3290

IRRC # 3290

October 2022

EMBARGOED MATERIAL

To Whom It May Concern:

I hope that this letter finds you well and in great physical and mental health. My name is Shalawn James and I am a member of the Medical Marijuana Advisory Board, serving as the chair for the Patient/Caregiver Subcommittee. More importantly I am the mother/ caregiver for my son who has suffered with Sickle Cell Disease since birth. Sickle Cell Disease plagues many with chronic pain and damage to organs throughout their bodies. Throughout my son's life my son has suffered multiple strokes, a major brain bleed, numerous infections, and hospitalizations. Since the inception of the medical marijuana program my son's quality of life has vastly improved.

As he enters adulthood my concerns increase for him and his ability to safety and effectively navigate the program independently. The implementation of increased labeling and testing standards are paramount to ensuring he continues to receive a safe, quality product. I fully support the new labeling and testing measures for the Medical Marijuana Program. What some may deem as an inconvenience, is literally life and death to the patients that utilize this program throughout the Commonwealth.

It is my hope that the patient, and their safety is given priority over convenience and profit.

If you have any further questions or concerns, please feel free to contact me at 717-562-8035.

Respectfully Submitted,

Shalawn L James

Green Thumb

EMBARGOED MATERIAL

325 W. Huron Street
No. 700
Chicago, IL 60654
312.471.6720
gtigrows.com

Tuesday, October 18, 2022

Via email:
Independent Regulatory Review Commission
Commonwealth of Pennsylvania
irrc@irrc.state.pa.us

Re: Final-Form Rulemaking #10-219 (IRRC #3290): Medical Marijuana

Dear members of the Independent Regulatory Review Commission (IRRC) and Department of Health,

On behalf of Green Thumb Industries, Inc. ("GTI"), I respectfully submit these written comments in response to Final-Form Regulation #10-219: Medical Marijuana. GTI operates over 75 retail locations and over 15 cultivation and production facilities across 14 highly regulated cannabis states. We appreciate the opportunity to provide input based on our experiences and in the spirit of optimizing Pennsylvania's medical marijuana industry.

I. §1141a.21. Definitions; Medical Marijuana Waste

We appreciate that the Department and IRRC have created an exception for certain returned products. However, it is not clear whether the receiving dispensary must immediately deliver the product directly to the correct dispensary or if the product can be returned to the originating grower/processor for delivery to the correct dispensary. A receiving dispensary should be able to return the product to the originating grower/processor and this should be made clear in the regulations.

For the same reasons described in the final-form regulations, we would request further clarification that "Medical Marijuana Waste" does not include medical marijuana products immediately returned to the grower/processor that initiated the delivery:

> (iii) The term does not include medical marijuana products erroneously delivered to a dispensary other than the dispensary intended for sale, provided that the packaging remains unopened, with tamper-evident seals intact, and the medical marijuana products are immediately delivered to the correct dispensary~~.~~ or returned to the grower or processor that initiated the delivery.

II. § 1151a.27. Requirements for growing and processing medical marijuana

Section 1151a.27(c) provides that "a grower/processor shall maintain a log of all actions taken to detect pests or pathogens, and the measures taken for control."

We would suggest adding the underlined language to section 1151a.27(c) as follows: "a grower/processor shall maintain a log of all actions taken to detect pests or pathogens, and the measures taken for control~~.~~, including decontamination methods.

III. § 1151a.34. Packaging and labeling of medical marijuana products

§ 1151a.34(d)(17) provides that each label must "be conspicuously placed on the package" and "be firmly affixed to the container directly holding medical marijuana product…and be firmly affixed to outer packaging if used."

We appreciate that the Department understands the complexity of affixing a label to an item that is so small that it does not have enough space. We also appreciate that the Department agrees the vape cartridge itself is the medical marijuana "product" and made the appropriate clarifying revisions. We would request confirmation that a syringe is also considered a "medical marijuana product" similar to a vape cartridge.

* * *

Thank you for your consideration. We are available to answer any questions you may have and would welcome the opportunity to provide additional information, especially as it relates to best practices in other markets.

Best Regards,

Tiffany Newbern-Johnson
Director of Government Affairs
Green Thumb Industries, Inc.

EMBARGOED MATERIAL

RECEIVED

Madison Brame

OCT 18 2022

Independent Regulatory Review Commission

From: Molly <mlly_rbrtsn@yahoo.com>
Sent: Tuesday, October 18, 2022 10:57 AM
To: IRRC
Subject: Department of Health Medical Marijuana #10-219 (IRRC# 3290) Comments

To whom it may concern:

I am writing to you as a former member of the Medical Marijuana Advisory Board, a patient advocate, and as a concerned citizen.

I want to express my support of the regulations, as submitted, by the Department of Health. I would specifically like to point out the importance of stringent lab testing requirements and more detailed labeling.

I have been part of countless patient workgroup meetings where it was asked of the industry (via PCC) to list all ingredients and here we are several years later and we see nothing of the sort. This leads me to believe the industry has no intention to do what is best for patients unless required by law to do so.

If the Department of Health is able to require certain standards, the patient community's requests will be honored and the industry would have no choice but to adhere to the requirements of the regulations. Those of us who lobbied the legislature for this law have invested countless hours in trying to ensure the program is governed responsibly, with a patient-centric approach.

If we allow the medical marijuana industry to dictate the manner in which this medicine is provisioned, I fear it will mirror the unscrupulous pharmaceutical industry; quality will diminish, patient safety will be undermined, and PA's Medical Marijuana program will fall victim to the almighty dollar.

Thank you for your consideration.

