching and adsorption / desorption	
835.1410	Volatility – laboratory	Conditionally required. (See CFR 158 for more details.)
835.8100	Volatility - field	Conditionally required. (See CFR 158 for more details.)
835.6100	Terrestrial field dissipation	
835.6200	Aquatic field dissipation	Conditionally required. (See CFR 158 for more details.)
835.7100	Ground water monitoring	Conditionally required. (See CFR 158 for more details.)

[2] The studies listed in this table were compiled from the "Environmental fate data requirements table" in 40 CFR §158.1300. Please see the CFR for the full table, all applicable footnotes, and several additional studies which are not typically required but may be required in specific instances.

STATE OF COLORADO

OFFICE OF THE GOVERNOR

136 State Capitol
Denver, Colorado 80203
Phone (303) 866-2471
Fax (303) 866-2003

John W. Hickenlooper
Governor

D 2015-015

EXECUTIVE ORDER

Directing State Agencies to Address Threats to Public Safety Posed by Marijuana Contaminated by Pesticide

Pursuant to the authority vested in the Governor of the State of Colorado, and in particular, pursuant to Article IV, Section 2 of the Colorado Constitution, I, John W. Hickenlooper, Governor of the State of Colorado, hereby issue this Executive Order directing state agencies to address threats to public safety posed by marijuana contaminated by pesticide.

I. Background and Purpose

Pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act, the Environmental Protection Agency (the "EPA") regulates pesticides that are sold and distributed in the United States. Before a pesticide can be distributed, the EPA performs a comprehensive scientific risk assessment of the product. The EPA's evaluations are conducted to prevent potential harm to humans, wildlife, and the environment. The EPA also evaluates and approves the language that appears on each pesticide label to ensure safe use of the product.

Because marijuana remains a schedule 1 narcotic under the Controlled Substances Act, the EPA has neither assessed the potential health hazards posed by treating marijuana with pesticides, nor has it authorized the application of any pesticide specifically for use on marijuana.

The State of Colorado regulates pesticide use pursuant to the Colorado Pesticide Applicators' Act and rules promulgated under the Act. It is a violation of state and federal law to use pesticides in a manner that is inconsistent with the EPA's label directions or otherwise unsafe. When a pesticide is applied to a crop in a manner that is inconsistent with the pesticide's label (an "Off-Label Pesticide"), and the crop is contaminated by that pesticide, it constitutes a threat to the public safety.

Until scientific assessment establishes which additional pesticides can be safely applied to marijuana, marijuana contaminated by an Off-Label Pesticide shall constitute a threat to the public safety.

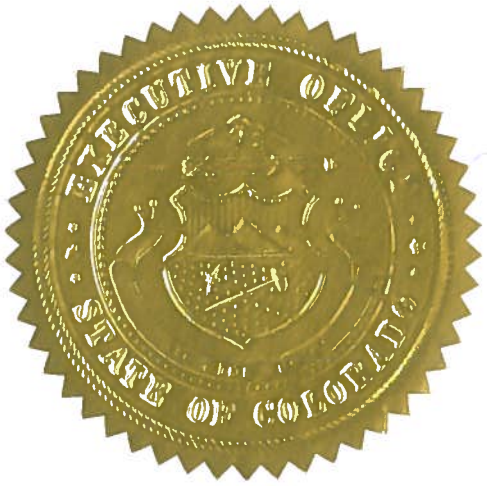
II. Declaration and Directives

1. The Colorado Department of Health and Environment ("CDPHE") shall hereby deem all marijuana contaminated by an Off-Label Pesticide a risk to public health, and the Department of Revenue is authorized to find such contaminated marijuana a threat to public safety.

