Testimony in OPPOSITION of HB 2097 HD1

Submitted by:
Peter Oshiro
Resident of Mililani.

Aloha Chairs Lee and Takumi and Members of the House Committee on Consumer Protection and Commerce, and the Committee on the Judiciary.

Mahalo for allowing me to testify.
I am testifying as a private citizen and my testimony has not been approved or endorsed by the DOH.

I stand in Strong Opposition to HB 20987 HD1 for the following reasons:

1) There are no scientific or medical studies to date, which concludes that the practice of "remediating" cannabis/cannabis products that have failed mold/yeast product standards is safe. Please keep in mind that many 329 card-holders are immuno-compromised due to disease or the treatment of adverse medical conditions.

    a) Would you allow restaurants to remediate unwholesome, "moldy" food by washing it off, cooking it off, or dipping it in a chemical that removes the mold?!

2) Disturbingly, the DOH has allowed industry to do exactly that beginning around the Fall of 2017. No dispensaries were ever inspected under HAR §11-850-75 Quality control, health, safety, and sanitation standards prior to opening. That is the only section of the existing rule that addresses public health controls over the industry to prevent adulteration of cannabis products which may have been produced under insanitary conditions. You all would be surprised if I told you that as of today, the DOH had not made even ONE unannounced inspection of any dispensary by persons qualified to recognize and prevent environmental factors that protect communicable disease transmission at least at the level of a food establishment as intended for in HAR 11-850-73 (requirement that dispensaries have food establishment permits issued under Har 11-50, Food Safety Code, to enforce the section of the rule that is supposed to protect the health of 329 card holders. The Food Safety Specialists that inspect our restaurants take ~3 years to learn their craft. The Med Cann program sent one of their staff to a 90 minute Food Handlers Education Class geared for a 6th grade education for back food establishment employees. The only routine inspections of the dispensaries being done, were to ONLY address diversion of cannabis and not sanitary conditions or sanitary techniques being used by industry to manufacture and package cannabis/cannabis products. The DOH has knowingly allowed industry to violate HAR §11-850-85 (c) which clearly prohibits the dispensing of ANY product that have not met standards designed to protect public health from high levels of pesticides, yeast, mold, bacteria and various other contaminants.

3) For good reason, this proposal does not set a maximum level of how much mold or yeast that would be allowed in order for the adulterated cannabis product to be remediated. Under this proposal, cannabis products that that have unlimited amounts of mold or yeast would be allowed to be further processed for ingestion or inhaling after being "remediated".

a) Common sense would dictate that there should be a point where the cannabis has so much mold and yeast that it must be destroyed. It is curious that the point at which the product must be destroyed has already been determined by the DOH and codified in the current rule.

b) Trace elements of the dead mold and yeast colonies will be concentrated in any extracted product, and even though the "remediated" product may pass the testing for mold and yeast after being "remediated", there are no studies that show that the trace elements or by- products of mold and yeast colonies that were exposed to varying "remediation techniques" produce no long or short term maladies. Can you imagine "vaping" these unknown compounds into the lungs of unsuspecting 329 cared holders. Or spraying these into your mouth or consuming pills made from adulterated source product.

c) I can already hear proponents of this measure state that some other states allow this practice. This is especially apparent in "recreational" States that have already succumbed to "Regulatory Capture", including Hawaii, whereby industry has influenced regulatory to do an about face to their rules under the guise of losing or going out of business which in turn affects the coffers of government tax take from the industry.

d) Because the DOH refused to do any regulatory lab testing, we already have an unholy alliance whereby we rely on results that are paid for by industry. There is absolutely a place for third-party lab testing (to ensure QC of a product for industry), but if you want unbiased, uninfluenced lab results, the DOH must collect and test regulatory samples at a determined frequency to keep the system above board. Shopping for labs is a frequent practice in States that allow 3rd party testing as the sole regulatory source.

4) There is already scant research regarding the safety of any cannabis/cannabis product, why on earth would we intentionally add the unknown variable of remediating adulterated product that is intended to be used by persons treating various medical conditions?!

