UNITED STATES DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION

Hearing

IN THE MATTER OF:	DEA Docket No. 1362
Schedules of Controlled Substances: Proposed Rescheduling of Marijuana	Hearing Docket No: 26-96

Monday,
July 13, 2026

700 Army Navy Drive
Arlington, Virginia 22202

The above-entitled matter came on for hearing, pursuant to notice, at 9:00 a.m. EDT.

BEFORE:

THE HONORABLE DEREK C. JULIUS,
Chief Administrative Law Judge

APPEARANCES:
On Behalf of the Government:

JARRETT T. LONICH, ESQ.

MACK J. SWAN, ESQ.
ALEXIS B. ATTANASIO, ESQ.
DAVID C. MALEY, ESQ.
Office of Chief Counsel
Drug Enforcement Administration
8701 Morrissette Drive
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[redacted]

On Behalf of Phillip A. Drum, Pharm.D.:

DR. PHILLIP A. DRUM, pro se

On Behalf of Smart Approaches to Marijuana:

JOHN M. McNICHOLS, ESQ.
Torridon Law PLLC
[redacted]

On Behalf of the States of Nebraska, Idaho, and Indiana:

JOHN M. McNICHOLS, ESQ.
Torridon Law PLLC
[redacted]

ALSO PRESENT:

GRAYSON E. PHILLIPS, ESQ., Law Clerk

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P-R-O-C-E-E-D-I-N-G-S

(9:00 a.m.)

JUDGE JULIUS: We are on the record.

Today is July 13th, 2026. This is Day 9 of the matter of Schedules of Controlled Substances: Proposed Rescheduling of Marijuana, Hearing Docket Number 26-96, DEA Docket Number 1362.

First order of business, I'll take appearances. Mr. Lonich, who is here on behalf of the Government today?

MR. LONICH: Yes, Your Honor. For the Government, Jarrett Lonich, Mack Swan, Alexis Attanasio, and David Maley.

JUDGE JULIUS: Welcome, Counsel.

And on behalf of Smart Approaches to Marijuana?

MR. McNICHOLS: John McNichols, Your Honor.

JUDGE JULIUS: And the Opposed States?

MR. McNICHOLS: John McNichols.

JUDGE JULIUS: Very good.

And Dr. Phillip A. Drum. Good morning, sir.

DR. DRUM: Good morning.

JUDGE JULIUS: And are you representing yourself --

DR. DRUM: Yes, I am.

JUDGE JULIUS: -- still? Very good.

And so that means that we have not present today National Drug and Alcohol Screening Association; DUID Victim Voices; Dr. Finn, M.D.; and the Tennessee Bureau of Investigation. Anyone here on behalf of those parties?

(No response.)

JUDGE JULIUS: Very good. They had indicated they did not intend to appear for today's hearing, so that is consistent.

Any preliminary matters before we begin with Dr. Drum's case in chief?

MR. LONICH: Nothing from the Government, Your Honor.

MR. McNICHOLS: Not for us, Your Honor.

JUDGE JULIUS: Thank you.

Good morning, Dr. Drum. You weren't here when I gave the original instructions on Day 1. You'll have 15 minutes to provide an opening statement, and then we'll have you take the stand. I'll swear you in, and then you will have two hours to provide your testimony. You're a pro se

participant, so I can give you some leeway. I'm not going to make you ask yourself questions. That would be sort of nonsensical, but, you know, I understand that you have a PowerPoint that you plan to use to guide --

DR. DRUM: Yes, sir.

JUDGE JULIUS: -- your testimony? Okay.

Mr. Phillips, our law clerk here, will hold up a sign when you have five minutes left, should you get close to your two-hour mark, and then he'll hold up a sign when your two hours is expired, and then you'll have to conclude at that point. I suppose he'll be showing it to you from over here --

DR. DRUM: Yes.

JUDGE JULIUS: -- in the witness stand.

And we will plan to take a comfort break about midway through. So depending on how long your presentation lasts, I can give you a heads-up when it's around 10:30 to see if you want to find a place that would be a good pausing point just so we can take a 15-minute comfort break.

DR. DRUM: Perfect.

JUDGE JULIUS: Okay? Any questions for me?

DR. DRUM: No, not at this time.

JUDGE JULIUS: All right. If you'd like to make your opening statement from the podium, please feel free to begin whenever you're ready, sir.

DR. DRUM: So good morning, Your Honor. My name is Phillip A. Drum, PharmD. I'm a licensed pharmacist from the state of California. I'm a pro se witness, and I hope the Court will have a little patience with me as being in the courtroom and courtroom procedures are foreign to me.

I am both an interested person and a person adversely affected or aggrieved by the proposed rule of marijuana being rescheduled from a CS I to a CS III substance.

As a pharmacist, I'm responsible for protecting and educating the public about medications. We have a relationship between a provider and a patient to assure the patient is receiving the most appropriate medication for their illness, the right dose, are informed of potential drug-drug interactions, adverse effects associated with their medication, proper method of drug delivery and storage, among other items.

My second witness is Dr. Karen Randall,

who was until recently an emergency room provider. She's retired, as I will be soon. Her job was to diagnose and provide medical recommendations on how to treat a patient. She also provided prescriptions and orders on how to treat patients of all ages in an emergent situation at a busy emergency room at a hospital in Pueblo, Colorado.

In our roles, we have treated many patients who have utilized cannabinoids of one type or another. As medical practitioners, we must maintain our professional license by performing continuing education courses and staying current with current medical practices and medications being used and approved.

We have both been healthcare educators of medical practitioners and other members of society. We have both been health care -- sorry. We have become colleagues as a result of us having a common interest and joined the International Academy on the Science and Impact of Cannabis. I will be discussing how modern Western medicine has moved away from the 1880s medicine in which cure-all treatments were being pushed by members of society that were actually doing more harm to people than doing good.

Thankfully, the Food and Drug Administration was created in the early 1900s and removed products that were harming people. Many of these magic cure-all potions were plant products, some of which are-- chemicals such as formaldehyde were being put into milk and borax placed on meat.

Modern medicine still relies on portions of plants that are active chemicals. Most recently, the Pacific yew tree provided an agent used for cancers, but not the entire plant, as is being proposed today with marijuana.

The Controlled Substance Act of 1970 was very important to generate five levels of substances based on whether there is a true medical indication for use, the difference between a CS I and the other four levels, II through V. The other factors involve the risk of abuse potential, such as addiction, and dependence on the substance, such as psychological or physical symptoms of withdrawal.

As a pharmacist and provider, we both rely on the FDA to provide useful information commonly found in the FDA-approved package insert to guide us on proper use of medication; the

approved indications for use; pharmacokinetics of the drug, which involves the absorption, distribution, metabolism, and elimination of the active ingredient; interactions; appropriate dose of active ingredient; dose adjustments for various patient types; storage; the studies proving efficacy; the incidence of adverse effects; among other information.

We have yet to see this document that the FDA -- from the FDA, despite their claims of potential medical indications for marijuana.

Dr. Randall has extensive training and knowledge in the practice of pediatric medicine and will relate many cases involving marijuana in both children and adults. These not only include cases of pure addiction, but many possible permanent mental health, addiction, and physical changes that occur as a result of society's current allowance of marijuana use, both medical as well as recreational.

Many times patients cannot be immediately removed from the emergency room to other care areas due to lack of mental healthcare services in the communities. The frequent readmissions and lack of social services is

resulting in increased healthcare costs. This abnormal drug use has been promoted by the industry.

Parents have been duped into believing the minimal risk of a hallucinogenic substance, due to the approvals that have been made in states by the public and legislator, and even administrators, and will only increase when marijuana is federally deemed a medicine by moving it to a CS III substance.

As a pharmacist and provider, we are responsible for maintaining control of dangerous controlled substances, not gas stations, grocery stores, or local gymnasiums. We will discuss the adverse effects we have seen and are aware of many other adverse effects as a result when people use and abuse cannabinoids.

I will discuss the large number of studies performed on marijuana despite it being a CS I substance and the declining reports of medical marijuana despite increased federal research funding and offering additional sites for growing federally approved products.

Also, I will discuss studies involving medical marijuana use in veterans. We will

discuss hazardous chemicals, elements, bacteria, mold, and other products found in marijuana products and the failure of the states to regulate these products. We will also discuss how patients under the influence have become more violent, resulting in personal attacks of healthcare workers.

As a provider and pharmacist, we will discuss how the Prescription Drug Monitoring Program found in all 50 states affect our workflows and protect society.

Finally, as a clinical pharmacist, I will discuss the use of special drug -- of a special drug protocol used by the FDA that has been used to protect the public from drugs with a substantial risk versus benefit profile similar to marijuana.

That concludes my opening 15 minutes.

JUDGE JULIUS: Thank you, sir.

DR. DRUM: At this time, I filed a prehearing statement identifying and submitting prospective exhibits in accordance with 21 CFR 1316.59. I am familiar with each of the exhibits numbered 1 through 51. I have reviewed each of them. These are true and accurate copies of the

documents that they purport to be and are exhibits which an expert with an interest in marijuana drug information would use.

Your Honor, consistent with 21 CFR 1316.59, all exhibits identified in my prehearing statement were timely submitted as prospective exhibits in advance of this hearing, and I have confirmed their authenticity and accuracy and my reliance upon them.

So I move for the admission of Exhibits 1 through 51 into evidence.

JUDGE JULIUS: Any objection to exhibits Dr. Drum 1 through 51?

MR. SWAN: Yes, Your Honor, there is no objection through -- for the Exhibits 1 through 29.

JUDGE JULIUS: Uh-huh.

MR. SWAN: But we do have objections for the for the remaining ones.

JUDGE JULIUS: So 30 through 51?

MR. SWAN: That would be correct, Your Honor.

JUDGE JULIUS: And what -- is it the same objection to all of them or different?

MR. SWAN: So the first one, no, but

the -- the remaining is going to be the same -- the same two.

JUDGE JULIUS: Okay. And what are the objections?

MR. SWAN: So the first one for Exhibit 30, Your Honor, the State would object based on relevance, Your Honor. It appears that Exhibit 30 is a -- a website that's purporting to allow an individual to look up a recall of marijuana.

We would -- we would argue that at this point, given that this hearing is determined to -- I'm sorry, this hearing is for the focus of rescheduling of marijuana, the idea of looking up which marijuana was recalled, and specifically in California, we would argue that that's not relevant at this time.

JUDGE JULIUS: Can you explain what the purpose of submitting the website copy was?

DR. DRUM: Certainly. Again, as a pharmacist, I'll relate as to what I have to do as a pharmacist when a recall occurs, and I will then relate as to what the marijuana industry is doing at this time with those recalls. It's not consistent.

JUDGE JULIUS: Anything further on that

one?

MR. SWAN: Not for Exhibit 30, no.

JUDGE JULIUS: Okay. I'll go ahead and admit it, but it can go to weight.

MR. SWAN: Okay.

JUDGE JULIUS: Thank you. And then 31 through 51?

MR. SWAN: So 31, 32, 33, 34, 35, 42, 43, and 47 all purport to be the actual recalls. So, again, it's websites in which you can go and actually look at to see the actual recall.

Your Honor, we would argue that pursuant to Rule 407, this is a -- a subsequent remedial measure, that Rule 407 specifically intended to keep this information out. A recall, it -- we would argue that a recall is a remedial measure that is -- you know, that should not be admitted at this time, Your Honor.

So Exhibit 30 is the actual portal, but then 31, 32, 33, 34, 35, 42, 43, and 47 are each different recalls, and we would argue that those are remedial measures.

JUDGE JULIUS: Okay. Give me one second. Let me look at the language. So you're talking about Federal Rule of Evidence 407 regarding

subsequent remedial measures, evidentiary rule preventing parties from using evidence of later changes or repairs to prove that a defendant was negligent or at fault for an injury?

MR. SWAN: That is correct, Your Honor.

JUDGE JULIUS: Okay. I mean, the Federal Rules of Evidence aren't strictly applicable in these proceedings. They can serve as a guideline. So, sir, what is the purpose that you're submitting these documents?

DR. DRUM: The purpose is to let you know that the states are not truly regulating like they claim. In fact, I show you what they claim to be doing with mandatory recalls, and then I show you the examples of them not following through with their claim of mandatory recall.

Again, these are things that are readily available on the internet, sir, and they also will -- will display how these materials are hazardous. And, again, as a pharmacist, I have to relay I -- I receive, sir, on -- on a daily basis recalls from the FDA for medications -- and this is in my testimony -- and have to respond to them appropriately.

I have to ask the patient back for their

medications if it's a Class I or Class II recall and make sure that the public is being properly warned and -- and we are -- are receiving appropriate actions. What I'm showing is is that's not occurring with the marijuana industry at this time, sir, and the public is left to -- with the exposures of -- of medications that are -- that are hazardous.