2. Several executive branch agencies, including CDPHE, the Colorado Department of Agriculture ("CDA") and the Colorado Department of Revenue ("DOR") are statutorily charged with executing state policy governing cultivation and sale of marijuana. These agencies are hereby directed to utilize all existing investigatory and enforcement authorities established by law to protect against threats to the public safety posed by contaminated marijuana including, but not limited to, placing contaminated marijuana on administrative hold and destroying contaminated marijuana pursuant to existing law.

III. Duration

This Executive Order shall remain in full force and effect until amended or rescinded by further executive order or otherwise superseded by Colorado law.



GIVEN under my hand and the Executive Seal of the State of Colorado this 12th day of November, 2015.

John W. Hickenlooper
Governor

Colorado Department of Agriculture
Factual and Policy Issues Related to the
Use of Pesticides on Cannabis

The factual and policy issues encountered when developing the Pesticide Applicators' Act Rules which establish the requirements in which pesticides may be used for the production of Cannabis in Colorado are as follows:

1) Under Executive Order D 2013-007 the Colorado Department of Agriculture is required to establish a list of pesticides that are prohibited to use in the cultivation of retail marijuana under Title 12, Article 43.4, C.R.S.. These Rules, which are being simultaneously adopted under the PAA, regulate the use of pesticides on all cannabis, including retail marijuana, medical marijuana, and industrial hemp.

2) The use of pesticides in Colorado is regulated under the Pesticide Applicators' Act, sections 35-10-101 – 128, C.R.S. (PAA). Pesticide regulation is based on the labeling of the pesticide product, the language of which is enforceable under the PAA. Because cannabis is not a specifically listed crop on any label currently registered with CDA, products with broad label statements that do not prohibit use on cannabis are currently the only ones that may be used legally on cannabis in Colorado.

3) These Rules and criteria are being established to allow the use of certain pesticides in the cultivation of cannabis based on the available science and information CDA can confirm at this time. Without these Rules and the criteria they set out, the use of a pesticide that has not had a tolerance established for use on edibles (food), or the use of a pesticide that is not intended to be consumed through inhalation by smoking, could be allowed on cannabis by a broadly worded label, even though such use would be "unsafe" under sections 35-10-117(1)(i) and (2)(a) of the PAA.

4) Both the PAA and the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) require that all pesticides be applied in strict accordance with the label directions for the particular product. As part of the directions for use, pesticide labels specify the particular crops and/or sites to which they can be applied. Depending on the particular pesticide, the crops/sites listed on the label can be expressed very specifically (e.g., "wheat"), or more generally (e.g., "grain crops"). While a pesticide with a label that specifies "wheat" can only be applied to wheat, a pesticide that lists "grain crops" on the label can be applied to wheat, barley, oats, rye, etc. In determining which pesticides, if any, may be used legally on cannabis, CDA initially consulted with the U.S. Environmental Protection Agency (EPA) as to whether there might be any general crop groups, such as herbs, spices or vegetable gardens, into which cannabis might fit (note: there are no registered pesticides that specifically list cannabis as a crop on the label). The current position of EPA is that cannabis is not an herb, a spice or a vegetable. However, EPA agrees that, depending on actual label language, it is not a violation of a pesticide label under the PAA or FIFRA to use the product on cannabis if it has certain, very generally worded descriptions of crops/sites on the label, and the product's active ingredient is exempted from the requirement of a tolerance.

5) Tolerances are established by EPA in accordance with the Federal Food and Drug Cosmetic Act, U.S.C. Title 21, Section 408. A tolerance is the maximum amount of the active ingredient of a pesticide product that is allowed to remain in or on a food crop as residue after application of the product. Pesticide products that have significant toxicity, which could pose a hazard to public health if threshold amounts are exceeded when consumed and could result in acute or chronic poisoning, are required to have tolerances established by EPA. Tolerances for a given active ingredient typically vary depending on the specific food crop to which it is applied. EPA sets tolerances by determining that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residues at the tolerance levels established, including all anticipated dietary exposures. Exemptions from tolerances are established under 40 CFR, Part 180, Subpart D: 180.900: "… An exemption from a tolerance shall be granted when it appears that the total quantity of the pesticide chemical in or on all raw agricultural commodities for which it is useful under conditions of use currently prevailing or proposed will involve no hazard to the public health."