5) We really need to talk about vape products being produced at the dispensaries and how ill equipped the DOH is to regulate this industry.

a) In June of 2019, I sent an email to all DOH Administrators involved in regulating medical cannabis, warning them that some dispensaries were actually adding unknown, imported, un-approved ingredients to vape pens in direct violation of HAR. In September of 2019 we began hearing nation-wide concerns that persons were dying or becoming gravely ill from what appeared to be tainted, unregulated THC vape pens. In October of 2019, I have it on good word that someone from the DOH contacted the dispensaries warning them that the DOH would be "cracking down" on adulterated vape products being sold. So instead of taking clear regulatory action, or formally notifying industry to cease and desist from selling vape cartridges with illegal additives, the mixed message left industry to resort to a "Fire Sale" of vape products with unapproved ingredients. Cartridges that normally sold for $45-$60 for 0.5 gm were being sold for as low as $6 each in unlimited quantities "while supplies last". This allowed industry to literally flood the 329 card holder market with illegal vape pens. 329 Card holders were not told that these pens contained ingredients that were not approved by the DOH.

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

As a professional environmental law enforcer for over 3 decades now, if you want to ensure that industry follows the rule of law, you must give industry "crystal clear" instruction and consistent interpretations of the laws. It is critical that the regulatory program conduct unannounced inspections for the sole purpose of ensuring compliance with the law. If the dispensaries were at least inspected with the same vigor and frequency as a food establishment, food safety specialist would have easily identified illegal sourced products on the shelf. This means that you actually have to do inspections!!
The regulatory agency must be completely transparent to both the public and regulated industry in order to influence industry behavior, and not sweep major problems under the rug while boasting that the DOH has one of the strictest Med Cann programs in the Nation. This statement, which has been repeated ad nauseam to cover up DOH's ineptness, is no more than a bald faced lie when not even one inspection has been done at a dispensary for the purpose of enforcing HAR §11-850-75, Quality control, health, safety and sanitation standards.

Having to give and prepare this testimony is very difficult as I am extremely disturbed at how I truly believe the DOH is endangering the health and safety of the State's 329 Card holders. I am more disturbed by the years of sweat and the very steep knowledge curve that my program has gained in assessing the safety and practices of the cannabis industry which apparently resulted in my program being recently removed from any aspect of interfacing with this industry to protect public health. Appearances allude to the DOH attempting to cover up past egregious actions by replacing my program's involvement with regulating this industry. It is odd that the Food Safety Branch even recently participated in the 2019 legislatures' PIG regarding edible cannabis products to assist the legislature in regulating this industry. We chaired the manufacturing of cannabis edibles sub-committee.
Our program has been removed from regulating this industry and has been replaced with a neophyte program with no track record of any accomplishments or abilities and no applied knowledge of how medical cannabis is processed. This is the same Food and Drug Branch that was abolished in 2012 due to major performance issues and resurrected in early 2019.
I can only surmise that the DOH was afraid that my program would take the necessary action to reverse wrong doings of the past and give the DOH another black eye.

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

STATUS OF CANNABIS DISPENSARIES
Apr 4, 2019

Introduction:

Survey results of the Medical Marijuana Dispensaries in Hawaii and the current status of inspections done under HAR §11-850 designed to protect public health.

HAR section §11-850 -75 Quality Control, health, safety, and sanitation standards. is the only section in the rule that is designed to protect public health by ensuring that cannabis/cannabis products are properly handled, extracted, refined, and packaged to prevent possible adulteration and to reduce risk factors that may contribute to illnesses.

It is the view of the author that one of the critical first steps to ensure that the DOH has a handle on regulating industry practices designed to prevent the public from being exposed to undue risk from consuming cannabis/cannabis products, is to create a risk-based inspection and enforcement protocol. (See attached draft MOA).