And I could -- I'll -- I'll be able to explain and show you the length of time it's taking for them to respond, and that's completely inappropriate. Six months later is when they -- they put out their warnings, and those products are consumed by that time.

JUDGE JULIUS: Anything further -- further from the Government on that objection?

MR. SWAN: No, Your Honor.

DR. DRUM: If we're going to be leaving the Government -- the -- the states to, you know, protect society, they've been doing a very poor job.

MR. SWAN: I would object to that, Your Honor.

JUDGE JULIUS: Understood. Sustained.

So the -- the scope of Rule 407 is that

if a party takes a measure after an injury occurs that would've made their earlier harm less likely to occur, evidence of those measures is not admissible to prove negligence, culpable conduct, a product defect, or the need for a warning.

But generally, a court may admit this evidence if it is offered for another valid purpose such as impeachment, proving -- proving ownership, control, or the feasibility of precautionary measures if those are disputed.

I think here we're not really looking at issues of negligence or culpable conduct. We're looking at, in a sense, precautionary measures because this is a -- a rescheduling hearing.

I'll overrule the objections and allow the -- the evidence that's been identified in, but it'll go to weight based upon the testimony and -- and how it proceeds from there.

MR. SWAN: Very well, Your Honor.

JUDGE JULIUS: Sure.

MR. SWAN: And there's 36, 37, 38, 39, 40, 41, 42, 45, 47, 48, 50, and 51.

JUDGE JULIUS: Okay. And what is the objection to those?

MR. SWAN: Your Honor, we're going to be

objecting based on Rule 403, the excluding relevant evidence for prejudice, confusion, waste of time, or other reasons.

Your Honor is inclined to -- to admit it based on the relevance of it, Your Honor. However, these exhibits are comprised of newspaper articles. These articles and the opinions therein are not coming from a source of reliability. Exhibits 1 through 29 that the Government is not objecting to are all published research articles, and we -- we understand that those have reliability to it.

Therefore, these -- these articles that Mr. -- I mean, Dr. Drum is purporting to admit, they have not been reviewed by peers in the industry, to my knowledge. The Government is not in a position to cross-examine them or the -- the authors.

We do believe that admitting them would do more confusion than harm, and that is exactly what Rule 403 is trying to prevent. How do we know that these authors did not have a biased opinion when they wrote these articles? Again, it goes more so to the reliability and the fact that we cannot effectively cross-examine the -- the

author or the actual article.

I understand with the -- again, with the -- the ones that are published, they've been peer tested. They have been peer -- peer reviewed, so there is some reliability there. We don't think there's reliability with these exhibits, Your Honor.

JUDGE JULIUS: Would you like to be heard on the objection, Dr. Drum?

DR. DRUM: Again, it -- it is out in -- and -- and -- it is out in the public. It's public information that's been, again, countered by the industry. And it's the truth. It's the truth that I see in patients and -- and know to be true.

The -- the phytoremediation is in a peer-reviewed journal, sir. And that's one of those -- those articles.

And so these are -- these are -- these are documents to -- that -- where the industry is purporting one thing. This is what -- what is being seen in the public. And so, you know, again, I -- I'm saying this is -- this is what we're seeing. Unfortunately, yeah, people haven't collected that data into studies. The ones that I've -- I've provided, there are -- there are

plenty of other studies, and I'll talk about that, discussing the harms. But these are the ones that I found that were -- that are, you know, indisputable that these are -- are occurring in society.

JUDGE JULIUS: Anything further from the government?

MR. SWAN: Nothing further, Your Honor.

JUDGE JULIUS: I understand the nature of the Government's objection. I think it goes more to weight. Certainly, based on the inability to cross-examine, if you think there's bias, things like that, the Government is free to make those arguments with regard to weight that should be afforded those documents.

MR. SWAN: Thank you, Your Honor.

JUDGE JULIUS: Any further objections?

MR. SWAN: That will be all.

JUDGE JULIUS: Okay. Thank you. So 1 through 51 will be admitted over the objections as noted.

(Whereupon, the above-referred to documents were received into evidence as Dr. Drum Exhibits 1 through 51.)

JUDGE JULIUS: Anything further before we commence with direct testimony from Dr. Drum?

(No response.)

JUDGE JULIUS: Hearing nothing, Dr. Drum, if you would please come around to the witness stand. And watch your step there.

DR. DRUM: Okay.

JUDGE JULIUS: And before you're -- before you're seated --

DR. DRUM: Yes.

JUDGE JULIUS: -- if you could please raise your right hand.

WHEREUPON,

DR. PHILLIP A. DRUM

was called for examination and, having been first duly sworn, assumed the witness stand, was examined and testified as follows:

JUDGE JULIUS: Thank you very much. You may be seated.

As I said, I'm not going to make you ask yourself questions, but you will have an opportunity to be cross-examined by the Government.

DR. DRUM: Yes.

JUDGE JULIUS: So they will ask you

questions or have an opportunity to do so. When it comes to that time, please wait until the entire question is asked before you start your answer.

DR. DRUM: Okay.

JUDGE JULIUS: And if you don't ever understand a question that you've been asked, just state that you don't understand the question. The attorney will rephrase it in a way that you do understand. If you answer a question without saying that you don't understand the question, we will assume that you did understand it.

DR. DRUM: Very good.

JUDGE JULIUS: Sounds good. I believe it looks like your PowerPoint is up on the screen both in front of you and on the monitor behind you, so the Court can see it.

If you would, please, just state and spell your full name for the record.

DR. DRUM: My name is Phillip A. Drum, PharmD. It's P-H-I-L-L-I-P A D-R-U-M.

JUDGE JULIUS: Thank you, sir. And please feel free to begin your presentation whenever you'd like. If, for whatever reason, you would hear the word "objection" from the Government, just stop. I'll address the

objection, and then we'll move from there.

DR. DRUM: Very good.

JUDGE JULIUS: Okay?

DR. DRUM: Thank you.

JUDGE JULIUS: Thank you.

DIRECT EXAMINATION

DR. DRUM: So if I can have the next slide, please.

Okay. I would like the Court to know that I'm here today at my own cost. I own no stock in any pharmaceutical company and have no financial interest in today's hearing. I have even had to use vacation time at my place of work to be here today and tomorrow.

All of my opinions are based on the federal definition of marijuana, okay? 21 U.S.C. 82 -- 802(16)(A). Okay?

Exhibit 1, sir, Your Honor, is my CV. I -- I have been a California licensed pharmacist for the past 40 years. I attended UC Davis for two years, followed by four years at UC San Francisco School of Pharmacy. I next performed a residency in hospital pharmacy practice for one year.

I then worked several years as an

inpatient hospital pharmacist with a -- a practice specialty in oncology. Then I moved into pharmacy management and ambulatory care practice at a VA for 11 years, for actually multiple VAs. Most recently, I have worked the past 20 years as a clinical manager and a senior inpatient pharmacy consultant.

I have been active in teaching pharmacology to multiple healthcare professionals across multiple colleges. I have been active in support of safer roadways for supporting state safety bills. I also received ARIDE training, which is Advanced Roadside Impaired Drug Enforcement from law enforcement.

I was appointed to the California Highway Patrol Impaired Driving Task Force and given multiple presentations on the impact of marijuana and driving.

Your Honor, at this time, I tender myself as a provisional expert in the field of hospital pharmacy practice with vast knowledge in the area of marijuana and impaired driving.

JUDGE JULIUS: Consistent with the Court's preliminary order, I will go ahead and accept the provisional expertise, which will be

subject to challenge in the closing -- written closings by the other parties. But please go ahead and continue, sir.

DR. DRUM: Understood.

Next slide, please.

Okay. The reason why I'm here today is to argue that there's no current scientific indication or medical use for a plant-based marijuana product. I'm raising this point since the FDA has not approved a marijuana product drug -- again, the entire plant -- nor produced the package insert for one of -- a medical indication for marijuana because the scientific data has failed to support it.

Marijuana is comprised of over 100-plus cannabinoids and 200 terpenes, which provide scent and flavor, and flavonoids providing color and antioxidant activities, a so-called need for elements to -- to create a controversial and unproven entourage effect.

Many of the claims of -- of the individual chemicals' actions are in early-phase studies in animals or cell lines and not near the phase 3 human studies. As you know, there are three pillars of -- to the controlled substance

levels: abuse potential, accepted medical use, and dependence. Without proven medical use, marijuana must stay as a CS I because the difference between a CS I and II through V is the -- that medical indication for use.

Next slide, please.

I feel that we're putting the cart before the horse here. We're changing the -- the CS status, the horse, and then we're going to get the FDA approval second. This is -- in my 40 years as a pharmacist, I haven't seen this happen. I'm not aware of this happening.

In fact, in 2018, the second cannabinoid, CBD, known as Epidiolex, was FDA approved when the initial recommendation was for it to be a CS V substance. Following the FDA approval for pediatric epilepsy, it was later changed to not a controlled substance by the DEA.

Plants are not medical therapy in the United States. Herbal medicine has been used elsewhere, but pharmacists do -- do not dispense whole plants as medicine in the U.S.

There are individual active chemicals/molecules that come from plants that are made into medicines. That have -- that has been

the practice in the -- in the United States. Why? Well, because there are multiple components to the plants that may be harmful and are unnecessary and interact with other drugs, and other external items may be easily added to plants, such as bacteria, chemicals, mold, and fungi that make them dangerous.

I will go on to discuss the adverse effects and risks associated with marijuana products, hopefully address some that you may not have heard already. I know you've heard many people speak already, and I -- and I've seen your warning about not repeating yourself, so hopefully I will not do that for you.

I will discuss how researchers are able to perform research on CS I despite the claims that they cannot, and compare the amount of studies and costs of these studies to other drugs. I will discuss many of the failures of the current state-run marijuana programs placing Americans at risk and the potential way forward that could help address many of these questions.

Next slide, please.

Botanical drugs approval require the same rigorous clinical trials and manufacturing

standards as conventional drugs. We -- we need this. It's very important. There are many drugs that are plant-based, and some have been designated as over-the-counter even, like cascara, psyllium, and senna, but they're not the entire plant. These been -- have been recognized by the FDA as being safe and effective and are OTC products.

Next slide, please.

The delivery of -- so the -- in 1906, we had the Food and Drug Act. The delivery of smoking a carbon-based carcinogenic plant as a medicine is not consistent with U.S. medicine. In 1906, the Food and Drug Act -- and, again, just to step back, you know, tobacco is not a medicine in -- in -- in the United States. It was purported in the past, but, again, we clearly know that it's not.

The 1906 Food and Drug Act was passed by Congress and signed by Theodore Roosevelt to prevent the manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious food, drugs, medicines, and liquors. What is being proposed by HHS is a step back to the days before the FDA.

We have allowed the public to vote on

what is medicine based on intentional misinformation from a group who has had a history of providing addictive substances for profit. We have been studying marijuana for multiple decades and have the evidence to prove this is not a safe medication.

Normally, a pharmacist receives an FDA-approved package insert to be able to assess the appropriateness of the medication. I'll talk more about this shortly. It's our duty to assure the medication and dose is appropriate for the patient and properly counsel the patient on the proper use, storage, and monitoring issues.

Next slide.

Again, this is not U.S. medical therapy. I -- I don't hand over periwinkle plants. Periwinkle plants do contain vinca alkaloids that I used in chemotherapy.

The next is eucalyptus. We know that there are cough and cold preparations that come from eucalyptus.

Digitalis foxglove is the next one that we can -- we've created digoxin, an antiarrhythmic and -- and heart agent from.

And the Pacific yew tree there at the

end, I was in practice at the time when -- when those plants were actually being harvested for Taxol, and -- and they were becoming short-lived because people were going out and cutting them down to make the Taxol before the -- before it became synthesized. Again, Taxol is used as chemotherapy in -- in patients.

The whole plants are not used as medicine in these cases. The active molecule is removed from the plant and later usually synthesized for the active chemical.

Next slide.

This is not a route of administration for medication, again, but it is burning a carbon-based compound that's -- that is -- that is not the route of administration for medication. Common routes of the flower or concentrates are to be administered by this route.

These methods generate toxic chemicals by burning the carbon-based plant materials and which others can also breathe in through secondhand smoke. This is also especially concerning for other people around, especially children in the households.

So, again, what we see here is a joint,

we see here a bong, and then we see here at the end a blowtorch in which they're -- they're heating the high concentrates of THC.

Next slide, please.

This is from a medical marijuana state store only. This is from Arkansas. And you can see the various products that are available then in a medical marijuana state. And so notice the categories of products available, proposed medicine: flower form, vaporized form, concentrates, edibles, tinctures, and topicals.

