Act 230 Legislative Oversight Working Group (LOWG) - *Products Subcommittee*

Product Committee Members

Michael Takano (Chair, Dispensary-Maui)
Pono Life Sciences Maui, LLC
808-489-9454 ext. 706
917-548-4116 cell
mike@ponolifesciences.com

Bill Jarvis (Patient Advocate, License Applicant)
bill.jarvis@koloaventures.com
733 Bishop Street
Suite 1200, Honolulu, HI. 96813
808 224-3500

Jon-Paul Bingham (Patient safety, education)
College of Tropical Agriculture
University of Hawaii
jbingham@hawaii.edu

Karen Kahikina (community safety)
Highway Safety Specialist
Hawaii Department of Transportation
869 Punchbowl Street, Room 405
Honolulu, HI 96813
Phone: (808) 587-2355
Fax: (808) 587-6303
karen.g.kahikina@hawaii.gov

John McAuliffe (community safety)

Highway Safety Specialist
Hawaii Department of Transportation
Phone: (808) 587-6359
Fax: (808) 587-6303
john.p.mcauliffe@hawaii.gov

Christopher Garth
HDA
1110 Nu'uanu Ave. #6
Honolulu, HI 96817 USA
(808) 351-8733
christopher@hawaiidispensaryalliance.org

Dr. Racquel Bueno (dispensary, patient safety, education)
Chief Scientific Officer
Pono Life Sciences
808-489-9454 ext. 707
bueno@ponolifesciences.com

Philip Thompson (dispensary, product safety, education)
Chemical/Manufacturing Engineer
Pono Life Sciences
808-489-9454 ext.
pthompson@ponolifesciences.com

Invited

- Senator Rosalyn Baker, Co-Chair
- Representative Della Au Belatti, Co-Chair
- Representative Joy San Buenaventura
- Professor Susan Chandler, Facilitator, UH-Manoa Public Policy Center
- Carl Bergquist, Drug Policy Forum of Hawai„i
- John-Paul Bingham, University of Hawai„i, College of Tropical Agriculture
- Christopher Garth, Executive Director, Hawai„i Dispensary Alliance
- Wendy Gibson, Drug Policy Forum of Hawai„i/Medical Cannabis Coalition of Hawai„i (alt.)
- Richard Ha, Lau Ola, Dispensary Industry Representative (Hawai„i County)
- Bill Jarvis, Qualifying Patient over the age of 18
- Stacy Karcher, APRN/RX

- Rob Lee, Department of Transportation, Airports Division (alt.)
- Peggy Leong, Hawai„i Department of Health (DOH), Medical Marijuana Dispensary Licensing Program Supervisor (alt./presenter) Assoc.
- Ally Park, Laboratory Representative
- Jari Sugano, Parent of Qualifying Patient under the age of 10
- Professor Colin Moore, Director, UH-Manoa Public Policy Center
- Keith Ridley, Hawai„i DOH, Office of Healthcare Assurance
- Scottina Ruis, Hawai„i DOH, Medical Marijuana Registry Program Coordinator (presenter)
- Michael Takano, Pono Life Sciences, Dispensary Industry Representative (Maui County)
- Calvin Tong, Honolulu Police Department
- Thomas Wills, University of Hawai„i Cancer Center
- Patricia Wilson, Honolulu Police Department (alt.)
- Greg Yim, MD
- Michael Contrades, Kauai Police Department
- Thayne Taylor, Hawai„i Dispensary Alliance

Meeting Minutes

Tuesday, December 20, 2016

2:00P

700 Bishop Street, 15th floor, Honolulu, HI

Attendees:

Mike Takano

Bill Jarvis (patient advocate and license applicant)

Karen Kahikina (Public safety)

John McAuliffe (Public safety)

Jon-Paul (Patient safety, education)

Dr. Racquel Bueno

Philip Thompson

Goals:

Determine scope of what sub-committee can achieve during this legislative session:

- report for next meeting

- end points

- perpetual work product

Discussion:

Define problem and work towards solution, while understanding the major stakeholders and respective priorities.