It is critical that the DOH have updated SOP's for the manufacturer of each of the many varied cannabis products being manufactured statewide.
To date, there have been no unannounced inspections, for any of the dispensaries in the State to determine compliance with 11-850-75. Thus far, only surveys have been done to vaguely familiarize ourselves with the highly technical manufacturing processes currently employed by the cannabis industry.

Problem:

1) One of the early, critical public health issues in the cannabis industry dealt with non-compliance regarding the "extraction" of cannabis products that have failed lab testing.

The problem began early in the dispensary licensing process when the dispensaries first started failing testing standards for mold/yeast. The first dispensaries (MGT, Aloha Green) were opened with no dispensary inspections to determine compliance with 11-850-75.

The DOH intentionally misrepresented HAR to industry by specifically informing industry that they can re-mediate cannabis product(s) for patient use, that have failed laboratory standards set forth by HAR. This is a direct violation of 11-850-85(c) which prohibits the dispensing of any product that has not met standards designed to protect public health from high levels of pesticides, yeast, mold, bacteria and various other contaminants. Allowing the reprocessing of cannabis flower/product that has failed public health standards is irresponsible at best, violates the provisions of HAR 11-850, and may be hazardous to patients' health, especially those that are immunocompromised due to chemo, radiation therapy, or other pharmaceuticals.

The practice for the local industry prior to May 2018, for flower that failed mold/yeast Max contamination levels (MCL), was to extract the adulterated product which would remove evidence of any mold/yeast. The solvent action of heat/pressure/supercritical CO2 will denature mold/yeast to the

point it will not be detected. This process is analogous to toasting moldy bread to remove traces of mold.

Aloha Green, Noa Botanicals and Cure Oahu were all "extracting" flowers that failed testing standards as part of their normal SOP due to "regulatory capture".

A second survey of all dispensaries were done on the following dates.

9/24/18	Aloha Green (Whitmore Village)
9/27/18	Green Aloha (Kapaa)
10/10/18	Maui Wellness (Kula)
10/11/18	Cure Oahu (North Shore)
10/15/18	Noa (Kunia)
1/18/19	Big Island Grow (Hilo)

Aloha Green, MGT, Noa Botanicals, and Cure Oahu were all still processing flower that has failed mold/yeast testing standards.

Since the first surveys were done in the fall of 2017 to check compliance with 11-850-75, all three Oahu dispensaries have altered the way they handle cannabis flowers that have failed mold/yeast standards. **All the major dispensaries (MGT, Aloha Green, Noa Botanicals, and Cure Oahu) now routinely "remediate" failed product with UV light, 95%+ ethanol, CO2 or a combination of one or all three PRIOR to beginning any organic extraction using supercritical CO2 as the solvent.**

The dispensaries now claim that they are extracting flower that is now deemed to be "clean", as cannabis flowers remediated by exposure to UV, ethanol, or pressurized CO2 show no evidence of mold/yeast colonies upon retesting. Retesting does not check for other toxins and/or trace amounts of possible contaminants left behind by the moldy/yeasty flower.

Solution:

The DOH must either halt the practice of industry remediating product that has failed testing standards or change the rules to specifically allow it under certain conditions. (Did HRS recently pass that bans that practice altogether?). It will now be difficult to gain compliance as industry has invested thousands of $$ in equipment designed to remediate flower that has failed mold/yeast standards as the DOH has led them to believe that the practice of remediation was acceptable.

Problem:

2) Highly varied extracted products are now being produced at the 3 main dispensaries on Oahu and at Maui Grown Therapies. Vape oil cartridges, shatter, rosin, purified elixirs, confections (mints), THC infused olive and vegetable oils, capsules, lozenges, coconut oil (MCT) based tinctures, mist sprays, topical gels, and body oils. **None** of these extracted processes have been inspected through unannounced routine inspections and reviewed for safety or compliance with 11-850-75 by the DOH since opening in 2017.

DOH must begin a comprehensive inspection of all extraction processes at all dispensaries engaged in extractions.
Infused olive and vegetable oils must be reviewed for shelf stability due to c. bot risk.