As you can see there, the RVR flower is 31 percent THC. As you undoubtedly know, the standard marijuana was 0.5 to 2 percent in the 1960s of THC. The Deli-style flower is listed at 26.4 percent. The maximum FDA provided medication, medical marijuana product, has been half of that value. I'm talking about those that are coming out of the Mississippi lab.

So about 13 percent THC or less is what they've been providing and what the researchers have used in their studies. They are not using the vape pen-provided concentrates that reach 80 to 90, up to 99 percent THC.

Next slide.

This is also available -- readily available on the -- on the internet as products that people are selling. And these -- the industry has been selling and continues to sell these products with very close names that are normal to candies or food and can easily be -- lead to confusion in small children.

Not only these products, you can see that they don't contain childproof caps like what I have to provide as a pharmacist when I'm dispensing, you know, dangerous medications to -- to people. And as a result, we -- we've seen many issues with children accessing these products.

Next slide, please.

Again, now I'm going to go into -- again, we have no Food and Drug approval for marijuana currently.

Next slide, please.

A pharmacist, a provider, a nurse, or patients or caregivers need the FDA-approved information to be able to accurately dispense, prescribe, and administer a medicine, especially a controlled substance.

So what's in the package insert is what

I have listed here, things like indication for use, description of the active molecule, the clinical pharmacology of that molecule, the pharmacokinetics of that active ingredient, the absorption or bioavailability of that product depending on the route of administration, the distribution. So that's how it gets distributed throughout the body, that active ingredient. The metabolism, how that product is being broken down. The elimination out of the body, whether, you know, through GI route or urine or other methods. The dose of the active ingredient is in there.

The route is then specified that this is oral or this is topical. The frequency is specified. The adjustments that may be necessary depending on the type of patient, so things like children or people with kidney failure or hepatic or liver failure, how to adjust the dose.

Can -- is it safe in pregnancy, and can you give it to a pregnant woman? That information is in the package insert. Adverse effects. The clinical trials that were used to approve the drug are also listed in that package insert, so I can review them to see the types of trials that were used to then create those indications that created

the approval.

Again, contraindications, warnings, precautions, drug-drug interactions are listed on this package insert. Overdosage management is in this package insert as well as how to store the product, and there usually is a section, too, maybe on patient instructions on how they can take it and understand -- not the -- not the medical use that's in the rest of it.

Next slide, please.

So, again, these are true of what I call medical marijuana products. Again, what this is, is they're -- we're showing a picture there of the tablets, the gel form caplets, if you will, of dronabinol, which is also known as Delta-9 THC, I'm sure you're aware.

One thing that -- that's interesting to note is that dronabinol itself is in two different classes of controlled substance. Syndros, the liquid version, of 5 milligrams per mL, is a CS II, whereas dronabinol, the oral tablet, is a CS III.

And I'll tell you more about this later because that's very interesting, that the DEA has already made that designation that it's different because liquids tend to be absorbed quicker than

oral tablets. Oral tablets must be broken down in the -- in the stomach before it's released into the intestines, which then it begins to get absorbed. So you reach peak levels much faster with liquids than you do an oral tablet, okay?

And, again, stomach acids also break down then the product, too. So, again, I'll talk more about this later.

The smoked marijuana, if truly is -- is deemed to be a drug, which it hasn't, is actually closer to the pharmacokinetic absorption characteristics to a liquid version of THC than the solid. The -- so a CS II would be potentially more appropriate level for marijuana because of its rapid absorption.

It also, if it's smoked, goes in through the lungs. It does not go through the liver where the metabolism occurs. And so it goes right then up to the brain and other parts of the body without that first pass metabolism that oral products undergo, okay? And, again, I'll talk a little bit more about that later.

So, again, it's those -- those elevated levels that tend to lead to the adverse effects and -- and addiction potential in people, too.

Next slide, please.

So this is the package insert of -- of Syndros, again, readily available out on the internet. And, again, just to point out, you can see there I highlighted this is a CS II and -- and this was revised as of 2020. This is the latest version that I found on the internet. And other drugs that are approved at multiple controlled substance status level is codeine.

So, again, Ty-Co Number 3s and 4s or Tylenol with codeine Number 3s and 4s are -- are a CS III. But when codeine is above 90 milligrams, it becomes a CS II. So there are many substances. There's more than 10 other substances that cross multiple controlled substance levels. So please don't feel that because it's Delta-9 THC, but, again, they're claiming other components are necessary, that it needs to be a CS III like dronabinol is.

There are many drugs that are multiple levels, okay? And so things like the barbiturates, amobarbital, pentobarbital, secobarbital, they cross the CS II and CS III levels. Okay? So barbiturates do this as well. Dextropropoxyphene does this. It's a CS II or a

CS IV. Again, depending on dosing, depending if it's added to other products, that tends to bring the level down because providers know they can only give, for example, with Tylenol with codeine, so much acetaminophen in a day; otherwise, it damages the liver.

So that's why -- that's why it's been put in a lower class, because the -- they've limited the amount of codeine, but also the doctors know they can't over-prescribe it.

This is what happened with oxycodone, for example. Percocet, before it became oxycodone by itself, Percocet had the limitation, having acetaminophen with oxycodone. When they pulled out the oxycodone alone, that's when we hit the fan and had problems in the 1990s, then on, because now it wasn't being protected by having the acetaminophen in it.

Percodan was the same way. Percodan had aspirin with oxycodone, but once they pulled that oxycodone out alone and claimed that it wasn't addictive and could be used for pain at all levels, that's when the usage went through the roof because there was no cap on it like there was with Percodan and Percocet.

Providers knew they couldn't give too much Percodan and Percocet because of the acetaminophen and aspirin. Get it?

So, again, there's other products. Again, GHB is a I or a II -- or a III. Sorry. LSD precursors by itself is a I, but it's also a CS III. So there are multiple products that cross controlled substance levels.

Next slide.

And so with my example that I showed you previously, 10 milligrams is the largest size of dronabinol. Actually, you know what? Did I miss something? Actually, I did. If we could go back -- sorry. Is that okay?

JUDGE JULIUS: Yeah.

DR. DRUM: Go back two slides. I missed -- I missed the bottom portion of -- one more slide. That one.

Just to add, again, we know that the FDA-approved indication is increased appetite from HIV weight loss, not general anorexia. Again, nausea and vomiting associated with chemotherapy for dronabinol.

Nabilone, which is Cesamet, it's also now been around so long. Again, these drugs came out

in 1985, so they're generic, but it's really no longer used in the United States. That's a CS II. It's a cannabinoid that's a CS II.

Cannabidiol, again, as we -- as I mentioned, in 2018 was approved. Again, it was originally coming out of the FDA as a CS V, and, again, that was then changed to a non-controlled substance. Again, that's available as a liquid and, again, it's for those three indications listed there.

Next slide.

And the next slide again. Sorry for that.

So what's the equivalence of an FDA-approved THC product to one of these, you know, products that they have out on the internet? So here's an example of 42 marijuana approved products or marijuana medicine that I -- I consider, you know, medical marijuana is Delta-9 THC -- is 10 milligrams, and it takes 42 of them to make that one bar, the 420 bar that's listed down there at the bottom. That bar contains 420 milligrams of THC.

In California, and I'll talk more about this later, they claim to have a serving size of

10 milligrams. So that would mean that there has to be a designation for what is 10 milligrams in a bar, and in this case, they would have to have 42 designations to identify those 42 individual 10-milligram doses. Again, I'll talk more about this later.

Other issues are things like cookies that -- that it's being placed in. And, again, who eats a tenth of a cookie? So people then are easily able to consume the whole cookie, especially children, and not knowing that they're getting a 100 milligrams worth of THC.

Next -- next slide, please.

Again, we have no FDA-approved products for -- or package inserts for any of these products. Again, these things are available on the internet.

So this is ganja gum. Again, bioavailability differs on the way that a drug is administered. So something that's a gum that's kept in the mouth is kind of more like an oral, sublingual version, if you will. And the sublingual versions, again, bypass that first pass effect going through the liver, can get absorbed in the mouth, and then can go back up to the --

you know, goes to the heart, then back up to the brain, and goes throughout the body.

There are tampon products that are out there with THC in them. Again, the vaginal route is a -- is an approved route for administration of medications, especially commonly over -- overseas. But they've placed THC in -- or -- or components of marijuana into tampons, into inhalers that look like normal medication products that are inhaled, and those last three there are transdermal patches.

I know it's small, but, again, it's -- and it's various types: CBG, THCA, THC Indica patches that are placed on. Again, we know that -- that those are -- are readily -- we have estrogen patches, testosterone patches.

So, you know, medication is absorbed, especially fat-soluble medications, are absorbed through the skin. Again, they're going to bypass that first pass effect as well. But the skin typically acts as a very good barrier from absorbing too much chemical into the body, and it also starts getting metabolized as it's going through those routes.

Again, the more dangerous ones are the

ones that are in the mouth and those inhaled products. So, again, they avoid that first pass liver effect, too, unlike the oral agents, and they tend to then be -- you give them in -- in smaller doses because, again, the dose could be very large.

Next slide.

Okay. So this is now Exhibit Number 2. On page 5 is Figure 1. And, again, I'm sure you've heard this already, so I don't want to belabor the point, but the THC content has been rising over time. And that's what -- that horizontal axis is years starting in 1995 and going to 2012. And then on -- on the vertical axis is the THC content in percent going up over time.

What's interesting, though, I see, is what happened over those time periods as well. Okay? So in 1996, in California, it was approved as a medical product. So back then, you could see it was around 4 percent THC. Again, these were products that were taken in by the DEA, and this is reported by the DEA ,what were the percent THC at that time.

So prior to 1996, the DEA was saying marijuana is about 4 percent. Okay? Seventeen

years later, in 2012, we know the first two states then approved marijuana recreationally, and by 2012, the THC content being captured by the DEA had tripled, up to 12 percent by that time.

Why did that happen? Well, again, I would propose that, again, in 1996 we had medical marijuana, and they quickly found that that wasn't controlling the people at those lower amounts, and they began synthesizing it, and we started seeing then other medical problems come about.

In 2004, we started seeing things like the cannabis hyperemesis was being -- was being seen, first papers in Gut coming out in 2004, because, again, they were now starting to create very high THC content to keep these people on the marijuana products because they were -- it -- it wasn't working. It wasn't as effective anymore if they -- they kept them at the low THC percent, and they had to continue to rise -- raise those levels.

This is now seen as well over time in the other graph that's seen on page 5 of Figure 1 that is showing the emergency room visits for marijuana, cocaine, and heroin. Okay? And so you could see then over time, the marijuana values alone in red were -- were continuing to increase

every year, again, the emergency room visits for marijuana. The blue bars are the -- is when it's being used in combination with other products, and you could see those are going up as well.

The next area is the -- the cocaine use that's been seen in emergency rooms. And, again, you can see that it's kind of gone up and gone down, and -- and it kind of vacillates. And you can see then it's also being used in combination as well, the blue bars.

Finally, heroin is there at the end, and you can see that heroin has been a very slow climb up over time. And, again, the combination products, the combination is -- is seen as well.

But only marijuana was associated with a statistically significant increase in the number of visits during this time period. There was a 62 percent increase when used in combination and 100 percent increase when being used alone.

Next slide.

Okay. So I usually do this as well. You're -- I probably can buzz through this really quick for you because I think you understand this quite well. But, again, something that I would do to the lay public to get them to understand,

you know, what was that old marijuana like? And I usually relate it to -- to alcohol because the -- the industry loves to compare themselves. You know, we're like alcohol. Let's treat us like alcohol. And so I do. And -- and so, again, that old marijuana was like a Budweiser. Okay? Again, nothing against Budweiser. I'd put any standard beer up there. But it was like that, whereas the new marijuana is more like Jack Daniels.

The 20 percent THC in a joint is much higher than the 0.5 to 3 percent, which was in those original joints back in the '70s. Okay?

And so then they created a product called butane hash oil, and they started creating this product in the late '90s in -- in larger quantities, again, to be able to keep these people on the marijuana products, and that's more like Everclear, which is 90 to -- a high percentage of -- of -- percent alcohol. That's what your BHO or butane hash oil is really like.

And they have these creative names: shatter, wax. They call it snake tails if they put it on top. They put the BHO on top of a -- a joint.

Again, some of the estimates that are out

there on the internet state that 64 joints are equal to 4 blunts, which is equal to 1 dab of -- of 80 percent THC. Again, the -- the -- the weight of these dabs is very minuscule in that it takes 50 dabs to make the weight of one penny. So that's how small and light these dabs are. Okay?

Next slide.

Again, GRASE products. I'm sure you recognize this as well. These are generally recognized as safe and effective. Once marijuana is made a CS III, will it be conferred as having current medical use? Is the next pillar that we're going to then take it out of the controlled substance status and allow the industry and others to use it? Will it become the next drug like hemp?