Next steps:

Create gDoc and gSheet for foundation to our ultimate goal recommendation.

Open Regulatory Issues

1. Permitted Manufactured Marijuana Product

Act 230, Section 17 (July 11, 2016)

The types of medical marijuana products that may be manufactured and distributed pursuant to this chapter shall be limited to: (1) Capsules; (2) Lozenges; (3) Pills; (4) Oils and oil extracts; (5) Tinctures; (6) Ointments and skin lotions; (7) Transdermal patches; (8) Pre-filled and sealed containers used to aerosolize and deliver marijuana orally, such as with an inhaler or nebulizer; and other products as specified by the department

HAR 11-850-72 (a) (December 7, 2015)

A dispensary licensee may manufacture marijuana products limited to capsules, lozenges, pills, oils and oil extracts, tinctures, ointments, and skin lotions.

HRS 329D-10 (July 15, 2015)

The types of medical marijuana products that may be manufactured and distributed pursuant to this chapter shall be limited to: (1) Capsules (2) Lozenges; (3) Pills (4) Oils and oil extracts; (5) Tinctures (6) Ointments and skin lotions; and (7) Other products as specified by the department

As used in this section, "lozenge" means a small tablet manufactured in a manner to allow for the dissolving of its medical or therapeutic component slowly in the mouth. [L 2015, c 241, pt. of 2]

2. Paraphernalia

Act 230, Section 6 (July 11, 2016)

"329-43.5 (a) "Except as provided in subsection (e),-it is unlawful for any person to use, or to possess with intent to use, drug paraphernalia to plant, propagate, cultivate, grow, harvest, manufacture, compound, convert, produce, process, prepare, test, analyze, pack, repack, store, contain, conceal, inject, ingest, inhale, or otherwise introduce into the human body a controlled substance in violation of this chapter. any person who violates this section is guilty of a class C felony and upon conviction may be imprisoned pursuant to section 706-660 and, if appropriate as provided in section 706-641 fined pursuant to section 706-640."

329-43.5 (b) Except as provided in subsection (e), it is unlawful for any person to deliver, possess with intent to deliver, or manufacture with intent to deliver[-i.l drug paraphernalia, knowing[~] or under circumstances where one reasonably should know, that it will be used to plant,propagate, cultivate, grow, harvest, manufacture, compound convert, produce, process, prepare, test, analyze, pack, repack, store, contain, conceal, inject, ingest, inhale, or otherwise introduce into the human body a controlled substance in violation of this chapter. Any person who violates this section is guilty of a class C felony and upon conviction may be imprisoned pursuant to section 706-660 and, if appropriate as provided in section 706-641, fined pursuant to section 706-640.

329-43.5 (e) (2) Subsections (a) and (b) shall not apply to a person who is authorized to:

Dispense, manufacture, or produce marijuana or manufactured marijuana products pursuant to and in compliance with chapter 329D, while the person is facilitating the medical use of marijuana by a qualifying patient pursuant to part IX of chapter"

Acquire, possess, cultivate, use, distribute, or transport marijuana pursuant to the definition of "medical use" under section 329-121, while the person is facilitating the medical use of marijuana by a qualifying patient;

Age Limits 329-43.5 (c) Any person eighteen years of age or over who violates subsection (b) by delivering drug paraphernalia to a person or persons under eighteen years of age who are at least three years younger than that adult person is guilty of a class B felony and upon conviction may be imprisoned pursuant to section 706-660 and-, if appropriate as provided in section 706-641, fined pursuant to section 706-640.