6) Section 3 of FIFRA provides EPA the authority and 40 C.F.R., Parts 150-167, outline the requirements to register a pesticide with EPA. Pesticide labeling is derived through EPA risk assessments required to be conducted as a condition of registration that determine the manner and rates of application in which a pesticide may be used on a site or a crop without resulting in adverse impacts to public health or the environment. To date no risk assessments have been conducted specifically for pesticide use on marijuana.

7) Risk assessments have been conducted to determine what pesticide active ingredients are tolerance exempt. EPA has determined that for those active ingredients determined to be tolerance exempt, " …the total quantity of the pesticide chemical in or on all raw agricultural commodities…will involve no hazard to the public health."

8) EPA requires that a pyrolysis study be conducted during the risk assessment process for products intended to be smoked such as tobacco, unless EPA has exempted the pesticide from pyrolysis studies due to the nature of the pesticide.

9) The Colorado Food and Drug Act (CFDA) provides the Colorado Department of Public Health and Environment (CDPHE) with authority over cannabis contaminated with pesticide residues ("adulterated" under the CFDA) that is very similar to the authority used by FDA to deal with pesticide contamination of all other agricultural crops. The CFDA gives CDPHE specific authority over "unsafe" "pesticide chemicals" in "raw agricultural commodities," the definition of which is broad enough to include cannabis which is grown, harvested and then processed and sold for consumption through various means, including ingestion as a component of food (in edibles).

   Under the CFDA, "food" is defined to mean "articles used for food or drink for man or other animals…and articles used for components of any such article." C.R.S. § 25-5-402(11). "Food" includes any "raw agricultural commodity," which is "any food in its raw or natural state…." C.R.S. § 25-5-402(21). Cannabis, which is grown and used as a component in many forms of edible food products, thus qualifies as a raw agricultural commodity under the CFDA. Although not all cannabis is used in edibles ("food" under the CFDA) cannabis can be used for any purpose after harvest, including food use, thus warranting treatment of all cannabis crops as a food for pesticide regulation purposes. Under section 25-5-410(1)(b)(II) of the CFDA, "a raw agricultural commodity" is "deemed to be adulterated" if "it bears or contains a pesticide chemical which is unsafe within the meaning of section 25-4-413(1)" unless the concentration of the residue is less

than the tolerance set for the commodity or is tolerance exempt as provided for in section 25-5-413(1). Section 25-5-413(1) in turn states that, "[a]ny pesticide chemical in or on a raw agricultural commodity…shall be deemed unsafe for the purpose of application of section 25-5-401(1)(b)" unless there is a tolerance established for that crop and the residue level is within that tolerance. Thus unless a pesticide found on a cannabis crop has a tolerance for use on cannabis or is tolerance exempt, its presence in any amount on cannabis constitutes adulteration that renders the cannabis unsafe for human consumption under the CFDA as a matter of law. These Rules reflect and follow the General Assembly's determination in the CFDA that consumption of food containing pesticides without a tolerance or exemption is unsafe. The Rules thus prohibit the application of such pesticides to cannabis as similarly unsafe as under the PAA in order to prevent adulteration from pesticides as addressed in the CFDA from occurring.

This approach for regulating pesticide use in order to prevent contamination of cannabis is the same as EPA and CDA apply to any other multipurpose-purpose agricultural commodity that can be used in food after harvest. It reflects the fact that neither EPA nor CDA have any way of knowing or controlling what a grower of such crop chooses to do with the crop once harvested. For example, under EPA's registration system, any pesticide labeled for use on cotton, which once harvested can be used for both fiber and food (in the form of cotton oil), must have a tolerance established and be labeled for food use even though the particular cotton crop to which it is applied in the field may not ultimately be used as food.