Molly Robertson

EMBARGOED MATERIAL

DH, MMRegulations

From: Sam Tracy <sam@vsstrategies.com>
Sent: Wednesday, October 19, 2022 11:58 AM
To: DH, MMRegulations
Cc: Milan Patel
Subject: [External] PathogenDx comments on proposed final medical marijuana regulations
Attachments: PathogenDx comments on proposed final medical marijuana regulations.pdf

Hello Mr. Collins,

I have attached written comments on the proposed final medical marijuana regulations, submitted on behalf of Milan Patel, founder and CEO of PathogenDx (cc'd). These comments focus on opposition to the proposed regulatory ban on PCR testing, instead preferring that decisions on testing method approvals be left to case-by-case review by the Department.

Please let us know if you have any questions or would like additional information.

Thank you,
Sam

SAM TRACY
Associate
mobile: 860-970-6119
sam@vsstrategies.com
VSStrategies.com

PathogenDx
Setting the standard in DNA testing

Comments on Proposed Final Medical Marijuana Regulations

Pennsylvania Department of Health

Submitted by:
Milan Patel, Co-Founder & CEO
PathogenDx, Inc.

Thank you for the opportunity to comment on the proposed final regulations for Pennsylvania's medical marijuana program. As a company focused on developing microbial and pathogen testing methods, equipment and kits for marijuana and hemp, we believe that testing is an integral part of regulating medical marijuana, and want to lend our expertise to ensure Pennsylvania's testing program protects public health and operates in line with the latest scientific data.

While there are some positive changes to the testing regulations, we are strongly opposed to the proposed ban on PCR testing. Many PCR tests — including our own — are being used successfully in dozens of state marijuana programs, and have been certified by third party organizations such as AOAC to be just as effective as plating and other methods that would not be banned under these proposed regulations. Banning PCR is not based on any scientific evidence, and decisions on the approval of testing methods are better left to Department review rather than enshrining in regulation. Therefore, we strongly support removing this proposed ban.

Recommendations:

Remove the ban on PCR testing found in § 1171a.29. Testing requirements.

Proposed Language:

§ 1171a.29. Testing requirements.

> (e) Sampling and testing under this chapter shall be conducted with a statistically significant number and size of samples and with approved methodologies to ensure that all harvest batches, harvest lots and medical marijuana products are adequately tested for contaminants and that the cannabinoid profile is consistent throughout the harvest batch, harvest lot or medical marijuana products. All testing methods must be fully validated to address the accuracy, precision, specificity, linearity, range, and sensitivity of the testing method.
>
> ~~(e. I) PCR testing is not an approved methodology.~~

Reasoning:

PCR testing is at least as effective as plating, and superior for detecting certain contaminants.

Plating has long been the "gold standard" for microbiological testing, but recent scientific advancements have allowed for the creation of new PCR-based methods that are just as effective while obtaining

results much more quickly. This equivalency has been certified by third party organizations such as AOAC.

For example, AOAC certified our Quant[X] Fungal One Step method, which was independently validated at Q labs, finding no statistical difference from plating in the detection of TYMC.[1] Similarly, our Detect[X] assay for the detection of Aspergillus, Salmonella, and STEC was certified by AOAC, finding no statistical difference to traditional plating.[2] Both of these methods use End-point PCR microarray technology with a Live/Dead protocol to detect the presence of viable bacterial and fungal pathogens in cannabis and hemp, greatly increasing the efficiency of the process while achieving the same accuracy as plating. In addition to saving significant lab tech time for independent laboratories, this can also reduce backlogs for the entire medical marijuana supply chain. More importantly, ensuring the use of accurate molecular methods like PCR , it closely aligns turn-around time expectations of Grower/Processors to release tested products out to the market.

There are also certain drawbacks to plating that PCR-based testing methods are able to avoid. The issue with enrichment concerning microbial population composition is that there is always selection for some organisms that will outcompete others. For example, if you take a 1 gram of a sample and enrich at 37°C in Tryptic Soy Broth, the conditions are not optimal for Aspergillus, which is optimal at room temperature and actually needs at least 48 hours under those conditions to obtain sufficient enrichment. Certain bacteria could actually flourish and could even secrete molecules that inhibit growth or kill other microbial species,[3] thereby causing the laboratory technician to miss the one targeted species in his or her assessment. Items that impact microbial growth during enrichment include the type and volume of nutrients, cell mutations, and temperatures.[4] Conversely, it is possible that fungi like Aspergillus can inhibit bacterial growth.[5] These issues continue to confound enrichment plate culture based methods resulting in poor specificity of the test in calling out the correct result.

Decisions on approving testing methods are better left to Department evaluation, not enshrined in permanent regulation.

Most importantly, we are concerned with enshrining a ban on any testing method in regulation, especially when that regulation has not had room for ample public debate. It is particularly concerning that PCR is the only method being singled out with a regulatory ban, while qPCR and other methods are not addressed.

The proposed ban on PCR testing was not included in the original draft of these final regulations circulated in February 2021,[6] and was only added in this recent draft released September 2022. Since there was no public hearing on this new draft, we do not think it has received enough attention to be finalized. Adopting this without a public hearing could cause long-term problems for Pennsylvania's medical marijuana program, as it could be years before another round of rulemaking takes place.

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[1] #072105
[2] #012201
[3] Kerr, J. R. (1999). Bacterial inhibition of fungal growth and pathogenicity. Microbial Ecol Health Dis, 11:129-142.
[4] Westfall, C. S., & Levin, P. A. (2018). Comprehensive analysis of central carbon metabolism illuminates connections between nutrient availability, growth rate, and cell morphology in Escherichia coli. PLoS genetics, 14(2), e1007205. doi:10.1371/journal.pgen.1007205
[5] Furtado, N. A. J. C., Said, S, Ito, I. Y. & Bastos, J. K. (2002). The antimicrobial activity of Aspergillus fumigatus is enhanced by a pool of bacteria. Microbiol. Res, 87:207-211.
[6] See http://www.irrc.state.pa.us/docs/3290/AGENCY/3290PRO.pdf

Instead of banning any particular methods in regulation, we believe it is better to leave the review of individual testing methods to Department of Health staff, who can look at them on a case-by-case basis. In a field as constantly evolving as microbiological and molecular testing, it's important to independently review the science and new technologies to gauge the effectiveness of each proposed method. Such an approach would foster innovation, driving improved efficiencies in the laboratory testing space and improved quality of testing to ensure better health and safety for the public. The existing regulations state that the Department must approve methodologies, and that those methods must be fully validated. We believe this is sufficient to protect public health without a categorical ban on PCR or any other type of test.