Again, as we saw what happened to hemp in 2018 is that in the Farm Bill it was then moved, hemp and any of its metabolites, which tends to be CBD, and then they -- they convert it by using chemicals to other active metabolites, some that are even more psychoactive than Delta-9 THC, by the way.

And so, again, these are sold now. They -- they are -- have been deemed by the government as being GRASE products, generally safe

and effective. And, again, they're sold in gas stations all around -- around the United States at this time. And so, again, GRASE products really to me are, again, over-the-counter products like Tylenol, Omeprazole, aspirin, ibuprofen, cough syrup. Those are GRASE products in my view.

In Europe, these products are only sold in -- in pharmacies. They're not sold in gas stations there. They're sold -- if you've been to Europe -- I've been to Europe a few times -- you see the green signs, and you know that's where you have to go to get, you know, Tylenol and other products like that.

Next slide.

What I'd like to do now is shift gears a little bit and talk to you about the first patient that I experienced with the use of a cannabinoid, which was dronabinol or Delta-9 THC.

As I mentioned, I was an oncology pharmacist. And, again, most people don't understand what it is that I do. My parents didn't even understand what I did. I worked in a hospital, and I had various roles, but one of the things I would do is I would go on rounds with the oncologist. So when he saw the patients, I was

right there with him.

And so when we wanted to use -- well, the physician wanted to use dronabinol on a patient. And so I said, you know, you got to be careful doing this. This is our first patient, and let's start it with 2, 2-1/2 milligrams, the lowest dose. Again, 2.5, 5s, and 10s were dronabinol back in the day.

This is 1986, just approved in '85, and -- and so we gave it to a cancer patient that was receiving Adriamycin, which I'll show you in a bit is very what we call emetogenic, highly nausea and vomiting inducing, and was being used in breast cancer very commonly, and still is today. Call it red death. It's just -- it's horrible.

And, again, we gave the 2.5 milligram dose to this patient, and it caused hallucinations. The patient said --

MR. SWAN: Objection.

DR. DRUM: -- and I was in the room at the time she said it.

JUDGE JULIUS: One second. What's the objection?

MR. SWAN: Hearsay, Your Honor.

JUDGE JULIUS: Understood. But hearsay is admissible in administrative proceedings. It'll go to weight.

MR. SWAN: Very well.

JUDGE JULIUS: Thank you. Please continue.

DR. DRUM: So, sir, I was in the room at the time the woman said it, so it's not hearsay. The patient said it, and I heard it.

And she said, quote, "I would rather throw up all night than experience that again," that she was experiencing hallucinations. When I asked the nurse what happened, she said there were dancing elephants on the wall according to her. And so she was experiencing hallucinations.

Again, another part of my role that -- I had the immune-compromised patients on my floor. So back in the day, again, we're talking 1986, prior to AZT even coming out in '88, I had the AIDS patients on my floor. Many of them had cancers as well. And so they were immune-compromised. And, again, I know how to treat immune-compromised. So did the nurses that then cared for those patients.

So they were on my -- my floor, my

nursing units that I covered. And so with that, I did see some dronabinol use.

I could tell you from my experience, for AIDS wasting syndrome it was not very effective because, I think in part, I only saw them for a short period of time when they were in the hospital. And so we were treating them for their -- their, you know, their cancer that they may have developed. And, you know, we were just trying to save them.

Again, we didn't have the drugs like we have now for treating AIDS. And that came out in the mid-90s, and I treated patients with that. The protease inhibitors revolutionized how we treat AIDS patients. And there's really not a need anymore for dronabinol in those patients because we don't see that AIDS wasting syndrome, the cachexia like we used to see. Again, I saw that.

Again, I was in school in San Francisco from '82 to '86, and so, you know, I -- I was on units and saw those patients and know exactly, you know, what -- what, you know, I was -- I was seeing there. And we had no drugs at that time. AZT came out in '88. More drugs came out in the early

90s. And, again, I'm experienced in -- we're using them.

Since then, since I've gotten out of that practice, more drugs have come out, and it's -- it's much better controlled. It's almost like diabetes now. It's amazing.

Next slide.

So what I'd like to hear -- hear today -- this is Exhibit Number 3. This is from ASCO guidelines, or the American Society of Clinical Oncology. This rates the risk of chemotherapy agents that cause nausea and vomiting and the agents to use to prevent or reduce that nausea and vomiting.

So page 3 has this statement that -- that you see here on the slide. And this is again, in -- in 2020, "Cannabinoid use as an antiemetic agent for chemotherapy nausea and vomiting. Evidence remains insufficient for a recommendation to use medical marijuana" -- again, we're talking about the smoke versions -- "for nausea and vomiting for chemo and radiation. Evidence is also insufficient for using dronabinol and nabilone for nausea and vomiting caused by chemo and radiation." So they're very clear that we

don't even recognize this product.

Well, later on, on page 3, lower down, it discusses the breakthrough nausea and vomiting. It says that for those who still use -- who experience nausea and vomiting despite optimal prophylaxis that the only other area of potential use of dronabinol and nabilone use is only after trying the -- another agent, olanzapine.

The evidence quality for that recommendation is intermediate quality as determined by the use of -- of the group creating the document, and the strength of recommendation is moderate, not strong.

So the bottom line is no use of medical marijuana is still recommended. Even the FDA-approved dronabinol is a last resort to consider in breakthrough nausea and vomiting after other agents have failed. Why? Because we've gotten much better agents since 1985 when dronabinol was approved.

And I saw that with the -- with the agents that started coming out in the early 90s. We started getting other products that have much lower side effect profile. Again, remember the hallucinations in my patient. And I'll talk more

about that incidence of hallucinations later.

Next slide.

So this is also from Exhibit 3. And, again, if you look at this -- this chart -- this is -- this table -- Table 3 on page 9 and 10 is Table 3 on the recommendation of agents to use as antiemetics for nausea and vomiting for specific chemotherapy drugs.

So based on the emetogenicity of the agent, these are the products then that you should use for nausea and vomiting is what's on here. Okay? And if you look through this, you do not see dronabinol nor nabilone listed.

So, again, it just reiterates what I just told you is that we don't use this commonly at all anymore. Potentially for breakthrough is the only time that they would ever consider using dronabinol. So it's not used for highly emetogenic, it's not used for the moderately emetogenic, or the low emetogenic agents. Okay?

Next slide.

Next slide is Exhibit 4. I, as a pharmacist, have a duty to warn about drug-drug interactions with THC, and this is a -- an article that's specific for THC. I'll talk about CBD next,

which is also found in -- in marijuana.

So this is Exhibit 4. Figure 1 on page 5 is this table here. And as a pharmacist, I have a duty to warn the patient and provider and prescriber about specific items.

One of them is about the drug-drug interactions. And so if I'm seeing the patient's medical records and seeing the other medications they're on, I need to warn that provider based on the dose and things that he's using how we may -- what we may need to do to avoid these interactions, and there are many.

So those are -- there are some that may increase the THC effect, so it increases the likelihood of side effects from -- from THC. These drugs include AIDS drugs, antifungals, blood pressure meds, over-the-counter stomach medications, and chemo. So they can increase the THC effects.

There are those drugs that decrease the THC effect and makes the THC then seem less effective or potent. These include seizure medications and diabetes medications.

Then there are meds that the THC will impact, and they will make the other medications

less effective. And so these are things like blood thinners and cholesterol-lowering agents like simvastatin. So those drugs then don't work as well as we were anticipating them because THC is interacting, affecting what we call the enzymes that are then metabolizing them, and stimulating them to then chew up those drugs quicker.

They also increase the effect of other drugs, too, by leading then -- then to side effects. So these drugs then become more potent, if you will. And so those drugs include opiates, antidepressants, seizure meds, over-the-counter stomach meds, and the blood thinner warfarin, and that's very dangerous because warfarin, if it becomes more effective, it now leads to bleeds, and somebody could have a -- a cerebral bleed and have a stroke, essentially.

Next slide.

This is the same with my duty to warn about drug interactions now with CBD. So this is Exhibit Number 5, Table 2 on page 5. CBD is another common cannabinoid, again, that's in -- in the marijuana products, that also has several drug-drug interactions just like THC. It's also being used over the counter now that hemp is

federally approved. But it's also in the medical marijuana product. CBD is in there. It's one of those 100-plus cannabinoids, right?

So antifungal heart medications and antiemetics make the CBD readily more absorbed and can lead then to increased CBD side effects. Those side effects I'll go over shortly, but one of the most concerning ones is hepatic damage, so liver damage.

So if you're giving them this dose, it becomes this dose higher, and now it can lead to liver damage and other CNS side effects that are caused by CBD. Central nervous system side effects. Sorry, I'm, like, dropping in some medical terms here.

Some decrease the CBD levels, like seizure meds and AIDS drugs will decrease the CBD levels, making the child then that's using CBD more prone to having a seizure because now, instead of the level being here, it's going to drop, and the person -- now the child's going to have seizures that the CBD is not going to work for them in Dravet or Lennox-Gastaut.

Some medications increase the levels and, therefore, increase the side effect

risks -- are being raised by CBD. And so those include chemotherapy, antipsychotics, opiates, and statins. So, again, their levels go up when CBD is around. And, remember, CBD is only one of the many cannabinoids stated to be necessary in the medical marijuana products that are in unknown amounts in the marijuana product for that entourage effect.

I suspect that there's going to be many, many more drug-drug interactions with -- with cannabinoid number 3 through 100-plus. And, again, we don't know about the terpenes and the other flavonoids as well that may cause drug-drug interactions as well.

Next slide.

So, again, with that duty to warn, with -- with marijuana, again, I'm just reiterating that, again, 100-plus cannabinoids, 200-plus terpenes, and flavonoids. Again, it's an unproven claim that all chemicals are needed to produce the individual interactive and entourage effect.

So, again, if we know cannabinoid number 1 is THC and cannabinoid number 2 is CBD, what's the dose for cannabinoid 4 and 20? What's

the interactions with number 88? What are the -- what's the maximum dose for 92? We don't know. We have no package insert to tell us what are the drug interactions, what are the doses, what are the adverse effects.

So without that information, we're really handcuffed on being able to use these products. And we also know from the plants that there are various amounts of those other various products as well. It's not consistent.

Next slide.

So now I'd like to talk about some of the marijuana products and the adverse effect risk. Again, with -- these are the ones that, again, we -- we know about, the dronabinol, for example. So, again, my duty to warn is to warn about with oral dronabinol or Delta-9 THC, the adverse effects and -- pardon me.

Next slide.

And so I'm going to talk about now -- this is Exhibit Number 6. This is the package insert from dronabinol. Okay? And on pages 8 and 9 -- and, again, this -- this evidence was also present in the HHS document that you saw earlier. They -- they went over these adverse effects as

well.

But what's interesting to me is how they did not point out some of this information. And so I, as a pharmacist -- I don't understand what it means. What does 1 percent -- greater than 1 percent mean to you? To me, that could be 50 percent incidence. It could be 75 percent incidence. It could be 99 percent incidence or 1 percent incidence or 100 percent incidence, right? And so they didn't say that.

It says probably causal-related incident greater than 1 percent, and then lists a whole host of adverse effects: asthenia, palpitations, tachycardia, vasodilation, facial flushing.

Now, those that I just listed, those cardiovascular effects are very concerning to me if I have a -- if I have a, a heart patient because I don't want to be causing palpitations and tachycardia in a cardiac patient. In fact, typically we're giving beta blockers to slow their heart rate down, and here dronabinol will increase it and could potentially then lead to angina or -- or, you know, the pain, you know, in the heart type of sensation. And so that's very concerning. You know, the FDA is saying it's

greater than 1 percent.

What's also interesting on here is they do then give an asterisk and say the incidence of events is 3 to 10 percent. So clearly it's probably greater than 10 percent, because if it was 3 to 10, they would have asterisked it as such. You follow me? Okay?

So, again, abdominal pain, nausea and vomiting, dizziness is listed. Paranoid reaction, euphoria, abnormal thinking, and somnolence is the 3 to 10 percent range. But notice hallucinations is not listed as a percent, nor is anxiety, nervousness, ataxia, confusion, and which there's claims that we use it for anxiety, but yet this clearly shows you on -- the HHS document showed you that this is greater than 1 percent incidence.

Again, the other side, just for, you know, completeness sake, it says the incidence is less than 1 percent for the other types of adverse effects. But the side I'm most concerned with is that left-hand side going, whoa, really? Greater than 1 percent? What does that mean? Okay?

Next slide.

This is also in Number 6, Exhibit Number 6 on pages 4 and 10, that -- this talks

about the usual dose of dronabinol. Again, this is an oral. The dosage may be gradually increased to a maximum of 20 milligrams a day. Okay? So remember that number: 20 milligrams a day administered in divided oral doses.