Advertising 329-43.5 (d): It is unlawful for any person to place in any newspaper, magazine, handbill, or other publication any advertisement, knowing or under circumstances where one reasonably should know, that the purpose of the advertisement in whole or in part, is to promote the sale of objects designed or intended for use as drug paraphernalia Any person who violates this section is guilty of a class C felony and upon conviction may be imprisoned pursuant to section 706-660 and, if appropriate as provided in section 706-641, fined pursuant to section 706-640

HAR 11-850-33 (d) (3) (December 7, 2015)

"Retail dispensing locations shall not: Make available for sale or as gifts or premiums any supplies or paraphernalia that provide for the use of medical marijuana in smokable or inhalable form."

HRS 329D-16 (July 15, 2015)

"The department shall establish standards with respect to....(16) The enforcement of the following prohibitions against: (D) The distribution of marijuana or manufactured marijuana products, for free, on the premises of a retail dispensing location or production center"

3. Pre-filled Containers for Oral Delivery

Act 230, Section 17 (July 11, 2016)

The types of medical marijuana products that may be manufactured and distributed pursuant to this chapter shall be limited to: Capsules; (2) Lozenges ; (3) Pills; (4) Oils and oil extracts; (5) Tinctures; (6) Ointments and skin lotions (7) Transdermal patches; **(8) Pre-filled and sealed containers used to aerosolize and deliver marijuana orally, such as with an inhaler or nebulizer;** and other products as specified by the department.

HAR 11-850-33 (d) (2) (December 7, 2015)

Retail dispensing locations shall not: Dispense marijuana or manufactured marijuana products as pre-made or manufactured cigarettes or in any form prepared specifically for smoking or inhaling

Notes for Recommendations

State "Certified" Labels -->Product & Patient Safety

1. **Washington: Patients & practitioners to are the best decision makers, do not limit product offerings, but label and set standards**

- **WA DOH Findings:** At this time, the decision of what marijuana products may be beneficial is best made by patients in consultation with their health care practitioners. For this reason, the department will not limit the types of products available to qualifying

patients. Instead, the department intends to create standards for products that any consumer can rely upon to be reasonably safe and meet quality assurance measures.

- **3 Categories of Product Standards:**
  - **"General use compliant product"** means any marijuana product approved by the WSLCB, including edibles. must be labeled "Chapter 246-70 WAC, Compliant—General Use" and must use the logo developed and approved by the department Product servings <10mg of active THC and no more than 10 servings to not exceed 100mg of THC in a package
  - **"High THC Compliant"** means a marijuana product containing more than ten but no more than fifty milligrams of THC per serving or application. High THC compliant products must be labeled "Chapter 246-70 WAC Compliant – High THC" and must use the logo developed and approved by the department to indicate compliance with this chapter.The following is an exclusive list of marijuana products that may qualify for classification as a high THC compliant product:
    - Capsules;
    - Tinctures;
    - Transdermal patches;
    - Suppositories.
  - **"High CBD compliant product"** means any marijuana product, except usable marijuana or other plant material intended for smoking, approved by the WSLCB, including edibles, containing the following ratios:
    - Marijuana concentrates containing not more than two percent THC concentration and at least twenty-five times more CBD concentration by weight.
    - Marijuana-infused edible products containing not more than two milligrams of active THC and at least five times more CBD per serving by weight for solids or volume for liquids.
    - Marijuana-infused topical products containing at least five times more CBD concentration than THC concentration.

    High CBD compliant products must be labeled "Chapter 246-70 WAC Compliant – High CBD" and must use the logo developed and approved by the department
- **Also expanded testing standards, handling practices, and employee training requirements for the production of these products [Although the new WAS standards seem already covered in HAR**

Smoke-Free products--> Patient & Community Safety

2. **New York: Putting patients and community first by going smoke-free**

- Message From the DOH Commissioner: "Correctly, and in keeping with New York's longstanding commitment to eliminate all smoking, we chose to ban the smoking of marijuana and instead limit its delivery to alternative methods including vaporization, oils, pills, and other

consumables. The medical literature[1] demonstrates that the use of vaporization can deliver marijuana safely and effectively without the known dangers associated with smoking. New York State has devoted significant time and resources to eliminate smoking in all its forms, and tremendous progress has been made. The State's commitment to that end is unwavering, and we are pursuing a safe and effective method to deliver medical marijuana to eligible patients who may benefit."