10) Depending on how it is processed and sold after harvest, cannabis may be consumed through inhalation (smoking), ingestion (eating) and through dermal exposures (creams and lotions applied topically). Due to the lack of specific risk assessments or tolerances for use of any pesticides specifically on cannabis CDA, in accordance with the CFDA, has determined that it is unsafe to apply any pesticide to cannabis that requires a tolerance for applications to raw commodities or that is not approved for use on tobacco.

11) CDA has identified certain pesticide products whose use on cannabis would not constitute a violation of the label due to the very general use statements on the label. In addition, because the active ingredient(s) of these pesticide products are exempt from a tolerance requirement they in most cases provide for use on crops that may be consumed. However, broad labeling and a tolerance exemption for food use does not necessarily mean the active ingredient was tested or approved for use on products to be smoked, such as tobacco. Since cannabis may also be consumed by smoking, any pesticide product allowed for use on cannabis must also have active ingredients that are allowed for use on tobacco to ensure EPA has considered use on commodities intended to be smoked in their risk assessment.

12) CDA is proposing that the only pesticides allowed for use on cannabis be those registered with CDA in accordance with Title 35, Article 9, C.R.S. This will prevent the application of "home-made" pesticide concoctions containing active ingredients that may be unknown and could pose a serious health risk to the applicator and end user if consumed. This will also ensure that any pesticide product applied to cannabis has had a risk assessment conducted to determine allowed uses.

13) These Rules set forth the specific criteria, which if met, will prevent the use of pesticides for the cultivation of cannabis in an unsafe manner that would violate sections 35-10-

117(1)(i) and (2)(a) of the PAA. Section 3 registered pesticide products may be used on cannabis if:

a. The active ingredients have been determined to be tolerance exempt from the requirements of a tolerance, as established under 40 C.F.R. Part 180, Subparts D and E. EPA has established in the risk assessment process that these products are of lowest toxicity and therefore do not require tolerances to be established for use on raw commodities.
b. The label has broad language that allows the use of the pesticide on the site of application. The term "site" includes all sites of application, including interior, exterior sites, structures in which application may be made, as well as the actual plant or crop.
c. The pesticide product label expressly allows use on crops intended for human consumption. This is intended to prevent the use of pesticides on cannabis that although broadly labeled, are not tested or intended for use on food crops.
d. The pesticide's active ingredients must be allowed by EPA for use on tobacco. Pesticide products may contain active ingredients that have had risk assessments conducted for consumption in food, but those active ingredients may not have been tested or intended to be burned and inhaled. Requiring that all active ingredients in pesticides used on cannabis have EPA-allowed uses on tobacco, will ensure that EPA has considered this in their risk assessment process..
e. Some pesticide products may meet all of the required criteria except being expressly labeled for food use due to marketing toward other markets. Nevertheless, if CDA can verify with the manufacturer that the product's master label allows food uses and that all of the active and inert ingredients are allowed for use on food crops and tobacco, CDA through this Rule will have the authority to allow the product's use on cannabis.

14) Under the authority of section 24(c) of FIFRA, states may register an additional use of a federally registered pesticide product, or a new end use product, to meet special local needs. EPA reviews these registrations, and may disapprove the state registration if, among other things, the use is not covered by necessary tolerances, or the use has been previously denied, disapproved, suspended or canceled by the Administrator, or voluntarily canceled subsequent to a notice concerning health or environmental concerns.

These Rules will allow the use of pesticide products on cannabis that have gone through the 24(c) registration process. The 24(c) process will require additional data submission specifically to address use on cannabis, including residue studies and considerations for extracts as well as submission of specific use instructions for use on cannabis. EPA will review this information and deny the registration if it does not support the use.

15) EPA has determined that certain "minimum risk pesticides," commonly referred to as "25(b) pesticides," pose little to no risk to human health or the environment. EPA has exempted them from the requirement that they be registered under FIFRA. These products must still be registered with CDA and meet minimum FIFRA standards for labeling requirements and claims.