So, again, 2.5 milligrams every 4 hours as needed for pain, not to exceed 20 milligrams, would be something like I would see as an order. Okay? Or 5 milligrams twice a day, not to exceed -- or 5 milligrams 4 times a day, not to exceed 20 milligrams, okay, is what a physician would write. Okay?

Okay. So now let's also look then for the other, the -- in the next section, the overdose section, which is defined as the estimated lethal -- lethal -- so they do acknowledge a lethal human dosage of intravenous dronabinol. And there is an IV THC product -- I'll talk more about that in a bit -- is 30 milligrams per kilo or 2.1 grams or 200 -- 2,100 milligrams in a 70-kilo person.

So, again, that's what we call an average person, although nowadays the average American is probably a tad bit more than that.

But look at the next line. It goes on to say, "Significant CNS symptoms in antiemetic

studies followed oral dosage of 0.4 milligrams per kilo." And they spell that out for you: 28 milligrams in a 70-kilo person or a 154-pound person. So they're saying significant CNS symptoms occur in somebody that gets 28 milligrams of THC. Okay?

So remember that number now: 20 milligrams a day, 28 milligrams is going to cause central nervous system, significant -- this is the FDA talking here. This is the FDA package insert.

So I'll show you later, marijuana in California, medical marijuana is deemed a 2,000-milligram product, is allowed, and I'll show you that -- that evidence. It's in -- it's in our -- it's in our documents in California. And, again, as I mentioned, 70 kilos is a 154 person -- a 154-pound person.

So 2,000 milligrams is 71 times -- 71 times that 28-milligram dose. Okay? And the 420 bar that I showed you, that's 15 times that 28-milligram CNS-inducing product. Okay?

So this is what's allowed in our current state-run marijuana programs. Americans are at risk, and they are suffering from it. We know

that we've seen, you know, mental health issues, driving crashes, and others as a result of allowing the states to continue to use this product in these huge doses that are completely inconsistent with what the FDA warned about.

Next slide.

Now, here's the duty to warn. Again, this is Exhibit 7. Pages 1 and 3 go into the damage that's seen with CBD. Okay? So these are the adverse effects, and this is something that I found a lot of people don't know is that there's a hepatic injury under warnings and precautions.

So, again, hepatic liver damage. So Epidiolex can cause transaminase elevations. Concomitant use with valproate and higher doses of Epidiolex increases the risk of transaminase elevations. See the full prescribing information for serum transaminase and bilirubin monitoring recommendations.

And so they recommend a baseline, and then they recommend it typically monthly or -- or maybe a little less frequently, but that -- you do have to follow this to make sure that the liver dysfunction is not occurring.

One of the concerning things that I have

with dronabinol is back in -- in 2018, they listed -- the FDA listed 17 post-marketing surveillance requirements for -- for CBD. Okay? Only seven -- seven of them are still outstanding. That's 41 percent are still outstanding today of those -- of those 17 concerns that they had, that they said, "You guys need to do post-marketing surveillance on this."

And the areas that are still outstanding is kidney and liver risk. Those are still outstanding. Animal embryo fetal is still outstanding, pre- and postnatal studies, animal toxicology, animal carcinogenicity, and use in pregnancy. Here we are eight years later and we still don't know the risks of that to patients, but the FDA has approved this drug.

Again, somnolence and sedation is listed as an interaction with -- as a -- as an adverse reaction to CBD. And -- and notice where it says, "Monitor for somnolence and sedation and advise the patients not to drive or operate machinery until they have gained sufficient evidence on Epidiolex." What does "sufficient evidence" mean to you?

JUDGE JULIUS: I think the word is

"experience."

DR. DRUM: Okay. Experience. I'm sorry. Sufficient experience.

JUDGE JULIUS: Just to correct the record.

DR. DRUM: Yes. So what does "sufficient experience" mean to you? Is that a day's worth, a week's worth, a month's worth? What does that mean? So it's very inconsistent and very unclear from the government telling the people, you know, until you gain enough sufficient experience to be able to drive.

We know from -- from THC studies that they cannot appropriately determine if they're impaired or not. There's Marcotte studies out of UC San Diego that state that. They think they're able to drive within 90 minutes, and they've been proven that they can't drive for hours.

Suicidal behavior and ideation is listed for CBD as well. Okay? And so, again, these -- these are the warnings that are out there, and, again, it goes into more detail on the other side on the hepatic injury and damage that can happen from CBD.

Next slide.

This was -- this was what I provided you about the concerns that I had with the dose of THC. So this is Exhibit Number 8, and if you go to page 80, you'll find this. This is the cannabinoid concentration limits in the state of California. "THC concentration limits in edible cannabis products shall not contain more than 10 milligrams of THC per serving." So there's that serving size, which is, again, I'll remind you, the maximum oral dose of dronabinol.

100 milligrams per package. So what they're talking about here, meaning you can have the 10-milligram gummy bears and have 10 of them in a package. Or you could have a cookie that's in a package, and it'd be all 100 milligrams. Okay?

And then, if you go further down, you'll read about how a cannabis or a cannabis concentrate may contain more than 1,000 milligrams of THC per package but not more than 2,000 milligrams of THC per package if the product is labeled for medical use only.

Now I go back to 20 milligrams a day from the FDA and 28 milligrams to cause the -- the CNS adverse effects. And they've allowed

2,000 milligrams of a concentrate to be used. Okay? And that's the shatter and wax and other things like that, right?

And so this -- if we're going to leave this back to the states to control this, we are putting our population at risk.

MR. SWAN: Objection, Your Honor.

JUDGE JULIUS: Basis of objection?

MR. SWAN: Your Honor, I understand that the witness -- I mean, Dr. Drum -- is reading from the exhibits that are already admitted, but I think the -- the commentary or the testimony leaving things to the states, that's outside of his expertise, that the Court has taken under consideration, and we're now talking about the legal enforcement of different states on marijuana. And I would -- I would argue that Dr. Drum is no legal expert at this point.

JUDGE JULIUS: What is the basis for your opinion with regard to states?

DR. DRUM: My -- my concern is -- is the risk that I've -- I've already shown you from the FDA, that they've -- they've told us that these doses are the maximum doses that should be, and the state of California has -- has gone beyond

that.

JUDGE JULIUS: I understand the -- the nature of the objection, I think.

DR. DRUM: And I -- I retract "states" and say the state of California, if that's better.

JUDGE JULIUS: No.

DR. DRUM: Because that's clearly what I'm showing.

JUDGE JULIUS: Yeah. I think with regard to state regulation, I think is a little bit outside the scope of this. I think to the extent you want to focus your testimony more on the -- the dangers --

DR. DRUM: Sure.

JUDGE JULIUS: -- that you perceive --

DR. DRUM: Right.

JUDGE JULIUS: -- or -- or opining on --

DR. DRUM: Sure.

JUDGE JULIUS: -- based upon a potential rescheduling, that would be most helpful --

DR. DRUM: Okay.

JUDGE JULIUS: -- to this Court in making a determination in this case.

DR. DRUM: Right.

JUDGE JULIUS: I understand.

MR. SWAN: Thank you, Your Honor.

JUDGE JULIUS: Thank you, Counsel.

Please proceed, Doctor.

DR. DRUM: Okay. So next slide, Exhibit 9, is the report and recommendations of a high-potency cannabis thinktank in the state of California.

This was an October 2024 report. And this was a independent science -- scientific committee comprised of scientists and medical experts convened by the California Department of Public Health to look at issues surrounding high-potency products that have been in the state already for eight years after recreational approval in 2016.

Figure 1 is on page 9 and -- and reports the display again at what we've seen before. On the horizontal axis is over time, and on the vertical axis is the percent THC as it's been rising over time. Okay? So we constantly see this reported.

And, again, P.S., the Mississippi federal labs is -- is providing the medical marijuana for the NIH study, was providing 2 to 6 percent THC in the 2010s, and now in the 2020s,

they're providing a 13 percent THC product.

So those studies that are being done are woefully underreporting the adverse effects that we are seeing in the real world. Since the researchers are not using the state-approved products, they tend to be using the Mississippi lab products, which are lower percent THC concentrations for their studies.

They claim they can't because they've said, "The federal government can come after us, and so, therefore, we're -- we aren't using our state products. We're using" -- even though they are funded by the states, they still are using products that are from the Mississippi lab, the federal products.

With that in mind, again, they looked at 68 California samples taken from San Diego and the Central Valley retailers. They sampled. The average was 21 percent in San Diego and 24 percent in the Central Valley. Of the 68 California samples, only 23 were below. So 23 out of 68 were below 20 percent, and none were below 10 percent. Okay?

And so the federal, again, THC concentrations that we -- they were providing in

a Mississippi lab, 2 to 6 percent in the 20-teens, and now up to 13 percent. But still, there's no -- but none -- none are being sold in the flower form less than 10 from this study. Okay?

Next slide.

So in most states, this -- how -- how is your product being selected? This is the person now in most states is -- the budtender is the person that's actually selecting the product for the patients, not a pharmacist. And the physicians, when they're recommending, a recommendation is different from a prescription, as I'm sure you're aware.

And so this is who's legally allowed to select medical products, and usually the amounts and frequency for the patient, and educate the patient. So, again, we don't know that they're receiving these medications. They're not putting these products into the prescription drug monitoring programs that we as pharmacists are required to do in all 50 states. I'll talk more about that later.

But, again, we're not seeing necessarily their marijuana use that's going on. And so it makes it very difficult for us to be able to

provide the information when we don't know that they're getting it. Okay?

Next slide.

This is Exhibit 10, page 1. Again, our duty to warn. This is a study about cardiovascular effects. I don't know, again, what -- what you've heard, but this is from Journal of the American Heart Association study in 2024. So a fairly recent study by Jeffers, which looked at the association of cannabis use with cardiovascular outcomes among U.S. adults.

This is a self-reported study of over 430,000 people from 27 states and -- and territories -- and two territories. This was a telephone survey in which the mean age of the -- of the patients were 45, a range of 18 to 74 years old. Four percent were daily cannabis users, 7.1 percent were non-daily users, with a median of five -- five doses per month. Okay? So maybe once a week -- just a little bit more than once a week use.

The daily use of cannabis had a statistically significant increase in the risk of myocardial infarction, known as a heart attack. There was a 25 percent increase and a stroke risk

increase of 42 percent. Okay?

The -- the higher the use, the more days per month, was associated with a higher risk even when controlling. So they did control for tobacco use, age, sex, diabetes, alcohol use, education, and physical activity. So they did, you know, account for that in the -- in the non-users. Okay?

Next slide.

This is Exhibit 11 on page 1, more issues about cardiovascular effects. So this is cannabis use for chronic pain patients, cardiovascular safety in a nationwide Danish study out in 2023. They looked at the first six months or 180 days of first use of medical marijuana in over 5,000 patients that were using it for pain. The median age was 59 years of age, with 63 percent women.

They compared to a control group of equal age and sex. So they did compare it to a group, then, non-users of equal age and sex, and they found a doubling in the risk of arrhythmias that was occurring. The biggest risk were those that had cancer and cardiometabolic disease or -- which is known as, you know, insulin resistance, obesity, and chronic inflammation.

So, again, the concerning issue here

is -- is that they did match this, and they saw an incidence of arrhythmias doubling within six months.

Next slide.

Exhibit 12, page 1. These are adverse effects of head and neck cancer. This was -- these were patients they -- they looked -- this is 20 years worth of data in 64 healthcare organizations. And they reviewed the charts for patients with and without cannabis use disorder -- you're familiar with that term, correct? Okay -- who had head and neck cancer and compared it to those that didn't have cannabis use disorder.

And so what they found was, in 116,000 cannabis use patients with a mean age of 46 years of age, they compared 3.9 million people, non-cannabis users, with a median age of 60. Okay?

In the cannabis use disorder group, they found higher rates of oral cancer, relative risk of 2.5. That means two and a half times more likely to have developed the -- the oral cancer. Okay? 4.9 times more oropharyngeal, 8.3 times or 8.4 times more laryngeal cancers. And -- and then these patients that they were looking at had

comparable alcohol and tobacco use in the non-CUD patients. Okay?

Next slide.

This is Exhibit 13. Again, a -- a more recent study on page 1, and then on page 8 is the Figure Number 9 over there to the right-hand corner. Again, these are North American rates in cannabis and the states, and they were looking for breast cancer patients that were diagnosed with breast cancer or testicular cancer.

And, again, the age range is listed there: 20 to 34 in breast; and, testicular, 15 to 39. The time period was for 19 years from 2000 to 2019. And they found a high correlation between increase in the rates of cannabis to the number of cannabis legalizing jurisdictions.