Solution:

Dispensaries must be classified by risk, based on the variety and types of extracted products being produced and inspected at a commensurate frequency.

Problem

3) A transparent inspection program should be created to inform public regarding inspection findings/action similar to the restaurant inspection system.

I'm sure the public would be curious as to how a regulatory program that oversees the cannabis industry has not issued even one violation letter or formal violation notice to date, for failing to meet laboratory testing standards or any other requirements under HAR 11-850 as a result of inspectional findings.

Solution:

The DOH must create a progressive enforcement system to suspend products from commerce that do not meet testing standards after repeated failed testing results.
Penalty guidelines must also be created and enforced for violations of 11-850 revealed during routine inspections, or for egregious or repeat violations.

The DOH must create administrative penalty guidelines for this industry to be a viable regulatory program.

P Oshiro 4-4-19

Partnership Agreement

Medical Cannabis Dispensary Licensing Program and the Sanitation Branch

I. Purpose

HAR Chapter 11-850, Medical Marijuana Dispensaries, Subchapter 6, Product and product standards requires the application of environmental sanitation theory to effectively enforce the subchapter specifically designed for quality control, health, safety, and sanitation standards.

Section 11-850-73 was written with the intention that cannabis dispensaries obtain DOH food establishment permits under HAR 11-50 for cannabis products intended to be ingested orally, but conflicts with legal definitions of adulterated food products prevent this issuance of food permits required by this section.

The Sanitation Branch agrees to assist the Medical Cannabis Dispensary Program with the following:

II. Sanitation Branch Responsibilities and General Requirements

Enforcement actions by the Sanitation Branch will be limited to the provisions of HAR 11-850, Subchapter 6 and §11-850-85, Laboratory standards and testing, through the following activities:

1) Building Plan reviews for any new or remodeled dispensary facilities if required.
2) Drafting of enforcement protocols for violations of Subchapter 6 and §11-850-85.
3) Provide review and approval of SOP's for the manufacture of cannabis and cannabis products, including but not limited to harvesting, drying, curing, extraction, infusing, manufacturing, and packaging of cannabis products.
4) Approve SOP's for the manufacture of edible cannabis products
5) Inspect dispensaries for compliance with HAR 11-850, Subchapter 6, and investigate violations of HAR section §11-850-85, Laboratory standards and testing. Inspections for new openings, routine compliance inspections, consultations, complaints of illness, general complaints and follow-up compliance inspections to be provided.
6) Develop protocols for recalls, embargoes, and seizures for cannabis/cannabis products that are adulterated; failed to meet lab standards set forth in HAR 11-850, or were produced under conditions that may lead to adulteration.
7) Develop DOH sampling protocol for laboratory testing of cannabis products.
8) Issue violation letters, warnings, cease and desist orders, Notice of Violations and Orders (NOVO).
9) Establish inspection frequencies for dispensaries using risk-based principles. Inspection frequencies will focus on the complexity of the dispensaries manufacturing processes and volume of product.

All proposed regulatory actions initiated by Sanitation Branch shall be reviewed and approved by the Program Manager of the Medical Cannabis Licensing Program AND the deputy AG assigned to the Medical Cannabis Dispensary Licensing program prior to issuance of formal enforcement documents.

Copies of all Routine and follow-up inspections conducted by Sanitation Branch shall be emailed to the Medical Cannabis Licensing program by COB on the day of the inspection, or no later than noon of the next working day if electronic submittal is not possible.

The Medical Cannabis Licensing program, Program Manager, the Deputy Director for Health Resources, or the Director of Health reserves the right to terminate this agreement immediately for any reason.

The Sanitation Branch agrees to give the Medical Cannabis Licensing program adequate notice of at least 60 days, if the Sanitation Branch wishes to terminate this agreement.

All parties agree that the long-term goal of the Medical Cannabis Licensing program will be the establishment of a Sanitarian position or its equivalent to encompass the duties and responsibilities outlined in this partnership agreement.

The undersigned agree to operate according to the provisions of this Partnership Agreement.