- New York State Medical Marijuana Overview "Medical marijuana is only available in smoke free forms." This ensures the safest delivery methods for patients"
    - Capsules for oral administration
    - Liquid or oil preparations for metered oromucosal or sublingual administration or administration per tube
    - Metered liquid or oil preparations for vaporization
    - Approved medical marihuana products may not be incorporated into edible food products by the registered organization, unless approved by the commissioner
- Each registered organization may initially manufacture up to five brands of medical marijuana products and is required to offer one brand with an equal ratio of tetrahydrocannabinol (THC) to cannabidiol (CBD) and one with a low-THC to high-CBD ratio, among the initial five brands manufactured. In addition to the two required brands, registered organizations also offer brands that have varying ratios of THC to CBD.
- NYSDOH recommends working with the registered organizations to make more brands of medical marijuana products available to patients. In addition, NYSDOH will continue to evaluate scientific and technological developments that support the addition of new routes and forms of administration of medical marijuana products.

Edibles→ Product & Patient Safety

Risks: Community Safety (Diversion, impaired driving); Product safety (more volatile expiration dates depending on foods; As an example, Illinois limits edibles to food that do not require refrigeration)

3. Arizona:
    1. Must apply for an additional Food Establishment License for "Potentially Hazardous Food"
    2. Before preparing, selling, or dispensing marijuana-infused edible food product obtain written authorization from the Department to prepare, sell, or dispense marijuana-infused edible food products;
    3. If the dispensary prepares the marijuana-infused edible food products, ensure that the marijuana-infused edible food products are prepared according to the applicable requirements in 9 A.A.C. 8, Article 1;

[1]See Findings on Vaporization below

Meeting Minutes

Thursday, January 5, 2017

11 AM

Teleconference

The current law, rules and regulations falls short of meeting the needs of patients:

- Transdermal patch (limiting)
  - Replace with transdermal delivery device[2]
- Paraphernalia (Vaping) [HAR vs. Act 230]
  - Supplies that provide for mmj use in smokable or inhalable form prohibited in HAR but permitted in Act 230
  - Pre-filled sealed containers to aerosolize with an inhaler or nebulizer allowed (Act 230) vs. pre-made and prepared manufactured medical marijuana in any form for smoking or inhalation not allowed (HAR)
  - Demonstrations in-store and purchases off-premises online (oregon)

  - Upside findings on Vaporization:
    - DC DOH presentation on MMJ Adverse Effects and Drug Interactions (PG 17)

[2] For recent developments in transdermal delivery mechanisms including chemical penetration enhancers, physical permeabilization (sonophoresis, iontophoresis and microneedles) and novel nanocarriers. See: 1) Zhang H. et. al. Breaking the skin barrier: achievements and future directions. Curr Pharm Des. 2015;21(20):2713-24. https://www.ncbi.nlm.nih.gov/pubmed/25925124 2) Prausnitz MR, Langer R. Transdermal drug delivery. *Nature biotechnology*. 2008;26(11):1261-1268. doi:10.1038/nbt.1504. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2700785/

        - Vaping cannabis reduces the ingestion of smoke-related toxins and carcinogens such as carbon monoxide, tar, ammonia and hydrogen cyanide that are typically inhaled when smoking cannabis, while increasing the cannabinoid: by-product ratio (Abrams et. al. 2007) (Moir D. et. al. 2007) (Pomahacova B. et. al. 2009)
        - Cannabis users perceive vaping to be safer or less harmful to their health compared to combustible smoking methods, and an increased effect for the same amount compared to combustion. (Malouff et. al. 2013)(Etter JF. 2015)
        - A survey of 6,883 cannabis users found that vaporizing, compared with smoking, causes fewer respiratory symptoms (coughing, wheezing, shortness of breath, mucus production) (Earlywine and Barnwell 2007).
        - Because of the tars and gases produced during the combustion process, cannabis smoke is toxic to airway tissue, and probably carcinogenic (Fung et. al. 1999).
        - Analysis of vapor from a vaporizer recovered 89.1% THC and 9.5% smoke toxins; in contrast, cannabis smoke from a pipe recovered 10.8% THC and about 87% smoke toxins (Chemic Laboratories 2003).
        - Significantly reduces Toxins (Pyrenes and Polynuclear Aromatic Hydrocarbons) in marijuana smoke (Gieringer, St. Laurent, and Goodrich 2004)