And so because cannabis has already been legalized federally in -- in Canada, they tended to have a broader and earlier full legalization than we did. And the Canadian rates are actually seen to be in -- even more increased than we've seen in the U.S. in these areas. And so the rate in legal cannabis states, there was a 26 percent increase in breast cancer and a 17 percent increase -- as compared to a 17 percent increase

in the non-cannabis legal states. So 26 versus 17; and, testicular, 24 percent increase versus 14 percent increase.

So overall there tends to be increasing, but those that are cannabis legal states tend to have higher incidence of breast and testicular. And we are seeing this in -- in cell lines, the riskiness of -- of marijuana use in causing that, and I'll show you that later as well. In California are -- are reports, which apparently the government doesn't want you to see.

MR. SWAN: Objection, Your Honor. Objection, Your Honor.

JUDGE JULIUS: Sustained on that last comment.

DR. DRUM: Okay. You'll -- you'll see it in the -- it's in our California reports.

Again, another duty to warn that we need to warn people about is the issue of operating heavy machinery and driving. And so -- next slide.

This is, again, readily available from our cannabis department. That this is for the -- from the California Department of Cannabis Control, readily available out on the internet about the -- the need to warn about pregnancy and

lactation. In both CBD and THC, active ingredients in marijuana have warnings in their FDA-approved package inserts about driving, as I pointed out previously. They both have that, which also includes that operating heavy machinery.

They list this here as well, and they say the effects of cannabis may include trouble with thinking, seeing or hearing things that aren't real -- again, hallucinations -- feeling like it's time -- that time is moving slower or faster for them, again, things that may be dangerous in somebody that's driving and operating a vehicle.

We've also seen that their hearing is affected; their visual fields are affected as well. And so that's very dangerous. And their ability to judge distances, and hearing, and -- and vision that's necessary to operate a car.

Next slide.

This is, again, also from that same site that has the pregnancy and lactation risks. So, again, the warnings from the California Department of Cannabis Control. And they -- they state about, again, the risk of -- of, you know, applying

cannabis-infused creams or lotions.

No matter how much you consume, cannabis, THC, and other chemicals will be passed to your baby through placenta and breast milk. Very clear. If -- if you use medical cannabis, make sure you talk to your doctor about alternative treatments during pregnancy or while breastfeeding.

And they go on to warn about the pumping and dumping that you may have heard about as the way people then can consume something, and then they -- they -- they pump that -- that milk, and instead of giving it to the baby, they dump it. Well, the concern, again, as we know, Delta-9 THC is a fat-soluble molecule, and they recommend against that, because, again, for you to get rid of that THC, it takes a long time, and so it is maintaining in that breast milk for a while.

Next slide.

So this is Exhibit Number 15, and go to page 6. This is Figure 3. And so what this is is the high feeling after IV, oral, or inhaled marijuana. So I warned you, here comes the IV marijuana that was done in studies.

So, again, these are older studies, and

this gives you then the -- on the horizontal axis, it's time after administration in hours, and so it goes from zero to six hours that they were measuring this over. And then on the vertical axis is the relative high. They asked the person on a relative scale of 0 to 10, How high are you right now? Okay?

And so they administered intravenous 5 milligrams. A smoked version was 19 milligrams, and an oral version was 20 milligrams. And as you can see, both the intravenous and smoked version peaked early on, within about 10 to 15 minutes, right? It's very quick within -- within that first hour that you see that peak.

The difference then seen with the oral, that the peak is between two to four hours, is where it finally peaks and at a much lower level. So you could see that the -- that the IV version has the highest level. The smoked version is just a step below it at a level of seven, whereas this is a level of four as to the projected high sensation. Okay?

And so very important to -- to -- to note this: that this is not going to peak like -- like a smoked version when you're taking an edible.

And a lot of people have gotten into trouble because they were expecting that 15-minute reaction with an edible, and that's not what happens. And so they take more and more, and then they end up getting into trouble as a result of that.

Next slide.

Also, from Number 15 is another very interesting study that's related in here. It's on page 6. It's Figure 4. And what this is, again, on the vertical axis, again, is that subjective high, but in this study they went from zero to five. And then on -- on the horizontal axis is the plasma THC concentration in nanograms per mL, and it's going from zero to six nanograms per mL.

This is a perfect example of why blood is insufficient evidence in cases and should be thrown out. The Department of Transportation does not use blood for marijuana for THC, right? They use urine metabolites. And by the way, you don't get a urine metabolite of even an inactive carboxy THC, psycho-inactive. You don't get that THC molecule without having taken THC. Your body does not naturally make THC in its body, okay? So it makes anandamide, which is a different complete

structure than -- than the CBD -- or, sorry, than the THC molecule. Okay? Than the cannabinoid structure.

So, again, with this one, what they did was they had the person eat a cookie of 15 milligrams of THC. Okay? So it was an edible. And what they did was after every 30 minutes they asked the person, "What's your level of high now?" and they drew blood. Okay?

So what you could see after 30 minutes, which is that first dot, is that the level was -- say it's about one. Sorry. Their -- their subjective high was about one, and the level was three. Do you see that? Okay.

And so then what happens after an hour in this study, after an hour, they were getting the peak plasma level of, let's call it, about six, five something. Okay? After an hour. And the subjective high was three, 60 percent of max. Okay?

But as the time went on, their -- their relative high kept going up and finally peaked at three hours. Okay? Like what we've seen before, that the high is, you know, two to four hours. So, again, it's repeating the same issue is that

at about three hours is when we see the peak subjective high, but look at what the blood level was at that time. It was the same level it was at 30 minutes: three.

So this shows you that the subjective high is at its maximum, but yet the blood level is the same level it was when the subjective high was at one. Okay? So this then shows you blood levels are worthless because you don't know. Was it taken -- did that person take that 30 minutes ago, or did they take that three hours ago? Okay?

Next slide.

This is Exhibit 16, page 158. Again, this one, again, is marijuana use and driving because, again, I need to educate somebody, and some -- people should be educating them on the ability to drive and operate heavy machinery, right, if they're taking this substance.

And so this was from "Monitoring the Health Concerns Related to Marijuana in Colorado," a study that came out in 2016 in which they convened a group of experts to look at the data that they had at that time. And it says in number 9 on page 158, on time to wait before driving, it says, "We found substantial evidence that delaying

driving for at least six hours after smoking less than 18 milligrams of THC allows for the THC-induced impairment to resolve or nearly resolve for users who use less than weekly." Not daily users. Okay?

Then they also found, under number 11, "We found substantial evidence that delaying driving at least eight hours after oral ingestion of less than 18 milligrams of THC allows the THC impairment to resolve or nearly resolve for users who use less than weekly."

So for infrequent users it's six or eight hours, again, versus smoking versus oral. Okay? Very important.

So what's the -- what's 18 milligrams? Again, that gummy bear example, 10 milligrams in a gummy bear. It's a gummy bear and a gummy bear without its head. Rough estimate. So that means then you should not be driving for eight hours if you took that much. Okay?

So, again, less than two serving sizes, okay? Which is 10 milligrams, they claim, okay?

Smoked version. So let me kind of walk you through this. Twelve percent THC. If you have 12 percent THC in a joint, how much is

18 milligrams? If a joint is 500 milligrams, about half a gram. Okay? So then we multiply 0.12, 12 percent, times 500 milligrams. That means there's 60 milligrams of THC in that 12 percent THC product. Now remember, you can only do 18 and not be able to drive for six hours. So that means you and 2.3 of your best friends have to consume that joint for you to still get 18 milligrams. Get it?

Okay. And now let's do 23 percent THC. If you run the same numbers, again, it's you and 5.4 of your best friends. So meaning you can only consume one point -- one -- one over 6.4, one-sixth, if you will, 6-1/2 percent of that joint for you to have consumed 18 milligrams. Okay? That's how little it takes and for how long you have to wait. Okay?

Next slide.

So now I'd like to kind of walk you through the controlled substance studies that are being done currently on the CS I substance, because I know many people want to claim you can't study it, you can't study it, and it's just completely false.

JUDGE JULIUS: So it's almost 10:30.

DR. DRUM: Okay.

JUDGE JULIUS: I don't know if you want to start looking for a place that might be a good place to pause for our comfort break. I don't know if now is a good time --

DR. DRUM: How about -- how about --

JUDGE JULIUS: -- before you launch into this or?

DR. DRUM: Yeah. How about I do three more slides, and then we'll get into the veteran stuff afterwards, or we'll start the veteran stuff and -- so just a couple more, I think. Okay?

JUDGE JULIUS: Fine with me. Thank you.

MR. DRUM: All right. So can a CS I substance be studied? Okay?

So Exhibit 17. Again, my code of ethics requires that a pharmacist maintain professional competence, and I'm required to maintain 30 hours of continuing education, pharmaceutical or medical education, every two years. As such, I -- I'm very familiar with maintaining my pharmaceutical knowledge by performing drug information searches using PubMed searches of the Library of Medicine or NIH Reporter for current and past NIH-sponsored research studies. Okay?

So my Exhibit 17 is an affidavit that I've -- I've created of how I did this search. Okay? So this is a PubMed search, which comprises more than 40 million citations for biomedical literature from Medline, life science journals, and online books. It's from the National Library of Medicine that I walked past the other day here in D.C.

It provides scientific articles and reports from a large number of peer-reviewed articles of the search term for medical marijuana. So I put that search term in PubMed and it resulted in 11,608 results for medical marijuana. Okay?

And that was -- that was a search I performed on June 20th of this year, 2026. The maximum number of reports in one year was -- was in 2019, in which there were 945 reports. However, the number has been declining each year since.

And in 2024, there were 805 reports, which is a 15 percent reduction in the number of articles written since its peak in 2019; this despite the DEA offering additional federally legal medical marijuana cultivation sites other than the Mississippi lab over these last four years, as well as increasing federal funding.

Exhibit 18 is the other affidavit that I performed on the NIH Reporter. This is a database of research sponsored by the U.S. Government since 1985, commonly through the National Institutes of Health.

And so, in May of this year, I performed a search on marijuana alone, just the term "marijuana," and the reports yield 9,566 research projects and contracts and the publication at a cost of $4.2 billion, okay, is how much the U.S. taxpayer paid for that research. This is in addition to any privately sponsored research projects.

This result proves that one can study CS I substances despite what people are saying. That's still not approved by the FDA. I compared this to other analgesic agents, including morphine and ibuprofen, and you can see the number of -- of projects, contracts, publications, since 1985.

Morphine did have some more, and the reason why is because morphine is commonly used in a lot of surgical procedures and it gets listed in there. So just 500 more, but at a cost of 2.8 billion, those studies, and has an FDA-approved indication.

Ibuprofen, 1,120 studies, you know, one-ninth of the number of studies that marijuana has, at a cost of $336 million, and that has three FDA-approved indications.

Omeprazole, that purple pill that's over the counter, 395 research studies. Again, these are non-drug company sponsored studies. But 92 -- $90 million, seven FDA-approved indications.

And Semaglutide or Ozempic, right, everybody knows that drug, 149 projects at $105 million, six FDA-approved indications.

And so my -- my point is here, you can study a CS I substance much larger than these other common drugs at a much higher cost to -- to U.S. taxpayers with still no FDA-approved indication.

The next slide, I just want to -- we'll end on this one -- is the results of the VA results from the NIH Reporter. There were 76 studies, and that Exhibit 19 shows you those 76 studies that were performed at the VA. And so you could read through them as the -- as to the types of studies and the VA that was involved in those studies.

So, again, this is being performed at the -- at the Veterans Administration. Again, I worked there. I was an investigational pharmacist

when I was in -- in -- in Fresno and understand that investigational drug process at the VA.

And so I -- I think we could end here, and I'll come back and talk about those -- some of those veteran studies.

JUDGE JULIUS: Sounds good. Doctor, thank you.

We're going to take a 15-minute break.

DR. DRUM: Okay.

JUDGE JULIUS: If you need to walk around, stretch your legs.

DR. DRUM: Sure.

JUDGE JULIUS: Just, you know, anything like that. Just don't discuss your testimony with anyone during the 15-minute break.

DR. DRUM: Absolutely.

JUDGE JULIUS: We will come back at 10:50. That will be the 15 minutes. We'll be in recess until 10:50.

(Whereupon, the above-entitled matter went off the record at 10:34 a.m. and resumed at 10:51 a.m.)

JUDGE JULIUS: Dr. Drum, if you'd like to resume where you left off.

THE WITNESS: Certainly. Slide 45. So

what I'd like to take you through, next slide please, are some studies that were performed at the VA. My dad was a veteran for 20 years, was in Korea and Vietnam, and I worked at the VA. So, I'd like to go through these VA studies.