Our methods are currently in use in 36 cannabis programs throughout the country, and we would appreciate the opportunity to talk through our certifications and research with Department staff in order to discuss whether it meets the rigorous requirements already set forth in regulation.

Conclusion:

We thank you for considering our comments in support of removing the proposed ban on PCR testing. We respectfully request you make this change to protect patients and ensure Pennsylvania's medical marijuana program is in line with best practices.

Milan Patel
Co-Founder & CEO
PathogenDx
https://pathogendx.com/

DH, MMRegulations

From: Sam Tracy <sam@vsstrategies.com>
Sent: Wednesday, October 19, 2022 12:13 PM
To: DH, MMRegulations
Cc: Jill Ellsworth
Subject: [External] Willow Industries comments on proposed final medical marijuana regulations
Attachments: Willow Industries comments on PA DOH proposed final medical marijuana regulations.pdf

Hello Mr. Collins,

I have attached written comments on the proposed final medical marijuana regulations on behalf of Jill Ellsworth, founder and CEO of Willow Industries (cc'd).

These comments offer strong support for allowing the remediation of medical marijuana that fails testing for microbiological contaminants, as well as respond to the Department's request for scientific evidence that the processes used will remediate contaminants to acceptable levels.

Please let us know if you have any questions or would like additional information.

Thank you for your consideration,
Sam

SAM TRACY
Associate
mobile: 860-970-6119
sam@vsstrategies.com
VSStrategies.com

WILLOW
INDUSTRIES

Comments on Regulation #10-219: Medical Marijuana

Pennsylvania Department of Health

Submitted by:
Jill Ellsworth, Founder & CEO
On behalf of Willow Industries, Inc.

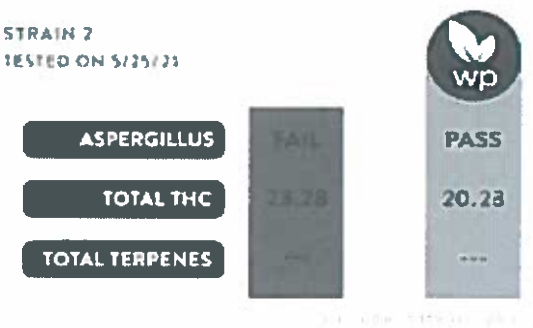
Thank you for the opportunity to comment on Regulation #10-219: Medical Marijuana, which establishes permanent regulations for Pennsylvania's medical marijuana program. We greatly appreciate the Department of Health's work to replace the current temporary regulations that currently govern the medical marijuana industry.

Willow Industries is a Colorado-based company that works with cannabis cultivators and processors across the country, with a focus on decontaminating cannabis to remove harmful microbes using ozone. As our equipment can also be used for remediation, we would like to offer our strong support for allowing the remediation of medical marijuana that fails testing for microbiological contaminants, as well as respond to the Department's request for scientific evidence that the processes used will remediate contaminants to acceptable levels.

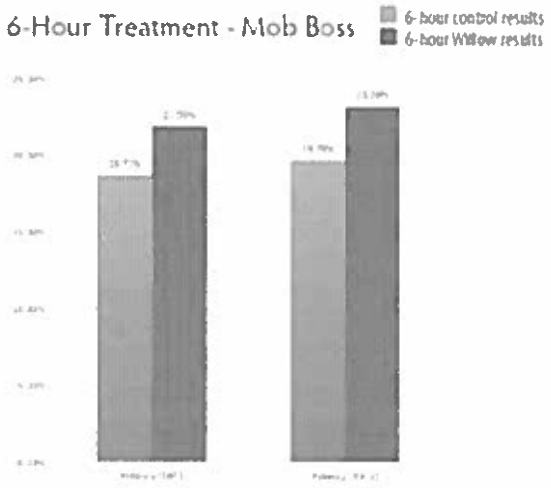
Scientific data shows that remediation can be effective

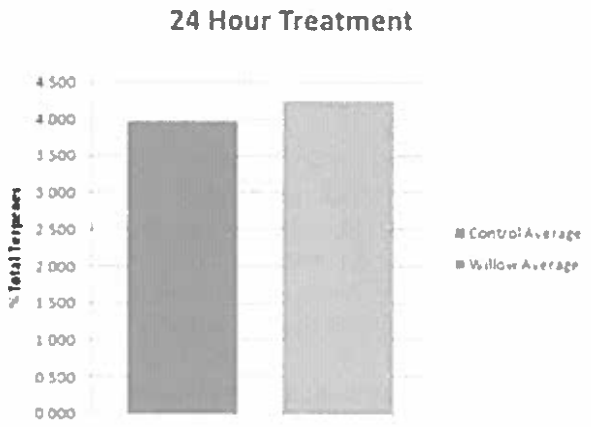
Currently, the only alternative to destroying a failed batch of medical marijuana is for it to be processed into topical form. It is true that many extraction methods used for the production of topicals can effectively remove microbial contaminants from medical marijuana that has failed testing. However, there are also many effective methods of remediation that do not involve extraction, and instead leave plant material in its current form.