    - Downside findings
        - Lack of data/ research on the long-term health effects of chronic vaping (Alan J. Bundey et. al. 2015)
        - Perceived health benefits of vaping may prompt the likelihood of trying cannabis, a younger age of onset, and positive first-time experience, and increased use (Alan J. Bundey et. al. 2015)

- Suppositories. Clarification - Are suppositories allowed? No. Does not constitute a "capsule"
    - Quick review of pros and cons
        - Require more stringent analysis of bioavailability
            - Need dosing limits
    - Research Takeaways:
            - Increased bioavailability (avoids first-pass metabolism)
            - Higher and sustained efficacy and plasma drug levels
            - Alternative to oral delivery with decreased negative "intolerable" side effects and lower bioavailability

Literature review:

1. Bypassing the first-pass effect for the therapeutic use of cannabinoids (1993) Suppository formulation of THC hemisuccinate ester led to sustained elevation of drug plasma levels. Higher, more sustained plasma drug levels should enhance antiemetic efficacy
2. THC Hemisuccinate in suppository form as an alternative to oral and smoked THC (1999) Studies have reported the inconsistent bioavailability of the oral soft gelatin capsule formulation, because of erratic absorption and variable first-pass metabolism of THC. Administration of the THC-HS via suppositories resulted in excellent bioavailability, sustained plasma levels of THC, and improved efficacy as compared to the oral formulations, suggesting the feasibility of this route for the delivery of THC in various therapeutic applications.
3. The effect of orally and rectally administered delta 9-tetrahydrocannabinol on spasticity: a pilot study with 2 patients. (1996) the relative effectiveness of the oral vs. the rectal formulation was 25-50%. The bioavailability resulting from the oral formulation was 45-53% relative to the rectal route of administration, due to a lower absorption and higher first-pass metabolism
4. Cannabinoids and MS (delivery mechanisms)(2002): Overview of anecdotal and clinical evidence of cannabis ingestion to relieve symptoms of MS. Identifies variability in bioavailability of orally administered cannabis, "narrow therapeutic window," and "intolerable" side effects. Suggests modes of administration that avoid first-pass metabolism of the absorbed drug including rectal suppository, aerosol/vapor, injection, skin patch, or sublingual or intrathecal route.
5. Comprehensive Review of Medicinal Marijuana, Cannabinoids, and Therapeutic Implications in Medicine and Headache: What a Long Strange Trip It's Been . Dr. J.W. Farlow described the use of marijuana suppositories as having "few equals in its power over nervous headaches" in 1889

MMJ State References

1. Oregon definition: ""Cannabinoid suppository" means a small soluble container designed to melt at body temperature within a body cavity other than the mouth, especially the rectum or vagina containing a cannabinoid product, concentrate or extract."

Extended topics:

> Marketing and Advertising
> Packaging and Labeling

Notes:

- JPB - Oregon Packaging and Labeling Pre-Approval. Comprehensive and detailed example.