There may be some 25(b) products that the manufacturer did not intend to allow end users to consume. The Rule will only allow the use of 25(b) minimum risk pesticide products on cannabis if the pesticide labeling allows use on crops or plants intended for human consumption.

16) The Rules will allow the Commissioner to prohibit the use of any pesticide that he determines could pose a threat to public health and safety or the environment, even if it otherwise meets the Rules' criteria. Pesticide use on cannabis is a newly regulated area of agriculture and new information is coming to light daily. This will give CDA the means to stop the use of any previously approved pesticide when new information or science establishes that such use would be unsafe.

17) Applying the criteria in the Rules to the more than 12,000 pesticides currently registered with the State of Colorado, CDA has determined that there are less than two hundred pesticides that can be legally used in the cultivation of cannabis. In order to inform cannabis growers which pesticides are available to them, CDA has created a list of pesticides that can be legally used. This list will be published on CDA's website and updated as needed.

COLORADO DEPARTMENT OF AGRICULTURE
PESTICIDE APPLICATORS' ACT
RULES AND REGULATIONS

EFFECTIVE MARCH 30, 2016

Part 17. The Use of Pesticides in the Production of Cannabis

17.01: Definition and Construction of Terms for purposes of this Part 17, as used in these rules, unless the context otherwise requires:

a) "Cannabis" means a plant of the genus *Cannabis* and any part of the plant.

b) "Human Consumption" means the consumption of cannabis by a person through oral ingestion, absorption through the skin or inhalation through smoking, vaporization or other means.

c) "Tolerance" means a level of pesticide residue in or on food that the Environmental Protection Agency has determined with reasonable certainty will not pose a hazard to public health when used in accordance with label directions.

17.02: Pesticide Use on Cannabis: These Rules establish the criteria under which certain pesticides may be legally used on cannabis in the State of Colorado. To assist cannabis growers, the Department will publish a list of pesticides that it has determined meet these criteria. As of the effective date of these Rules, there are currently no pesticides that are specifically labeled or have pesticide residue tolerances established for use on cannabis by the federal government or the state of Colorado. The Colorado Department of Agriculture does not recommend the use of any pesticide not specifically tested, labeled and assigned a tolerance for use on cannabis because the health effects on consumers are unknown.

17.03: Any pesticide used in the cultivation of cannabis must be registered with the Colorado Department of Agriculture.

17.04: Any pesticide registered with the Colorado Department of Agriculture may be used in accordance with its label or labeling directions for the cultivation of cannabis in the State of Colorado under the following conditions:

a) For products registered by the Environmental Protection Agency under Section 3 of the Federal Insecticide, Fungicide, Rodenticide Act:
   1) All active ingredients of the pesticide product are exempt from the requirements of a tolerance, as established under 40 C.F.R. Part 180, Subparts D and E, and;
   2) The pesticide product label allows use on the intended site of application. The term "site" for purposes of this Rule includes any location or crop to which the application is made, and;
   3) The pesticide product label expressly allows use on crops or plants intended for human consumption, and;
   4) The active ingredients of the pesticide product are allowed for use on tobacco by the Environmental Protection Agency.

b. Notwithstanding paragraph 3, the Commissioner has the authority to permit the use of a pesticide product, that does not expressly allow use on crops intended for human consumption if:

1) The active and inert ingredients are exempt under 40 C.F.R. Part 180, Subparts D and E, and;
2) The pesticide product label allows use on the intended site of application, and;
3) The active ingredients of the pesticide product are allowed for use on tobacco.

c) The pesticide product label specifically allows use on cannabis.

d) For 25(b) minimum risk pesticide products as defined in 40 CFR 152.25(f); the pesticide product label allows use on the intended site of application and allows use on crops or plants intended for human consumption.

e) For pesticide products with a Colorado Special Local Need registration, issued under section 24(c) of the Federal Insecticide, Fungicide and Rodenticide Act; the Colorado Special Local Need label allows use on cannabis.