For example, our WillowPure system uses ozone to kill microbiological contaminants on plant material, while keeping its physical form intact. The below charts represent "in the field" data from one of our partners in Nevada. **Prior to remediating with Willow, they failed for Aspergillus. After a 4-hour treatment in the WillowPure system, they passed Aspergillus testing and saw no degradation to cannabinoids or terpenes.**



Further, this process also does not disrupt the medicinal properties of the plant. Other studies have demonstrated that treatment with ozone does not reduce either the potency or the terpene content of usable cannabis:





As these studies show, ozone can be used to lower quantities of microbiological contaminants to compliant levels, without disrupting cannabinoid or terpene levels — and without needing to turn medical marijuana into topicals. We believe that this will be an indispensable tool for operators given Pennsylvania's mandatory tests for Aspergillus and Total Yeast and Mold, and that allowing licensees to remediate plant material will increase compliance while avoiding the unnecessary destruction of failed batches.

While remediating failed batches of cannabis via extraction is certainly preferable to destroying them, many operators would prefer to keep them in the form of plant material. High-quality plant material typically has a better sale price than extracted products, so being forced to convert it into a concentrate could lead to unnecessary economic losses. Additionally, even if pricing is comparable, many operators prefer the flexibility to respond to patient demand for various product types.

We recently worked with the Oregon Health Authority to update their regulations in a similar manner. Following numerous stakeholder meetings and public comment periods, Oregon updated their rules in early 2022 to allow for remediation methods other than extraction. We highly recommend joining Oregon and the many other states that allow such remediation processes.

Oregon's previous remediation regulations:[1]

> (6) Failed microbiological contaminant testing.

[1] See the track changes on new rules effective 3/31/2022: https://www.oregon.gov/oha/PH/DISEASESCONDITIONS/CHRONICDISEASE/MEDICALMARIJUANAPROGRAM/Documents/rules/PH_24-2022TrackedChanges-eff-March312022.pdf

(a) If a sample from a batch of marijuana or usable marijuana fails microbiological contaminant testing the batch may be used to make a cannabinoid concentrate or extract if the processing method effectively sterilizes the batch, such as a method using a hydrocarbon based solvent or a CO2 closed loop system.

As shown above, Oregon's previous language is similar to Pennsylvania's current remediation policy, as neither allow for remediation that leaves plant matter intact.

Oregon's current remediation regulations (with changes shown):[2]

(6) Failed microbiological contaminant testing.
(a) If a sample from a batch of marijuana or usable marijuana fails microbiological contaminant testing the batch may beither:
(A) Be remediated using a sterilization process; or
(B) Be used to make a cannabinoid concentrate or extract if the processing method effectively sterilizes the batch, such as a method using a hydrocarbon based solvent or a CO2 closed loop system.

As shown above, the new regulations allow for batches to be remediated using a process other than extraction, such as ozone. This gives operators the ability to leave medical marijuana as plant matter, rather than using extraction to create topicals.

We were highly involved in Oregon's rulemaking process to update these provisions, and would be happy to connect you with officials at the Oregon Health Authority if you would like to speak with them further about the reasoning behind these changes.

Remediation is already successfully operating in numerous state programs

Oregon is far from the only state to allow for remediation of medical marijuana. Remediation is allowed in the large majority of state-regulated medical marijuana programs, including mature programs like Colorado, Washington, Michigan, Nevada and Maine, as well as newer programs like Massachusetts and Arkansas.

These states share the Department's concerns that remediation might not always be effective at reducing microbial contaminants to acceptable levels. To address this, there are standard best practices in remediation policy, such as requiring remediated batches to pass a round of re-testing before being sold to patients.

For example, here is Colorado's remediation re-testing policy:[3]

"Remediation. The Regulated Marijuana Products Manufacturer may Remediate the Inventory Tracking System package, Harvest Batch, or Production Batch of Pre-Rolled Marijuana, if possible, and create two

[2] See new rules effective 3/31/2022. Track changes: https://www.oregon.gov/oha/PH/DISEASESCONDITIONS/CHRONICDISEASE/MEDICALMARIJUANAPROGRAM/Documents/rules/PH_24-2022TrackedChanges-eff-March312022.pdf

[3] See 4-135 – Regulated Marijuana Testing Program: Contaminated Product and Failed Test Results and Procedures in Code of Colorado Regulations (state.co.us)

new Test Batches, each containing the requisite number of Sample Increments. The new Test Batches are required to be re-tested for Microbial, Mycotoxin, and Water Activity contaminant testing. Such testing must comport with sampling procedures under Rule 4-110."

Requiring re-testing confirms that the remediation process was effective, ensuring that remediated medical marijuana is held to the same standards as medical marijuana that passes the first test.

Thank you again for your consideration of our suggestions. Please do not hesitate to contact us if you have any questions or would like more information.

Submitted by,

Jill Ellsworth

Jill Ellsworth
Founder & CEO
Willow Industries
jill@willowindustries.com

Madison Brame

From: Sher Simcisko <sher.simcisko@gmail.com>
Sent: Wednesday, October 19, 2022 3:44 PM
To: IRRC
Subject: Department of Health Medical Marijuana #10-219 (IRRC# 3290) Comments

Hello,

I am writing to express my concern for the safety of all PA patients. I believe that ALL ingredients should be listed on the labels. I also don't believe that the grower-processors should be adding additional ingredients that are not necessary for processing, with the exception of natural products (such as terpenes) from PA hemp.

Although I understand the law calls for child resistant packaging, so many of the packaging materials are very hard to open, particularly for those with arthritis or other issues. I can ask for a bottle with an easy open lid at the pharmacy for opiods. I wish that was an option for cannabis which is much safer.

Have a great day, in fact, have several in a row.