_____ _____

Michele Nakata, Program Manager,
Medical Cannabis Licensing Program — Date

_____ _____

Peter Oshiro, Program Manager,
Sanitation Branch — Date

_____ _____

Danette Tomiyasu, Deputy Director
Health Resources Administration — Date

_____ _____

Lynn Nakasone, Division Administrator
Environmental Health Services Division — Date

_____ _____

Keith Kawaoka, Deputy Director,
Environmental Health Administration — Date

_____ _____

Bruce S. Anderson, Director,
Department of Health — Date

How the State DOH is Gambling with the Health of 329 Card Holders and Jeopardizing the Reputation of the Cannabis Industry

May 2, 2018

This article is being written to encourage internal voluntary change within the DOH regarding the regulating of the medical cannabis industry in Hawaii.

The recent departure of the last Surveyor for the Med Cann program and the failure of the DOH to act on critical information regarding major deficiencies in regulating the Med Cann industry leads me to author this critique.

There is a major problem with a lack of basic regulatory infrastructure within the med cann program and with employee retention. All employees originally on the regulatory end of the med cann program has terminated their employment, the last two with 48 hrs notice. There are no longer any employees left to regulate diversion of product within the industry, nor is there any agreement with environmental health to date that delineates any responsibility to protect public health and product safety. Control of regulatory processes from harvest to sale, including solvent and supercritical CO2 extractions of product using cutting edge equipment and processes which rely heavily on applying public health theory in the manufacture of products to be inhaled, ingested, or applied topically to alleviate debilitating medical conditions.

The lack of basic regulatory controls, infrastructure, and risk-based decision making in regulating this industry are frightening. In addition, the DOH intentionally misrepresents HAR to industry by specifically informing industry that they are allowed to re-process cannabis product(s) for patient use, that have failed laboratory standards set forth by HAR. This is a direct violation of 11-850-85(c) which prohibits the dispensing of any product that has not met standards designed to protect public health from high levels of pesticides, yeast, mold, bacteria and various other contaminants. Allowing the reprocessing of cannabis flower/product that has failed public health standards is irresponsible at best, violates the provisions of HAR 11-850, and may be hazardous to patients' health, especially those that are immunocompromised due to chemo, radiation therapy, or other pharmaceuticals.

The lab testing standards were placed in the emergency rule for public health reasons, and the DOH must come out and reverse its position on this critical act of malfeasance. This poor decision by DOH now affects the reputation of the industry itself if they actually chose to re-process product that failed testing standards after DOH informed them that it was OK to do so.

This document will touch on the following deficiencies within the Med Cann program

I. REGLATORY FOUNDATION (HAR 11-850) for the Med Cann program is defective for the following reasons:

§11-850-75 Laboratory standards and testing. (c)
....for each batch of marijuana and manufactured marijuana products tested for that dispensary;... The certificate of analysis shall include the results with supporting data for the following:

The DOH standard set by 11-850 for *ANY* pesticide *regulated by the EPA, is 1ppm.* Many tolerances for pesticides are well below 1ppm for food crops.

§11-850-75 Laboratory standards and testing. (d)
The certified lab may retest or reanalyze the sample or a different sample from the same batch by following its standard operating procedure to confirm or refute the original result, upon request by the department at the dispensary licensee's expense.

A) This practice is defective from a regulatory standpoint as no other industry is allowed to "shop" regulatory results until you get a good sample. The original "hot" sample within the lot may be the result of spot contamination (like spilled toxic liquid) versus contamination that is homogenized throughout the lot. Your re-sample may be below tolerance, but everything around it in the same lot may exceed tolerance and be completely "hot", which in turn may imperil public health.

B) Industry has stated that they are under the impression that they can only retest once, but the rule does not state that. As written, the rule allows for indefinite retesting.

C) Pesticides residues have half-life degradation rates. Because there is no time limit on the re-test or re-analysis, the dispensary can choose to simply sit on a "hot" pesticide lot, and have it retested when the pesticide degrades and is no longer above 1ppm.