This is Exhibit 20, and this was a study that was a cannabis use disorder and suicide attempts in Iraqi and Afghanistan veterans by Kimbrel at the VA Durham. What they did here was this was a study of over 3,200 Iraqi Afghan vets. Cannabis use disorder was associated with both an increase by 68 percent suicidal ideation, with a very significant P value of .008, and lifetime suicide attempts of a 230 percent increase, with an extremely significant P value. The study did account for sex, PTSD, depression, alcohol use, non-cannabis drug use disorder, history of child sexual abuse, and combat exposure. CUD was a unique predictor of suicide attempts in this group of veterans. You can see on page 9, figure 1 that no lifetime cannabis use had half the rates of the current suicidal ideation and lifetime suicidal attempts compared to those with a lifetime history of cannabis use disorder. Next slide.

UNKNOWN FEMALE: Excuse me, Your Honor,

the microphone is not in the back?

JUDGE JULIUS: Oh, thank you, ma'am. Can the court reporter hear okay?

COURT REPORTER: It's working fine for me.

JUDGE JULIUS: Okay. So it appears to be a microphone issue with the gallery. We've got a thumbs up. Okay. So, sorry. Thank you, Doctor.

THE WITNESS: Okay.

JUDGE JULIUS: Please continue.

THE WITNESS: Next slide. This is Exhibit 22, cannabis and cannabinoid for pain and PTSD in military personnel and veterans. This was done at Walter Reed. This is in 2023.

In 2023, the cannabis use in the military was less than one percent. Again, this was a meta-analysis done on pain. In particular, they looked at pain results in 36 randomized control trials. Most showed no benefit. Two trials of low quality had an N of 231 patients, but they only used for 7 days in this study, so there was a low number of patients in this study and a very short duration. Six trials, also deemed of low quality, had 1,400 people in it, and they were using low-dose THC and CBD. There were 28 trials that showed

no benefit.

With regards to PTSD, there were two randomized controlled trials. Again, both with very small numbers. One had an N of 10, in which they used nabilone, which improved nightmares, but again, we're not using nabilone in the U.S. Again, the other study that had 80 patients in it, they used high THC, high CBD versus -- so it was high THC versus high CBD versus moderate THC and CBD versus placebo. Unfortunately, they were unable to blind this study because 100 percent of the patients that were on the THC product recognized they were on the THC product. Sixty percent of the placebo or CBD alone were also recognizing that they weren't on the THC product. So that's an inherent bias. They found no difference between the groups in PTSD control symptoms. All four had statistically significant moderate-to-large reductions in symptoms, but this displayed a significant placebo effect due to bias.

Therefore, the current body of evidence does not support the use of cannabis or cannabinoids for treatment of pain or PTSD in the military personnel or veterans was the conclusion of the study. Next slide, please.

Association among trauma, PTSD, cannabis use, cannabis use disorder in a nationally represented epidemiologic sample that was done out of the Richmond VA. This, they looked at 34,000 veterans, again average age of 48 years of age across the VA and the nation. There were interviews. Two times they did interviews with vets in '01 and '02, and then again, they followed up in '04 and '05.

They assessed cannabis use, cannabis use disorder, trauma history, PTSD, and other mental health disorders such as anxiety, panic, depression, alcohol, OCD, et cetera. Of the 34,000 of those with trauma, they had an increased likelihood of cannabis use, an odds ratio of 1.215, which is a 21 percent increase. Then, in those that had trauma plus cannabis use plus PTSD and increased use for cannabis use disorder, an odds ratio again also of 1.21. So again, another 21 percent increase in those 2,990 veterans. Again, PTSD was associated with greater odds of cannabis use disorder in this study. Next slide, please.

Correlates of recent and lifetime aggression among veterans with co-occurring PTSD

and substance use disorder. This was out of the Charleston VA. Again, a small N sample size of 97. They were looking at the prevalence of a recent, which was within the last 30 days of aggressiveness, as compared to lifetime aggressiveness. Thirty-nine percent had recent aggressive behavior, with 57.7 percent having lifetime aggressive behavior. What was interesting was those factors that concluded were those who had recent aggressiveness were among the cannabis use people, in addition to younger age, less education, severe PTSD, numbing symptoms, suicide ideation, more frequent alcohol and cannabis use, higher physical sexual abuse, greater combat exposure and aftermath. Again, the bottom line is here, this is a small study with high rates of aggressive behavior among veterans with PTSD, substance use disorder that were more frequent alcohol and marijuana users. Next slide, please.

Again, if we're considering moving the drug and calling it a medicine, we need to make sure that we have fail-safes in our systems then that we're using the marijuana and again, right now we're considering with lack of FDA oversight

and without their information. Next slide.

I just want to show you what's been happening in the States. This is Exhibit 25. This is a study that was done. On page 2 of Exhibit 25 is table 1 here. These are non-FDA-approved products that are being regulated by the state. The FDA's accuracy in dosing has to be 95 percent or above accurate in the dosing concentration. Okay? These were purchases made in 2014 of, again, this is edible -- and they were looking at the THC content in this study, okay? In 2014, they bought then 75 products in total from San Francisco, Los Angeles, and Seattle, and they were looking at the THC content. They tested it the accuracy with an HPLC, a high-performance liquid chromatography, to analyze how much THC is in those products. The LA products had more over-labeled, meaning they contained less THC than they said on the label, and the Seattle had more under-labeled products, meaning they contained more THC than the label stated. The true pharmaceutical allowance, again, is 5 percent, and these were off by 23 percent when under-labeled or off by a total of 13 percent. So again, bottom line is they were off by 13 percent, and then they were off by 29 percent when

they were over-labeled. Again, very concerning results that we are relying on these products to be accurately labeled and again, we need to be careful with these products that are out there because they're not consistent with what an FDA-approved product would have. Next slide, please.

Exhibit 26, table 1 on page 1. The same study group in 2016 now purchased CBD online. They found similar results. They were looking at oils, tinctures, and vaporized products. Twenty-six percent contained less CBD than was labeled or were over-labeled, and 43 percent contained more CBD than was labeled. They were under-labeled. Thirty–one percent were accurate. Again the totals were off by 5 to 13 percent, and so again, they can only be off by 5 percent for an FDA-approved product. This shows that, again, the states are not adequately able to protect consumers from products that can cause impairment, the liver disease that we see with CBD products if, again, 43 percent contain more CBD than what the product said. Very dangerous then for people to experience then adverse effects from CBD. Next slide.

Exhibit 27 is from the State of

California Environmental Protection Agency. Page 4 shows that cannabis smoke can cause developmental or is a reproductive toxicant. This is what we call our, in California, our Prop 65 list. This then has to be posted in any facility that has any of these chemicals in it. What they're looking at is carcinogenic or reproductive toxicant effects, okay, are the drugs that are in this list. And so cannabis smoke can cause developmental. If you go to page 13, you'll see marijuana smoke can cause cancer. If you go to page 21, you will see THC can cause developmental effects. So both cause developmental effects, AKA reproductive toxicants. Both are placed on the list after the public voted in 2016 for recreational marijuana. These were placed on the list, as you see, in 2020.

The cancer-causing effects of marijuana smoke was in 2009 after medical marijuana was approved in 1996 by our Prop 215, which was our medical marijuana in the State of California. Next slide.

Exhibit No. 28 on page 1. This is from California, again, regarding the Prop 65 warning from the Office of Environmental Hazard

Assessment, which goes into detail about the risk in pregnancy that THC has and also warns how THC exposure can occur and the various ways babies are exposed to THC. Mothers eating, drinking, smoking products with THC, or breathing in the air that has THC in it from others. It affects the baby's brain, behavior, or learning ability, makes the offspring more susceptible to drug addiction. Okay? It says it right there in the warnings on this slide and this page. Next slide, please.

Exhibit 29 is also from OEHHA in California. This is the one regarding cannabis or marijuana smoke. Similar warning, but notice the highlighted section on the additional toxic substances admittedly found in cannabis or marijuana smoke that cause cancer or reproductive harm. They include benzene, formaldehyde, and carbon monoxide, these are chemicals. They also acknowledge that there are metals in marijuana such as cadmium, chromium, lead, mercury, and nickel. These are all admitted here on this document. Next slide, please.

Again, as a duty to warn that I, as a pharmacist, have is for FDA recalls pharmaceuticals, and I receive not only

pharmaceuticals but also medical devices on a daily basis from the FDA. Right now I deal with medical devices in my facility. I help build drug libraries, and so I have to keep up on those medical devices as well and if there's recalls. Bottom line is I receive these on a daily basis from the FDA.

There are three levels of recalls that are sent out from the FDA. Class I are the most serious. There will be reasonable probability that they will cause serious adverse health consequences or death. Okay? These are the examples that are given by the FDA include contaminated drug with a life-threatening dosing error or malfunctioning device or failure during use and food with botulinum or listeria. Okay?

Class II may cause temporary or medically reversible harm. The probability of serious harm is remote. So that's a class II error and a medication with incorrect, but non-dangerous labeling, such as underdosing a patient, is dangerous, and you may have seizures then if you're not providing adequate CDD. Okay, so that would fit into a class II.

Class III are low risk, not likely to

cause issue or unclassified, and there's many of them that come in that level as well. Class I and II recalls require a pharmacist must contact the patient and must retrieve and replace the product. Okay? Next slide, please.

This is Exhibit 30. This is from California Department of Cannabis Control and was taken off of their website, which they claim as to what they do with a mandatory recall. Okay? This occurs when there's an immediate and serious threat to human life or health. Okay, so very consistent and similar to what the FDA does with a class I recall. They talk about notifying the licensee to cease distribution. DCC posts the recall information and the list of mandatory recalls on its website and sends a consumer advisory to provide information to licensees and customers about the recall. They're not collecting the data on who the patients are; how are they getting that to the patients other than potentially just posting it on their website and expecting them to go and read it from there? So, this sounds good that products are properly handled, remediated, and disposed of. This sounds good, but this is why I needed to show you what

they do in practice. Okay? So, this is what they do for a mandatory recall. Next slide, please.

Exhibit 31, pages 1 through 3 then show a report that I pulled in November of 2024 from their website. This was readily available and it's still there if you go back and look through the dates. To find the recalls, you'll see these dates included as well. These were 63 entries of voluntary and mandatory recalls since January 26th of 2022, okay, over 34 months. So that's 1.8 recalls a month. Less than one every two weeks is what they were recalling. Okay? Next slide, please.

This is an example of California Department of Cannabis Control recall. These are all voluntary recalls. This is something I accessed on June 22nd of this year. I went onto their website, again, readily available, and these were the products that were showing up then. They're all voluntary. If you notice, it's voluntary, voluntary, voluntary, voluntary, voluntary. These are not mandatory recalls and what were some of those? Well, the Karova edible says adulterated prohibited product was found in the product. Voluntary recall. How about the

West Coast Cure pre-roll? Adulterated microbial contamination, Aspergillus niger. Voluntary recall. Aspergillus can kill you. If you're an immune-compromised patient, that bacteria can kill you, and it's a voluntary recall. Next slide, please.

It's not only happening in California. This is happening throughout the United States, and that's what the next slides are showing you is to let you know that this is happening elsewhere as well. This is consistent that this is happening, and it's concerning to me that our patients may be getting these products even from other states that are then now infected with these potential problems.

Again, this is Exhibit 33 from the Colorado Department of Revenue Health and Safety Advisory for Slow Burn Farms. This is one of their examples of their reports that they made. On page one, it's the recall of a product on August 30th, 2024, of a pre-rolled marijuana product. It was found then to have, as you see, have Aspergillus and the pesticide thiabendazole in that product. Okay? Thiabendazole was above the limits allowed by the state. The product was sold between

February 8th of 2024 and July 22nd of 2024. One to six months later is when this product recall came out. That's what's concerning to me is that is this a timely enough recall for these products. Pages two and three show that this product was sold at over 35 legal marijuana shops. Next slide, please.

This is Exhibit 34 from the Cannabis Control Commission from the Commonwealth of Massachusetts. This discusses a mold issue in a product from Holistic Laboratories on page one. If you turn to page three, they describe the mold issue existed in the facility under 11A since November of 2020. It was finally verified and remediated by May of 2022, one and a half years later. Initial remediation started on April 21st, six months later.

Under 11E, they admitted that they knew to ask for specific types of testing to avoid detection, and they did so. Again, N, it says they did not cease production while it was remediated at the facility. Then something to note, we in pharmacy have to operate under USP Standards, United States Pharmacopeia. Sorry. And so the latest version that came out is USP

797, which really highly regulates us if we're compounding products. We have to, you know, have essentially close to a clean room like standard drug companies do and have to suit up and gown up and have air quality and pressure controls and things in our IV rooms in all hospitals. Okay? We can't afford to have mold in our products. We can't afford to have mold in our IV rooms. In fact, we test for mold and bacteria regularly in these rooms and have outside companies come in to make sure that our rooms are safe.