Sher Simcisko
1682 Bristol Ave #302
State College, PA 16801

EMBARGOED MATERIAL

Marcu Enterprises
347 Eighth Street
Suite 1
Jersey City NJ 07302
marcuenterprises@gmail.com
718 404-8206

RECEIVED
OCT 19 2022
Independent Regulatory
Review Commission

To: IRCC testimony

Date: October 19, 2022

RE: Comments related to Regulation # 10-219 Medical Marijuana

Dear Esteemed Committee Members,

I received my PhD for studying the pharmacology of cannabinoids at Temple University and have continued to conduct basic, clinical, and regulatory research projects. For over 20 years, in my capacity as a cannabinoid researcher and a court qualified cannabis and synthetic drug expert, I advocate for medical cannabis patient safety, help create safety standards for cannabis/hemp products, provide education, and speak with the media about the different risks associated with natural, synthetic, and artificially derived cannabinoids, and how to mitigate their unique risk profiles. As a trained ISO17025 cannabis laboratory assessor with A2LA, I understand the limitations of the current laboratory testing regulations and how the industry can exploit unintended loopholes thereby jeopardizing the transparency of these products and potential risk to consumers health.

In this letter, I share principles and issues that I have encountered since the first regulated, packaged cannabis product was sold to a qualified individual.

Following bioethics and public health ethics principles makes good business sense long-term for cannabis and hemp companies. Bioethics is good for business, good for long-term profits, and protects public health. If we continue to be short-term in our thinking it will lead to unethical practices at the expense of public health and financial stability.

Bioethics principles include labeling all ingredients on products, providing access to testing results to the consumer, as well as labels identifying potential risks. I recommend and strongly encourage regulators to require companies to have a concise toxicology with associated risks report available for each product and the ingredients listed on that product. It is a basic right for consumers to have access to ingredient listings, testing data, and toxicologic data – that went into formulating the product.

This action will help guard public health and reduce the occurrences of large recalls of products, where the source and possible consequences of the health issues are generally unknown.

Product safety issues can be short lived, acute, have traumatic effects and long-term consequences on the individual and the public. As a product safety consultant in the cannabis space, my colleagues and I

rarely find opportunities with companies willing to engage in research to understand the risks/potential safety concerns on their products.

Recent events, including issues that can disable the initiation of a product recall by regulators, have highlighted the importance of addressing product safety issues, and at the same time how little or poorly understood and unevolved is the approach to product safety.

Without product ingredient transparency and information on the risks of those chemicals and drugs, we have severely limited the ability to either treat medical conditions or to prevent health conditions associated with cannabis or hemp use.

An active, effective, centralized data gathering sentinel programs that tracks consumer experiences with cannabis and hemp products is needed.

Cannabis research and data generation is not a harmless activity for quiet nerds to conduct in a basement or attic. These efforts inform policy, health risks, and form the basis of intellectual property. Regarding looming health, issues my recent data (see attached PDFs) shows that, since 2018, there are increases in the reporting of D8-THC adverse events (AEs), occurring in mostly males aged 18 to 65 years in the US when compared to D9-THC products. The most urgent and important concern is our reported increase in an association of D8-THC labeled products with respiratory and cardiac issues from public health-related data sources (i.e., case reports, poison control centers, AEs databases, etc.). Additionally, our research has shown that there are far more adverse events reported over the last decades for illicit cannabinoid products over psychedelics or hallucinogens in the FDA adverse event database. Highlighting the need for effective product labeling, consumer education, and sourcing information to be transparent. As new cannabinoids flood the market unknown risks for which we understand very little about. Based on our findings we have found that adverse event reporting for cannabis and hemp products is extremely limited, difficult to report and not centralized. Hence, in absent of adequate regulations for products with unknown risks, we created an adverse event reporting tool for consumers that is easy to use. We receive hundreds of visitors/scans a month, of consumers and caregivers that interested in reporting unwanted effects from various cannabinoid products. This system could also serve as a way for companies to conduct post-market surveillance, it would be unethical to continue to allow products with no available toxicological or safety data to be sold without a robust sentinel program. At a minimum, medical cannabis patients are owed these considerations.

In this sector there are clear areas of interest from a safety and ethics perspective:

(1) What chemical entities are making their way onto the market? Are these the same molecules that are found abundantly in the cannabis plant and have long histories of ancestral use (i.e., THC, CBD) or are they rarely studied novel chemical entities (NCE) (i.e., THC-O, THC-P, HHC)?

(2) Where are these NCEs coming from (i.e., overseas manufacturers with little concern for downstream effects or domestic cottage manufacturers without the means to perform fundamental safety work) and what quality control or safety standards, if any are being implemented?

(3) What are potential long term health effects on the populations consuming these NCE compounds?

(4) What populations are drawn to using these NCE containing products?

(5) What are the barriers to accessing good quality, standardized product that drive usage to the little studied and potential unsafe NCE products (i.e., price, accessibility, lack of education)

(6) What is the average consumer's ability to learn about and understand the benefits and risks of consuming these NCE substances?

(7) In the event of an adverse reaction or event, what resource does a consumer have?

(8) How do patient and consumer experiences with unregulated products impact the trust and/or public perception of the field of cannabinoid medicine as a whole?

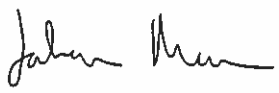
In my capacity as a cannabis expert, authoring the American Herbal Products (AHP) Cannabis monograph which is cited in cannabis regulations across the United States, including Pennsylvania's cannabis regulations and as the founding cannabis laboratory standards subcommittee chairman for the American Herbal Products Association and founding subcommittee chairman of the Association for Standards ASTM D37 Cannabis standards committee,

I strongly recommend our priority should be to protect cannabis patients, consumers, and public health while incentivizing long-term financial stability for the cannabis companies. Transparency is needed regarding the evidence used to approve and market products from both regulators and industry. Every company should have at least a literature review available, on their product assessing risks and toxicological factors. There should be a robust, sentinel reporting system available to consumers, to allow efficient post-market analysis of cannabis products, which usually come to market with no clinical or toxicological or pharmacological testing – that is expected of nearly every other consumable product from candy bars to alcohol beverages. Additionally, an independent body should be created to assess safety and risk claims, new data, and make recommendations to inform government and industry. If the consensus of scientific information is to be ignored, the decision and its rationale should be publicly available.