II. TRAINED REGULATORY STAFF

Nearly 100% employee defection rate from the med cann enforcement program has left the program void of any trained regulatory staff. There is no training protocol other than OTJ. Sanitation Branch has the only trained regulatory staff (Industrial scaled food manufacturing applied theory) available to evaluate manufacturing and extractions of cannabis products.

III. DISPENSARY INSPECTION PROGRAM NOT BASED ON HACCP (Hazard Analysis Critical Control Point) PRINCIPLES.

There is no regulatory distinction between critical and non-critical violations that are based on any public health protection priorities. This creates major problems for industry and the DOH as both have no idea where to focus their QC or regulatory resources if there are no risk-based regulatory priorities within the DOH. The glaring example of this failure is the mold/yeast standard violations by industry and the inability of the DOH to respond in a proper manner. Should this have been treated the same as a pesticide violation? What about a high bacteria count violation? Which ones can industry legally re-process – NONE at this time.

IV. COMPLIANCE AND ENFORCEMENT

Currently, there is no enforcement protocol for violations of testing standards and violations revealed during inspections. The lack of these protocols also place 329 card holders at undue risk as industry itself cannot discern what their responsibility is in preventing further violations or what kind of time frame is allowed for correction of specific violations and whether lack of compliance will lead to fines, permit suspensions or other penalties.

This was painstakingly revealed in the early months following the approval of Aloha Green and MGT (which by the way were issued dispensary licenses even though no evaluation regarding compliance with 11-850-75 was done. 11-850-75 is the ONLY section of the emergency rule that ensures public health and product safety during manufacture and packaging of product) when numerous violations of testing standards were revealed and the DOH had no clue as to what was causing it or how to deal with it from an enforcement standpoint, as no protocol had been developed after repeated warnings to do so by the food safety program to do so PRIOR to licensing. As the only person deemed to be a SME in

manufacturing/processing/testing and the evaluation of regulatory testing results, I was hesitantly brought in after the fact and was made aware that DOH informed industry that:

The cannabis industry has stated that they have been informed by the DOH that they are allowed to re-process marijuana products that fail standards set forth in §11-850-85 (c).

§11-850-85 Laboratory standards and testing. (i) states that:
The level of contaminants in marijuana and manufactured marijuana products shall not exceed the standards provided in subsection (c), and if any of the standards are exceeded, the dispensary licensee shall not dispense any portion of the batch of marijuana or manufactured marijuana product that does not conform to the standards.

§11-850-85 Laboratory standards and testing. (j) states that:
A dispensary licensee shall destroy a batch that does not conform to the testing standards set out in subsection (c) as indicated by the certificate of analysis; provided that a dispensary licensee shall quarantine a non-conforming batch until any retesting pursuant to subsection (d) is completed, after which the dispensary licensee shall dispose of or destroy the batch if the results of the retesting confirm that the batch is non-confirming.

The emergency rule was created whereby the DOH went out of its way to make sure that ANY product which failed subsection (c) standards must be destroyed, but after implementation, DOH realized that the failure to employ risk-based protocol when developing emergency rules leaves no discretion regarding the destruction of product that failed QC tests (mold/yeast, total viable aerobic bacteria) versus critical public health protection test results (mycotoxins, aspergillus, E. coli, heavy metals, solvents) that would render the product unsafe by any measure.

The rules intent and the actions of the department are in direct conflict, and industry and the consuming public should be given clarity as to what the departments intentions are with regards to this subsection.

It is critical that the department create and finalize enforcement protocols for all regulatory aspects within the Med Cann program as this should have been done **BEFORE operating licenses were issued to the dispensaries.**

The department needs to create specific enforcement protocol for varied violations of HAR 11-850, and define failure or substandard. Violations revealed during site inspections of the grow, manufacturing and retail facilities must also be "risk-based" and employ HACCP (Hazard analysis critical control point) principles to guide the enforcement protocol.

The lack of these protocols place 329 card holders at undue risk as industry itself cannot discern what their responsibility is in preventing further violations or what kind of time frame is allowed for correction of specific violations and whether lack of compliance will lead to fines, permit suspensions or other penalties.