2017.01 Subcommittee Report

[DRAFT]

PRODUCTS SUBCOMMITTEE REPORT
Act 230 Legislative Oversight Working Group
HB2707 CDI (2016), Act 230

January 25, 2017

Introduction	In 2000, the Legislature enacted the Medical Use of Marijuana Law, codified as Part IX of Chapter 329, HRS, the Uniform Controlled Substances Act. The law allows for the medical use of marijuana by qualifying individuals under certain conditions and includes registration requirements for medical marijuana patients and their caregivers. However, the law did not provide a legal method of obtaining marijuana. To bridge the legislative gap to address patient needs, Act 241 was signed in 2015, paving the way for a dispensary system and amended existing medical marijuana use laws. Act 241 and other laws regarding the medical marijuana program were further amended with Act 230 in July of 2016. Although these revisions and expansions of the law have been driven towards ensuring qualifying patients safe, legal access to medical marijuana, the current regulations regarding manufactured medical marijuana products lack specification and clear distinctions, limiting the ability of dispensaries to address patient needs and, consequently, the opportunity for qualifying patients to access a product best suited to their condition and health care preferences. We therefore found that the expansion and further specification of medical marijuana product definitions and regulations is necessary in the interests of the health, safety, and welfare of qualifying patients in Hawai'i. **<u>Manufactured medical marijuana products</u>**

	Act 241, which became HRS §329D in December of 2015, permitted Medical Marijuana Dispensaries, licensed by the state, to manufacture medical marijuana products, provided that any dispensary and/or producer must also obtain necessary licenses from the appropriate regulatory agency if engaged in the manufacturing of medical marijuana or any other activity that, independent of the medical marijuana program, would require a license. HRS § 329D-10 dictated that: "the types of medical marijuana products that may be manufactured and distributed pursuant to this chapter shall be limited to: (1) Capsules (2) Lozenges (3) Pills (4) Oils and oil extracts; (5) Tinctures (6) Ointments and skin lotions; and (7) Other products as specified by the department." HRS § 329D also called upon the DOH to establish Administrative Rules to govern medical marijuana dispensaries. In December, 2015 Hawaii Administrative Rules §11-850 were released. HAR §11-850-72 maintained that a dispensary licensee may manufacture marijuana products limited to capsules, lozenges, pills, oils and oil extracts, tinctures, ointments, and skin lotions, provided that a dispensary licensee shall determine the manufacturing activities required to produce the products intended for sale and shall obtain and maintain as current all required state and county permits or licenses for a particular manufacturing activity, including under chapter 11-50 for any product that is intended to be ingested orally or chewed. Act 230 Section 17 expands the parameters set forth in HRS § 329D regarding medical marijuana products to include: "(7) transdermal patches and (8) Pre-filled and sealed containers used to aerosolize and deliver marijuana orally, such as with an inhaler or nebulizer." Although Act 230 added pre-filled and sealed containers used to aerosolize and deliver marijuana orally, such as with an inhaler or nebulizer, to the list of approved products, HAR 11-850-33(d) states that Retail dispensing locations shall not:

	"Dispense marijuana or manufactured marijuana products as pre-made or manufactured cigarettes or in any form prepared specifically for smoking or inhaling" **<u>Paraphernalia</u>** HRS Chapter 329-43.5, of the Uniform Controlled Substance Act regulates paraphernalia: (a) It is unlawful for any person to use, or to possess with intent to use, drug paraphernalia to plant, propagate, cultivate, grow, harvest, manufacture, compound, convert, produce, process, prepare, test, analyze, pack, repack, store, contain, conceal, inject, ingest, inhale, or otherwise introduce into the human body a controlled substance in violation of this chapter. Any person who violates this section is guilty of a class C felony and upon conviction may be imprisoned pursuant to section 706-660 and, if appropriate as provided in section 706-641, fined pursuant to section 706-640. (b) It is unlawful for any person to deliver, possess with intent to deliver, or manufacture with intent to deliver, drug paraphernalia, knowing, or under circumstances where one reasonably should know, that it will be used to plant, propagate, cultivate, grow, harvest, manufacture, compound, convert, produce, process, prepare, test, analyze, pack, repack, store, contain, conceal, inject, ingest, inhale, or otherwise introduce into the human body a controlled substance in violation of this chapter. Any person who violates this section is guilty of a class C felony and upon conviction may be imprisoned pursuant to section 706-660 and, if appropriate as provided in section 706-641, fined pursuant to section 706-640. However, under HRS 329-121, qualifying patients have the right to use paraphernalia relating to the administration of marijuana to alleviate the symptoms or effects of a debilitating medical condition.