Transparency is key for the future success of this industry.

Thank you for taking the time to consider my comments. Please do not hesitate to contact me if you have any questions.

Respectfully,



Jahan Marcu, PhD
marcuenterprises@gmail.com

P3-71:"*FREE WEED THAT GETS YOU HIGH*": DID THE FDA AND CDC HEALTH ALERTS ON DELTA-8 THC REACH MAINSTREAM SOCIAL MEDIA?

Teresa A. Simon[1,2], Anthony Silverstone[1,3] Yomei P. Shaw[1,4] Jahan Marcu[1,5]

[1]Physicians Research Center, LLC USA, [2]Adjunct Fellow Univ of PA, Center for Public Health Initiatives, USA,[3] Fairfield University MPH Candidate, USA, [4]FORWARD, The National Databank for Rheumatic Diseases, USA, [5]Marcu Enterprises USA,

INTRODUCTION and BACKGROUND

Social media enables public sharing of information and emerging attitudes. Twitter is currently among the most popular. On September 14, 2021, both the FDA and CDC issued health advisories related to artificially derived delta-8 THC products, after poison control centers across the nation reported over 600 cases related to exposure to these products. The health alert seemed to receive minimal, if any, national news coverage.

OBJECTIVE

We sought to determine the impact of the CDC and FDA health advisories, as well as the sentiment and attitudes towards delta-8 THC, as mentioned on Twitter.

METHODS

Five hundred tweets before and after September 14th, 2021 (date of CDC and FDA health advisory) were extracted from Twitter using web scraping.

Posts were filtered using key search terms such as: "Delta 8", "D8", Delta 8 THC", and "D8THC"

A Likert scale of 1-5 was used to rate the tweets (the value of 1 being the most positive result, and 5 being the least positive result).

Each tweet was scored by 3 independent researchers. Knowledge and attitude change before and after the national health advisory on September 14, 2021, were analyzed quantitatively and qualitatively.

Strengths and Limitations

Self-reported views and experiences may be inaccurate. However, Twitter is a tool to monitor public health issues and has been used in previous studies.

Corresponding Author: pretnas@gmail.com

ICRS 2022 Galway, Ireland; presented June 29, 2022

Authors have no conflicts of interest.

Other relevant posters P3-53, P3-54, P3-70

RESULTS

Below are sample tweets pre (orange) and post (blue) CDC and FDA health advisory on September 14th, 2021

Consumer pre-FDA/CDC health warnings

"someone told me that delta 8 is giving people epilepsy"

"Guys just don't eat delta 8 gummies. That shit made my heart race and threw me into a panic attack and the ER lol"

"In 10 years, they're gonna b like "if you consumed delta 8 you may be entitled to compensation"

"no oversight in how they extract/synthesize delta-8. Chemist fear people are not properly prepping these products for safe consumption."

"Scientists are simply not worried about delta 8, it's completely fine. They are only worried about the byproducts of delta 8 synthesis, which is necessary to concentrate it enough"

Pre Health-Alert Tweets

"Isomers of THC are not the concern."

"Yes, yes you do Delta 8 is a hella good time for relaxation Just DONT eat them like candy you literally will die"

Post advisory tweets referring to CDC alert as 'misinformation'

"Delta 8 is great if you get from reputable companies. So much misinformation from people trying to ruin the market is terrible. The product is definitely helpful for quite a lot of people. As with anything know what you are getting into before jumping in blindly."

(reply to above tweet) "Agreed. It's cutting into the profits of big marijuana corporations & big pharma so it makes sense that they'd keep pushing a negative message!"

"The FDA and CDC can't regulate and tax, the delta 8 cannabinoid. So they slander and discredit its potential for helpful and healing properties. Alcohol has all the side effects of use as the Delta- 8 THC that are stated in the caption. So why not make alcohol illegal as well?"

Post advisory: would choose whole plant cannabis over delta-8 because safer

"It blows my mind that delta 8, which is CBD extracted into distillate, and then soaked in acid to produce a THC-like reaction is sold in every state, and buying Organic raised, pesticide free, cannabis is illegal."

Post advisory: Post advisory tweets dismissing CDC alert

"Delta-8 THC poisonings? The CDC's warning isn't what you think. Calm down. You're not poisoned. You're high. This is what happens when people can't buy safe, regulated products"

Post advisory tweets about "crackdown" on delta-8

"If it weren't for COVID-19, highly unlikely the Delta-8 THC boom would have lasted as long as it did without drawing unwanted attention from the feds. But Tuesday's FDA/CDC warnings likely the first move in a federal gov't crackdown."

"But they are catching on to delta 8 and a lot of states are banning it looooo"

Consumer sentiment post FDA CDC health alert

"I don't understand why the FDA and CDC can't get hemp products regulated. I get it that the marijuana industry is upset and lobbying against Delta-8 but come on...LEGALIZE AND REGULATE."

"Manufacturing of delta-8 THC products may occur in uncontrolled or unsanitary settings, which may lead to the presence of unsafe contaminants or other potentially harmful substances."

"While THC products are legal in many states, the FDA now stresses that no delta-8 products have been evaluated by the organization. The lack of regulated marketing of the product—and lack of warning labels—means that consumers may not know what they are getting themselves in for."

"The American Association of Poison Control Centers (AAPCC) began monitoring adverse events tied to delta-8 THC and found that from Jan. 1 to July 31, 2021, there were 660 reports of delta-8 THC exposure, nearly 20% of which required hospitalization, according to the CDC. I think the most (only?) helpful reminder from this is that Delta-8 THC products often involve use of potentially harmful chemicals to create the concentrations of delta-8 THC."