V. INDUSTRY AND COMMUNITY RELATONS

The intentional allowance by the DOH for violations of HAR is probably the worst example of attempting to foster industry and community relations. Instead of working out a solution in the "open" with regards to how to deal with industry failing testing standards, decisions were made by DOH to sweep these results under the rug by claiming it's not a problem and INSTRUCTING industry that they were allowed to re-process failed product rather than disposing or destroying it as HAR demands.

The Med Cann program manager continues to repeat this fallacy to any audience he speaks to, and states that this practice is acceptable. After repeated warnings that this is in direct conflict with HAR, the DOH Administration has failed to correct this situation and still allows industry to continue this practice. Deputy AG Tara Molnar, that represents the DOH's Med Cann program, has been notified of this transgression by email and has been asked to comment on this practice but there has been no response from her as to the legality of this practice to date.

VI. PROGRAM SUPPORT AND RESOURCES

After repeated requests, ad nauseum, there is still no clear delineation of responsibilities for the environmental program. The Sanitation Branch is the only program within the Med Cann program that has any expertise in enforcing manufacturing, packaging, regulatory routine lab testing of product, sanitation principles to ensure what the DOH continually claims to provide the Nation's highest standards of product as well as ensuring patient and product safety.

Employee retention is non-existent, as ALL employees on the regulatory end of the program have quit (very abruptly with the last 2 key employees, and all within the last

year) and DOH Admin is oblivious to the fact that it is a management problem that plagues this and other failing programs under his purview.

Due to a lack of planning and vision, it appears that this program also lacks the necessary resources to provide its employees with the basic tools necessary to function such as cell phones and laptops for the Surveyors.

Repeated requests for change and action to correct all of the deficiencies noted have fallen on deaf ears and it is apparent that the DOH is not willing to enter into the critical paradigm shift needed to right this program.

It has always been my M.O. to allow administration to make the necessary and pono changes on their own, and if they fail to do so after offering concrete solutions (as I always do) and with repeated public health and legal justification will I take steps to the next level to influence change. It should be clear to the department by now, that all of the technical expertise in crafting enforcement protocol for highly complicated programs that involve proper interpretation and creation of HAR rules and procedures that involve sampling product, evaluating highly technical manufacturing processes with scant enforcement history, and high level skills in industry and community relations belong with the Food Safety program. Again, our resources and expertise has been put aside and ignored in favor of very questionable management practices and poor track record of the existing manager.

My email of February 9 to Dani and Ginny requesting an emergency meeting on this issue has also been met with silence, so I can only assume that nothing will be done and the DOH (and an unwitting industry) will continue to mismanage the Med Cann program to the point that it begins to jeopardize the health of 329 Card Holders, if it has not done so already, as extracted, concentrated product that is inhaled or vaped is being sold, as well as infused edible vegetable oils meant to be ingested.

As you can imagine, I have always run the Food Safety Program/Sanitation Branch with the highest degree of integrity and governmental transparency, and knowledge of this malfeasant activity has caused me great stress. The record (endless emails) will show that all of my concerns reflected in this paper has fallen on deaf ears and I have no reason to believe change is forth coming.

This is an excerpt from a recent email from Cure Oahu – It gives the false impression that Ridley has expertise in extraction methods. This is the main part of the management problem – He know little about the extraction process – nor does he have a good grasp of Bio-Track and how it functions from a regulatory standpoint, yet now he is signing of on compliance with 11-850?

The Sanitation Branch posed questions #1-6 below – Ridley does not even know what to ask, as I'm sure he has no clue how extraction really works. Ridley AGAIN, did not coordinate any

environmental health inspection with Cure Oahu and AGAIN, we had to chase this information from behind.

The email excerpt below is from Kristen McReynolds of Cure Oahu:

Keith Kamita is working with Keith Ridley on bringing our extraction addition online. Keith Kamita passed along the below request for info. I've marked my responses in red. If you have any further questions on this system or need additional info let me know. My office number is in my signature and cell is (910) 389-4551.