	On the other hand, HAR 11-850-33 (d) (3) regulates that retail dispensing locations shall not: "Make available for sale or as gifts or premiums any supplies or paraphernalia that provide for the use of medical marijuana in smokable or inhalable form" Consequently, Act 230, Section 6 amended 329-43.5, to not apply to: a person who is authorized to: Acquire, possess, cultivate, use, distribute, or transport marijuana pursuant to the definition of "medical use" under section 329-121, while the person is facilitating the medical use of marijuana by a qualifying patient; and a person who is authorized to: Dispense, manufacture, or produce marijuana or manufactured marijuana products pursuant to and in compliance with chapter 329D, while the person is facilitating the medical use of marijuana by a qualifying patient pursuant to part IX of chapter HRS 329-43.5 also set forth age limits to the delivery of drug paraphernalia: (c) "Any person eighteen years of age or over who violates subsection (b) by delivering drug paraphernalia to a person or persons under eighteen years of age who are at least three years younger than that adult person is guilty of a class B felony and upon conviction may be imprisoned pursuant to section 706-660 and-, if appropriate as provided in section 706-641, fined pursuant to section 706-640." and limits to advertising: (d) "It is unlawful for any person to place in any newspaper, magazine, handbill, or other publication any advertisement, knowing or under circumstances where one reasonably should know, that the purpose of the advertisement in whole or in part, is to promote the sale of objects designed or intended for use as drug paraphernalia Any person who violates this section is guilty of a class C felony and upon

	conviction may be imprisoned pursuant to section 706-660 and, if appropriate as provided in section 706-641, fined pursuant to section 706-640" The existing law warrants the following concerns: Prohibition against purchasing paraphernalia by non-licensed dispensaries puts patients at risk of being convicted of a class C felony. Dispensaries as the only legal source of paraphernalia, disable patients' secure access to medical marijuana delivery channels that are best suited to their needs and put other suppliers at risk of unknowingly breaking the law. In highest interests of patient and community safety, there is a need to promote smoke-free products. Alternative, safe methods of use, up to speed with current medical technology, need to be provided in order to better meet patients' needs and to promote business and industry development.
Analysis	<u>The existing law does not fully meet patient product needs or community safety needs and can therefore be further detailed.</u> As an example, New York State's long standing commitment to eliminate smoking in all its forms, in the interests of public health, led the New York State Department of Health to limit marijuana delivery to highly-specific alternative smoke-free methods[i]: • Capsules for oral administration • Liquid or oil preparations for metered or mucosal or sublingual administration or administration per tube • Metered liquid or oil preparations for vaporization • Any form or route of administration approved by the commissioner. Smoking is not an approved route of administration

	Although it is a Class A felony in New York to manufacture, sell, or possess drug paraphernalia, which include objects, used or designed for the purpose of ingesting, inhaling, or otherwise introducing marijuana into the human body, licensed operators under the Compassionate Care Program may be approved by the DOH to manufacture or distribute medical devices, such as electronic vaporizers. One of the five licensed New York dispensaries is currently approved to sell their own pure-oil vaporizer designed for purity and effective delivery, free of any added ingredients, such as MTC oil.[ii] Minnesota has followed in suite and allows[iii]: · Liquid, including, but not limited to, oil · Pills · Vaporized delivery method with use of liquid or oil but which does not require the use of dried leaves or plant form; · Any other method, excluding smoking, approved by the commissioner. Putting patient needs first, The Minnesota program also offers a petition process for patients to propose, with evidence, additional delivery mechanism. As of August 1, 2016 the following were approved[iv]: · Edibles · Topicals · The marijuana flower (use of the plant) · Vaporization of the cannabis flower <u>Hawaii law can further expand and hone definitions to promote business and industry development.</u> Current industry data[c1] finds that over 50% of medical marijuana users prefer a manufactured ingestion channel over smoking the loose bud. The Hawaii medical marijuana program must be vigilant in meeting an increasingly diverse demand of delivery methods that allow patients to find a product best-suited to their medical needs and personal tastes.