CONCLUSIONS

To our knowledge, FDA and CDC delta-8 THC health alerts were not covered by the national news associations. Twitter, a social networking service with over 330 million active users, is a platform that showed an increase in delta-8 THC warnings post FDA/CDC Health Alert. Based on the types of tweets regarding the use of delta-8 THC, Twitter could become an avenue to quickly disseminate information on the risks and potential benefits of delta-8 THC.

P3-53 COMPARISON OF CANNABIS AND PSILOCYBIN ADVERSE EVENTS IN A NATIONAL REPORTING SYSTEM

Jahan Marcu[1], Teresa A. Simon[2,3], John Simon[2,4] Matthew Wabwire[2,4] Andres Gomez [2,3]

[1]Marcu Enterprises USA, Marcu and Arora, LLC USA, [2]Physicians Research Center, LLC USA, [3]Adjunct Fellow Univ of PA, Center for Public Health Initiatives, USA, [4]Drexel University, USA. Corresponding author contact: PRCtrials@gmail.com

BACKGROUND

In the United States, jurisdictions that have legalized adult use and medical cannabis are now also considering legislative changes to allow access to psychedelics, such as psilocybin containing mushrooms and products thereof.

The reported side effects of cannabis-derived products and psilocybin may appear similar, while the health risks are likely different under real world circumstances.

Traditionally, a product is studied in Phase 1-3 studies, where the benefit-risk profile is established prior to national approval and monitored subsequently after approval. One of the mechanisms for monitoring safety is the Food and Drug Administration (FDA) Adverse Event Reporting System (FAERS).

Products listed as Schedule 1 are deemed to have no therapeutic benefit and have a high potential for abuse.

Opioids, alcohol and nicotine have a high potential for abuse. Yet, FAERs seems to have a bias for reporting substance abuse and drug dependence for schedule 1 drugs. Abuse and dependence are not traditionally part of an adverse event profile but is something to be considered for risk.

OBJECTIVE

Given the increasing interest in these products, and real-world evidence suggesting concomitant use, we explored the prevalence of cannabis and psilocybin-related adverse events in a national reporting database.

METHODS

A US database designed to support the FDA's post-marketing safety surveillance program for approved drugs and biologics was accessed. Search terms listed as a suspect drug(s) included: psilocybine, cannabis sativa and 11-Nor-9-Carboxy-delta-9 THC. Alcohol and nicotine were added post-hoc. Demographics, calendar year, system organ class, and reaction type are reported

RESULTS

Number (%) of cases and most common adverse event reported in the FAERs Database by Product

	Schedule 1 Drugs						Substances on the Market			
Estimated Number of Users *	7.1 M hallucinogens (LSD,PCP,psilocybin, mescaline,peyote,MDMA) past year				49.6 M past year		57 M Tobacco or vaped past month		139M Any use past month	
	Psilocybine	%	Lysergic acid/ Lysergide	%	Cannabis flower	%	Nicotine	%	Alcohol	%
	N=36		N=235		N=6608		N=85,142		N=29,378	
Drug abuse	2	6	81	34	1,978	30	208	>1	4,839	16
Substance abuse	19	50	58	25	855	13	85	>1	933	3
Drug dependance	18	47	52	22	726	11	2,504	3	857	3
Euphoric mood	13	34	22	9	130	2	322	>1	149	>1
Hyperhidrosis	8	22	17	7	118	2	1,096	1	189	>1
Anti-social behavior	8	22	0	0	16	>1	10	>1	6	>1
Emotional poverty	8	22	8	3	11	>1	10	>1	3	>1
Overdose	1	3	14	6	537	8	1,888	2	2,916	10
Toxicity to various agents	1	3	28	12	839	13	344	>1	6,327	22
Nausea	8	22	15	6	164	3	7,630	9	553	2
Pain	1	3	4	2	227	3	1,977	2	216	>1
Medication error	0	0	1	>1	20	>1	214	>1	224	>1
Aggression	8	22	25	11	231	3.5	129	>1	522	2
Dysarthria	1	3	3	1	103	2	67	>1	245	>1
Drug ineffective	0	3	22	9	215	3	8,994	11	219	>1
Completed suicide	0	0	22	9	491	7	135	>1	7,056	24

*2020 National Survey on Drug Use and Health (SAMSHA)

CONCLUSIONS

There is an unmet to need to track adverse events and unwanted effects from psychedelics. Psychedelics are becoming decriminalized, psilocybin and MDMA are available as a therapeutic treatments in some places in the United States. There are over 100 clinical trials presently in phase I or phase II utilizing psychedelics as a form of treatment. The increased perception of, for example, psilocybin's safety may lead to increased use, and our only national database is not currently able to reflect the risks associated with exposure. Some of the criteria being tracked in FAERS is objectively not helpful to identify safety signals. As public health researchers, we lack access to systematic real-world data to assist the general public in making informed decisions. Whether it is alcohol, nicotine, opioids, cannabinoids, or psychedelics – the availability of a product does not make a product safer or more efficacious. To address an unmet need, we are piloting a complaint/adverse/unwanted effects tool to collect information on cannabis and hemp-products.

Strengths and Limitations

Some of the data reported is not helpful in understanding the risk profile. Duplicates are not removed;

Most likely only severe cases are reported. FAERs database is the only national database that allows the collection of any product on the market; Only 4 datapoints are required to become a case.

Multiple drugs can be listed as a suspect product.

These data are used for signal detection; A case can have multiple events reported.

Scan the QR code; You do not need to use cannabis to participate in this anonymous reporting system.

BudsInfo

The AE tool created to collect the unwanted effects of hemp, cannabis and cannabis-derived products; expansion to other products are in development.

ICRS 2022 Galway, Ireland, presented June 29, 2022

Authors have no conflicts of interest.