Also, I've let both Keith's know the current procedures for the extractor are a work in progress. We're waiting on a background check for a consultant who will be assisting with final details on this system. Once he's been cleared, he'll be visiting us on site to give advice on our processing procedures and at that time we expect we'll be making some adjustments to the SOP's. We'll keep you up to date on those changes.

1. *For the purpose of risk analysis, what is the typical volume of ethanol that must be used during one complete cycle of the CIP process after the 5 extraction runs? What % ethanol (HPLC grade) is being used for CIP?*
2. *Is ethanol the only flammable solvent used in your SFE process?*
3. *Section 3.3 of the Operation and Maintenance for the Extractor SOP – indicates that during the emptying of the cyclones, a portion of CO2 will be released. Approx. what volume of CO2 is released from one processing cycle ? - -Is the CO2 from off-gassing of the concentrate, or is it residual CO2 in the system (lines, valves, cyclone collectors, etc.) when disassembling lines, valving out? Or a combination of both.*
4. *What is the lubricant that is sprayed on the extraction vessel cap? (Food/pharmaceutical grade lube?)*
5. *Where are the extraction vessel chambers packed with product? (What room?).*
6. *What is "frit" that needs to be cleaned from the extraction vessel cap? Let me know if any further info is needed at this time.*

(Responses from Cure Oahu removed - confidential)

The above excerpt is to demonstrate to how complicated the extraction process is, yet any Ice Cream shop in Hawaii is under much stricter and standardized public health controls than any of the med cannabis dispensaries. There are multiple extraction methods being utilized by the dispensaries in addition to the supercritical CO2 extraction method above and it is amazing that the person in charge of the Med Cann program is oblivious and ignorant to the technical and scientific requirements of the program, the rule-making and interpretation of law, and industry and community relations by leading industry to believe that they are allowed to violate the provisions of HAR 11-850.

As always, I have made myself available and even offered the services of our program to assist the department, but it is obvious that the expertise and knowledge of our program is being used as a convenience for other managers to give an appearance that all is well.

I will be calling a press conference (On my vacation time) soon to explain to the media, industry and the general public my mana`o with regards to the Med Cann program.

With any luck, wholesale management of the program will be placed in better hands as the result of the press release. If not, at least my conscience will be clear in that I have made my best attempt to protect the health, reputation and continued success of Hawaii's Med Cann program in spite of the incompetence of the DOH.

This is the most painful and gut-wrenching decision that I have ever made in my employ at the DOH but there is no question in my mind that it is the right one. I am still ever hopeful that Ginny and Dani will make the right decision by placing the Med Cann program under the Food Safety program, as our program has a clear track record of success with major paradigm shifts and the ability to create world class regulatory programs with nearly identical methods and goals used to regulate cannabis. Our extensive contact with SME's in this field from Denver regulatory, Denver industry, and extraction equipment manufacturers that are pioneers in the regulated cannabis world, have led to an amazing, but steep learning curve in regulating this industry. It is sad that the same passion and integrity cannot be said of the current leadership of the Med Cann program. The Food Safety program from the outset has had to drag the Med Cann program into educating itself about this industry. We brought in the SME's from Denver and the extraction experts from Extractor Depot to educate the DOH, as well as introducing the DOH into the Management Symposium in Denver. You would think that this push would come from the manager of the Med Cann program.

As stated before, I can lay out an outline and vision for this program as well as re-writing HAR, creating needed enforcement protocols and introducing a risk-based approach to regulating this industry. The illegal re-processing of product that has failed testing standards can also be effectively dealt with in the interim, but it would take open and honest discussions with industry laying out the DOH intent of how to cure the possible regulatory nightmare that has been created.

Please get in contact with me ASAP if you wish to have a serious, frank and outcomes based discussion.

If DOH doesn't care about this, I'm sure the State's 329 Card Holders, the cannabis industry and the public will.

Peter Oshiro

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