	Transdermal [and suppository] delivery is proven as an advantageous form of drug administration because it avoids the first-pass metabolic effects of oral ingestion and can ensure stable blood levels of the administered drug over long periods of time, which can reduce side effects. Significant advances in the development of transdermal delivery mechanisms[v] including chemical penetration enhancers, physical permeabilization (sonophoresis, iontophoresis and microneedles) and novel nanocarriers, signal that the current permission of "transdermal patches," is limiting. More inclusive definitions could spur increased development of a local, technologically-driven and robust medical device industry adding value to the local economy.
Findings	1. Section 329D-10(7) HRS: The definition of "transdermal patches" can be more accurately defined to promote innovation and expanded patient choice. 2. Vaporization needs to be addressed ("remove inhalation in HAR 11-850-33?) (and as it relates to paraphernalia). 3. Section 329D-10 (2) (Lozenges) Edibles needs to be expanded (to include edibles?)
Recommendations	1. Transdermal patches devices; 2. Pre-filled and sealed containers used to aerosolize or vaporize and deliver marijuana orally, such as with an inhaler or nebulizer; and, nebulizer or (DOH approved) vaporizers; and[c2]
LOWG Discussion Items	1. Extend scope of Products subcommittee to include Advertising and Packaging (Section 329D-11 HRS) 11-850-93 HAR Advertising and displays prohibited. This allows only unlicensed dispensaries to advertise, which will mischaracterize the legal industry. Further, it prohibits dispensaries from advertising educational priorities. 2. What was the legislative intent to not include vaporization?

[i] CHAPTER XIII §1004.11 Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York,
[ii] NYSDOH-Approved electronic vaporization device manufactured by a licensed dispensary

[iii] Minnesota Statutes, section 152.22, subdivision 6.

[iv] Minnesota Department of Health, "Adding New Delivery Methods-Medical Cannabis" August 1, 2016; updated October 18, 2016
http://www.health.state.mn.us/topics/cannabis/rulemaking/adddelivery.html

[v] See: 1) Zhang H. et. al. Breaking the skin barrier: achievements and future directions. Curr Pharm Des. 2015;21(20):2713-24. https://www.ncbi.nlm.nih.gov/pubmed/25925124 2) Prausnitz MR, Langer R. Transdermal drug delivery. *Nature biotechnology*. 2008;26(11):1261-1268. doi:10.1038/nbt.1504. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2700785/

[c1]"pie chart" you mentioned? Where did you get this data? I found a market watch report that 45% of patients are "mom or dad" (middle aged) and prefer edibles or topicals. Whereas younger consumers prefer to smoke or vape.
http://www.marketwatch.com/story/mom-and-dad-make-up-45-of-medical-marijuana-patients-2016-02-24

Additionally, this article by reuters discusses the growing market for vaporizers, "Since 2008, the number of U.S. vape shops has grown to about 8,500, and the sale of electronic cigarettes and supplies climbed to $3.5 billion, according to Wells Fargo Securities analyst Bonnie Herzog."
http://www.reuters.com/article/usa-cigarettes-shops-idUSL1N1072E620150729

a. [c2][Maybe it's not a priority, but since it was discussed, we may want to recommend adding suppositories. It would be aligned with our general argument of more fully meeting patients' needs (more choice). In terms of efficacy, our research finds the following:

1. Increased bioavailability (avoids first-pass metabolism)
    1. Higher and sustained efficacy and plasma drug levels
    2. Alternative to oral delivery due to decreased negative "intolerable" side effects and reasons 1 & 2.