Other relevant posters P3-54, P3-70, P3-71

P3-70: AN UPDATE TO SAFETY DATA ON CANNABIS-LIKE PRODUCTS IN THE FDA FAERS DATABASE

Teresa A. Simon[1], John Simon [1,2], Jahan Marcu [1,3] Andres Gomez [1]
[1] Physicians Research Center, LLC, NJ USA , [2] Drexel University, PA USA, [3]Marcu Enterprises, NJ USA

Introduction

Health alerts on the dangers of the consumption of delta-8 tetrahydrocannabinol (THC) were issued from the United States Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) on September 14, 2021; Many states have banned delta-8 THC; While delta-8 THC is an isomer of delta-9 THC, some believe it is legal to synthesize delta-8 THC under the US 2018 Hemp Farm bill.

The FDA and Drug Enforcement Agency (DEA) websites list delta-8 THC as schedule 1 drug. Despite this conundrum and a lack of safety data, delta-8 THC and other derived products (e.g., HHC isomers, D10 THC, etc.) have exploded into the market.

Objective

This study was conducted to analyze epidemiological information on the nature and extent of Cannabis-derived products specifically delta-8 THC utilizing the FAERS database.

Strengths and Limitations

Data mining does not provide sufficient evidence on causality.
Many reports listed multiple medications as suspect.
More than 50% of delta-8 THC was the only product listed.
FAERS is a limited data source and underutilized by the public.
The rate of reporting an AE for an FDA approved, marketed product is about 6%.

Conclusion

Delta -8 THC continues to have a high number of respiratory adverse events (N=89) reported in the only national safety database (FAERS).

A PRR of 14 indicates respiratory events are 14 times more common in those where delta-8 THC was a suspect product.

It is unclear if delta-8 THC or another factor, such as an adulterant, is the cause of these events. These events could have more serious downstream effects such as cardiac events as a result of hypoxia reported in susceptible users.

The authors continue to monitor cannabis-derived cases reported in FAERS as well as launching a new complaint/adverse/unwanted effects reporting tool to collect safety data on cannabis and cannabis-derived products.

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Authors have no conflicts of interest; Corresponding author: prctrials@gmail.com

Other relevant posters P3-53, P3-54, P3-71

Methods

Utilizing the FARES Database, a database that was originally designed to support the FDA's post marketing safety surveillance program for approved drugs and biologics. We queried the database on January 22, 2022, which included all cases reported up to September 30, 2021.

The following search terms were used:

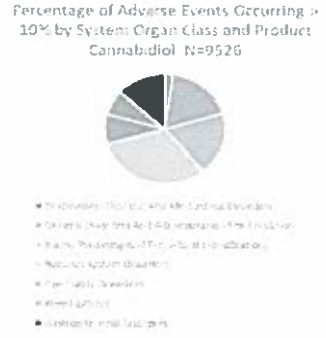
1. Cannabidiol; most cases (99% are epidiolex)
2. Delta-8 tetrahydrocannabinol:
   - device\herbals
   - device\herbals\nicotine
   - herbals
3. Delta-9 tetrahydrocannabinol
4. Marinol, a synthetic form of tetrahydrocannabinol

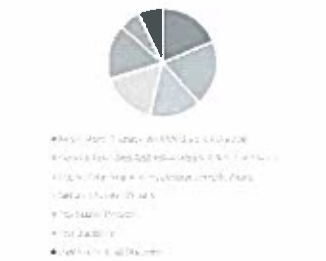
	Event P	All other events	
Product z	a	b	a+b
All other products or a good comparison product	c	d	c+d
	a+c	b+d	Total

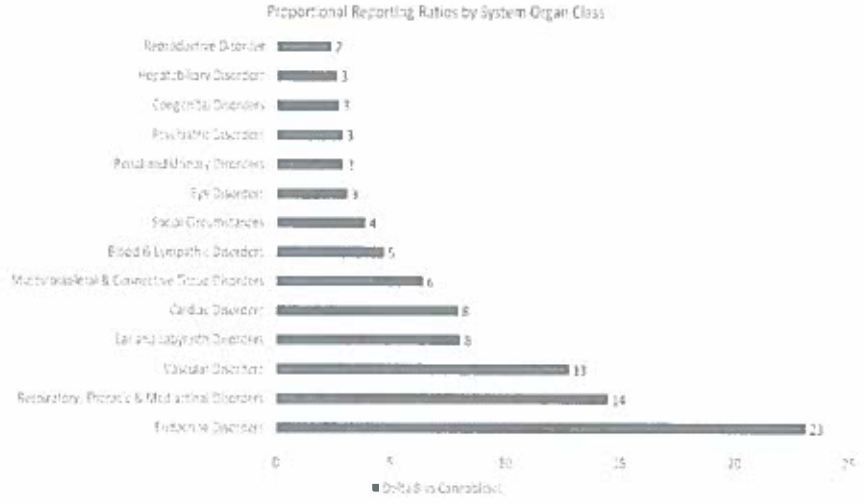
Proportional reporting ratio (PRR) were calculated to compare signal detection. A PRR of > 2 is considered a possible/potential signal.
The PRR = [a/(a+b)]/[c/(c+d)]

If the ratio of [a/(a+b)] is greater than the ratio of [c/(c+d)] then event P is "disproportionately reported" for Product Z when the rest of the database is considered as background or "expected".

Results







The authors present only clinically relevant and medically important data due to the limitations in space.

Total cases of: Delta-9 THC N= 52; Marinol N=507

Most frequent events (67%) occurred in the Injury and Poisoning SOC for Delta 9 THC and General Disorders and Administration Site Conditions for Marinol (38%)

For PRR, Delta-9 THC had 1 PRR > 3 when compared to cannabidiol

Marinol had the following PRR's > 3 when compared to cannabidiol: Vascular Disorders (PRR=10); Endocrine (PRR=7); Muscular Skeletal and Connective (PRR=6) and Cardiac Disorders and Blood and Lymphatic Disorders (PRR=5)