17.05: The Commissioner may prohibit the use of any pesticide product for the cultivation of cannabis if the Commissioner determines that such use poses a significant threat to public health and safety or the environment.

Testimony in SUPPORT of: HB1488 HD1 SD1, RELATING TO MEDICAL MARIJUANA

TO: COMMITTEE ON JUDICIARY AND LABOR,
TO: COMMITTEE ON WAYS AND MEANS
HEARING: Thursday, March 30, 2017 at 9:50 a.m. Conference Room 211

FROM: Wendy Gibson R.N./BSN. American Cannabis Nurses Association member.

Dear Chairs Keith-Agaran and Tokuda, Vice Chairs Rhoads and Dela Cruz,
and Members of the Committees,
My name is Wendy Gibson. I am a Cannabis Nurse who supports HB1488 HD1 SD1 to:

(1) Amend the definition of "adequate supply" of marijuana to include seven marijuana seedlings.
[Many patients need these additional seedlings to ensure that 7 USABLE plants will survive. The best medicines come from female plants. Males and hermaphrodites are usually discarded.]

(2) Amend the definition of "debilitating medical condition" to include lupus, epilepsy, multiple sclerosis, arthritis, and autism as conditions that qualify for the legal use of medical marijuana.
[We have substantial scientific evidence for these conditions. Patients with these conditions could have speedier access to their medicine than waiting to petition through the process that the Hawaii Department of Health is currently developing.]

(3) Amend the definition of the term "transport" to allow qualified patients and primary caregivers to transport up to one gram of medical marijuana for laboratory testing under certain conditions.
[Patients need access to laboratory testing to ensure that their products have no contaminants (such as mold). And, knowing the chemical composition of the phytocannabinoids will be useful for dosing the medicines.]

(4) Amend certain dates and deadlines in existing law to address the delays in implementation.
[**Please extend caregiver grows indefinitely. Patients will always need the right to grow their own specific strains** that work the best for them. Not all patients can grow or live close enough to a dispensary to buy from them].

(5) Establish new deadlines for the department of health to implement the dispensary system, including deadlines for implementation of the

department's computer software tracking system and laboratory testing program.
[I think the date for the DOH to consider whether existing dispensary licensees shall be allowed to increase plant count, increase the number of production centers, or increase the number of retail dispensing locations should be moved to March of 2018 rather than October 2018. They should have a good idea of where patients need better access by then.]

(6) Authorize an alternative means to track marijuana sales during any shutdown of the department of health's computer tracking system and require input from licensees.
[As long as it is a simple process, not requiring the establishment of an entirely new DOH department. Could be as simple as conference calling between the dispensaries and DOH with forms that can be used to track data for reconciliation once systems are up again.]

(7) Require retention of video security recordings of production centers and dispensaries for not less than forty-five days.
[Other states manage to operate with about 30 days.]

(8) Amend requirements for laboratory standards and testing to ensure product and patient safety at reasonable tolerance levels with reasonable cost. [We have models that work well in other states, such as Oregon that can be used.]

In addition, I would also like to see more patient protections. Hawaii's cannabis patients still lack protections at work and can be fired for a single, positive marijuana test. This is a discriminatory practice, unique to medical cannabis patients.

Please consider adding language similar to that of HB1010 RELATING TO EMPLOYMENT. This makes it unlawful for any employer to suspend, discharge, or discriminate against any of the employer's employees based on the individual's status as a registered qualifying patient under the Medical Use of Marijuana Law or an employee's positive drug test for marijuana components or metabolites if the employee is a registered qualifying patient under certain conditions.

Thank you for the opportunity to provide testimony on this measure.

Wendy Gibson PTA, RN/BSN.