What would happen if a person comes in the hospital and if it's a CS-III substance, it may be coming out of the pharmacy to deliver to the floor, and there's one pharmacist at 3:00 in the morning, and I get a call from the ICU to make a compound, have to go into my clean room and then have to also dispense cannabis to somebody up on the floor that has mold in it? That's the concern. Next slide.

Exhibit 35 then are examples of what I've pulled off the internet, this is not just something that's happening in California, Colorado, and Massachusetts. These are websites from 20 states that have had marijuana show

recalls. This is not an oddity or a rare occurrence. Again, the mold issue is highly problematic because of how much water the marijuana plant uses and consumes. Molds are very commonly found. Next slide.

Exhibit 36 is an editorial from the LA Times entitled California's Cannabis Regulators Failing the Legal Market and the Public. And from page one, again, it acknowledges that there's pesticides at levels above the state that exceeded federal standards for tobacco. The test found chemicals tied to cancer, liver failure, thyroid disease, and genetic and neurologic harm in unborn children. Some vape pens had pesticides levels high enough that could cause harm from a single exposure and that there were a few recalls that were occurring previously, 8 recalls in 2022 and 2023, and then finally there were 28 recalls so far in 2024.

They have picked up their number of recalls, but again, this has been getting sold in the State of California since 2018; approved in 2016, the sales started in 2018. By 2022 and 2023, they were doing minimal work in resolving these. Again, they talk about on page two, it took 41

days for the department to issue its first ever pesticide link recall. Next slide.

Exhibit 37, on pages one and two, again, this goes into the LA Times later that year, who also report again in 2024 how the California regulators have largely failed to address the contamination issues. They found high levels of pesticides in very popular vape brands. And again, this thing's reporting that their lab division chief that was seeking to involve criminal investigations was summarily fired in a lawsuit that was filed. The testing labs were willing to falsify testing results to allow products to make it to market.

So again, it's very concerning that there's pesticide contamination, allegations of lab fraud, illegal cultivation, and investigation of a tip of fentanyl in licensed products that are just being unheeded. Next slide.

This is Exhibit 38, page 4, the California Department of Cannabis Control received 85 contamination complaints from private labs on the safety certificates from private labs. Again, in the State of California, on page 6, they admit the lab testing is only performed in 2024 at

independent labs. There were no state-run labs to accredit to test pesticides. Okay? So they're relying on independent labs.

Again, independent labs have found 45 toxic chemicals in legal cannabis products, 29 exceeding state cannabis limits or the federal tobacco limits. Page five, table three, show the first five rows of 36 rows of chemicals that are tested. It displays how one chemical is not even being tested, but it's found; pymetrozine. Pymetrozine is an insecticide. It's the second one down there. It's an insecticide that's used on food crops, but it's not even screened in California cannabis and it's a reproductive toxin and carcinogen. Causes damage to endocrine organs in rats.

At page seven, it talks about Stiiizy making a vape product that carried more than 60 times the maximum federal level of pymetrozine, but it's still untested, and again, it's not on the list of 66 pesticides required to be tested in California. Next slide.

This slide again shows more testing problems, and again, it's not just California, even though that's where I come from, it's

throughout the nation that we're constantly seeing this. In 2024, Maine had no testing for a medical marijuana program that they legalized back in 1999. That's Exhibit 39.

Exhibit 40 is a lab of 15 illegal weed vape carts; 13 contained dangerous addictive substances, and all 15 were contaminated with cyanide. Again, the issue here is these things are making it to the market even though they're illegal and we're not stopping these from getting sold, and again, some patients are resulting in them being hospitalized and put on ventilators. Some patients may even need lung transplants, which typically only last like six years.

Exhibit 41, why California shut down testing at the majority of the pot labs. In a 2024 report on page one, they stopped two-thirds of the labs from further testing flower in the state of California, but did allow them to test edibles and vape pens. They did not meet the higher standards required of the flower at the time that they were implementing, so they shut down two-thirds of the labs, lowering the number of approved labs to 12.

Page two then talks about what happened

as a result of that that 87 percent of the 150 products tested lower for potency than what was on the label that they saw in 2022. So again, the accuracy was seen not to be there.

Exhibit 42, recall order of pot products after lab is caught faking test results in 2018. Again, pages one and two discuss how 850 batches, tens of thousands of pounds of flower, edible marijuana products had to be destroyed or retested because Sacramento-based Sequoia Analytical lab was caught falsifying their reports. Articles even admit that the metal testing had not even started in 2018. When sales started in 2018, they weren't testing for heavy metals at that time in the state of California, and I'll explain why that's important.

Exhibit 43, California marijuana recalls threaten state cannabis industry. Another article from December of 2018 discussing the Sequoia Lab and also mentions the self-proclaimed leading cannabis testing center, Steep Hill Labs in Berkeley, was suspended for 10 weeks for failing to meet state testing protocols for two pesticides. Next slide.

This is about fungal infections with

cannabis. A 2016 report displayed marijuana users were three and a half times more likely to have fungal infections than non-users. So this was looking at a database performed in 2016 of over 27 million people in the U.S. and their claims from outpatient visits and prescriptions and hospitalizations. They were looking at ICD-10 codes. Do you know what those are?

JUDGE JULIUS: If you could explain that, please.

THE WITNESS: Okay. ICD-10 codes are codes that we use in the hospital for diagnoses of issues. Things like fungal infections and mold infections have a certain ICD-10 code. What they did was they looked for those ICD-10 codes and compared them then to cannabis users versus non-users. Again, cannabis use has a specific ICD-10 code that then the hospitals will acknowledge this person was a cannabis user versus not. Okay? They then looked at the immune-compromised patients age, sex, U.S. regional locations, and tobacco use, and they found three and a half times increase in mold and fungal infections in users compared to non-users of cannabis in this study, by looking at the ICD-10 codes.

Exhibit 45, I don't know if you're aware of this case, but UC Davis researchers were finding mold and fungi in medical marijuana products and warned of the health risks in a 2017 Sacramento Bee article. On pages 1 and 2, warning that bacteria and mold were found in 20 Northern California marijuana growers and in dispensaries. This is especially lethal in people that are immune-compromised, and they need to avoid smoking, inhaling, and vaping aerosolized marijuana. Aspergillus species, which is the type of mold, is an especially deadly form of mold and fungi, and it's very difficult to treat. They mention the death of a patient from this mold that they related genetically back to his marijuana product that he was receiving.

Exhibit 46 talks about cannabis microbiome sequencing and reveals several mycotic fungi native to dispensary cannabis flowers. So in 2018, there's a research paper from F1000 researchers discussing that they identified the fungus found in cannabis products. Page 4 discusses how they analyzed the DNA sequencing of the mold of 17 cannabis products from Amsterdam and Massachusetts. They found presence of mold

products differed by different methods being used for testing. They showed that current testing measures may not be accurate for detecting the mold in products. That's concerning.

Exhibit 47, A warning to marijuana consumers. Oregon and Nevada recall mold-infected fungus and tainted cannabis. It's a 2023 news article. Page 1, not only are they discovering mold, namely Aspergillus, but also heavy metals, such as cadmium and mercury, in cannabis flower products. Seventy-five recreational retailers in Oregon sold the products over the preceding six months.

Page 2 starts with the warning of the mold, Aspergillus, being sold in specific products, displaying this is a common problem throughout the industry and may be problematic due to false negative reports admitted on page 3 of the report. Next slide.

This is Exhibit 48. It talks about potential of industrial hemp for phytoremediation. Again, industrial hemp is Cannabis sativa and so for phytoremediation of heavy metals. This is a review article from Plants in 2022. On page 1, how the plant, Cannabis sativa, can be used to

capture metal from the environment. It's a process called phytoremediation and it's due -- the U.S. Government's been doing this for decades, where they have an industrial waste site, and they'll put Cannabis sativa plants out there to absorb these heavy metals in those sites to clean up the ground, if you will. And the reason why they do this is that, again, that plant can take up these tissues, as it says.

On page 3 of the report, table 1 discusses the metals that are taken up and by which tissues of the plant; the root, the flower, the shoot, the leaves. It displays then chromium, zinc, copper, selenium, cadmium, lead -- Lead's on the next page, page 4, and nickel accumulates in Cannabis sativa plants.

Next, Exhibit 49 blood and urine metals among exclusive marijuana use in the Maine study from 2005 to ‘18. This is a 2023 report from the Environmental Health Perspective discussion, how in the National Health and Nutrition Examination Study, also known as NHANES, showed that when comparing over 7,200 participants by marijuana use, non-marijuana versus non-tobacco versus exclusive marijuana, versus exclusive tobacco, and

dual marijuana/tobacco users, they measured for five metals in blood and urine. Exclusive marijuana users had higher cadmium and lead levels in the blood and urine compared to non-users of both marijuana and tobacco. Cadmium excess can lead to kidney failure, weakness, headaches, respiratory damage, vomiting and diarrhea, anemia, and osteomalacia, which is like, you know, thin bones. Lead excess, as you know, is dangerous. It can cause kidney failure, neuromuscular and neurologic issues, memory loss, children intellectual disability. Yeah, that's why we took the lead out of paint, right? Okay, next slide.

Marijuana workers are also having reactions from some of these exposures. Exhibit 50 talks about highly toxic cannabis in Massachusetts. It's a Global News report from 2018. On page 1, it talks about the workers at the New England Marijuana Shop reporting to OSHA about being regularly exposed to mold and that they were being instructed by their supervisors to use hydrogen peroxide, who, later on, on page 2, talks about the workers breathing in the mold. Supervisors confirmed the use of hydrogen peroxide to treat the mold was an industry standard. People

were experiencing allergic reactions, throat irritation, and to go ahead and sell the products that were contaminated nearby that moldy material.

On page 3, the organization denied the presence of mold to authorities, claimed not to use hydrogen peroxide to authorities, and they also talk about the company using banned pesticides. Page 5 talks about one employee testing positive for cadmium and experiencing GI and neurologic symptoms.

Exhibit 51 is Green Thumb Industries, where they talk about a worker dying at an Illinois facility in 2023. Pages 1 and 2 talk about prior to their death, the worker was removed from a desk job to one in the production area of the grow. The worker died from chronic obstructive pulmonary disease, or COPD. Another employee also complained of experiencing coughing fits while working at Green Thumb Industries. The paper goes on to discuss another cultivation worker dying at True Leaf in Massachusetts from a respiratory reaction of inhaling ground cannabis dust. Again, these are OSHA violations by the workers. Again, I can't afford to have this happen in my pharmacies, to bring marijuana products into a

pharmacy.

We have sterile areas, and we have very small vault rooms. I don't know if you've ever seen one where we have to keep our controlled substances in a hospital pharmacy and that's what I am. They're very small rooms. They're maybe, like, six feet by ten, in which we keep all of our controlled substances in those room. We have to keep accurate counts. And if we would have to put a CS-III substance in that room, it would contaminate everything else that's in this room. And again, we deal with immune-compromised patients, cancer patients, and we're pulling out the morphine and other things out of that room that are now going to have mold from these other products that are in that room. Next slide.

Prescription drug monitoring programs are something that we've implemented as a result of the opiate problem. This has been instituted in all 50 states now. It's a state-run electronic database that tracks C2s through 4s or 5s, depending on the state. This documents who prescribed the medication, who received it. Are you familiar with prescription drug monitoring program?

JUDGE JULIUS: If you would describe it for the record?

THE WITNESS: Sure.

JUDGE JULIUS: Please. Thank you.

THE WITNESS: Okay. So who prescribes, who received it, who dispensed it, the date, the amount, and location where it was received. So that way we collect -- this information is sent into the state, okay? It started again, as a result of the oxycodone and opiate issues of the doctor shopping, where people were going to multiple pharmacies, seeing multiple doctors, and nobody ever putting that together.

So, what we used to do with C2s is we would get what was called a triplicate in the state of California, where the doctor would write on the triplicate, and keep a copy for themselves, and the patient came in with the two pieces left. I would then fill the medication out, keep a copy, and send the third copy to the state. That's how the state was collecting the C2 information before. This now is all electronic, and so what happens is, is the provider then prescribes the medication, comes to a pharmacy. We then put it into the system to say, okay, we're dispensing

this drug from this doctor at this date, this time, this amount, and we send it off to the state. Now, the state is running reports, and they can see the pharmacies that are dispensing. We are supposed to look to make sure that the person's not doctor shopping and getting opiates and things from other places, right? If we see that, then we need to contact that doctor back and say, hey, are you aware that they got this? They were supposed to look. When they prescribed it, they're supposed to look for the first time, at least in California, not every time that they prescribed a new opiate for a patient, they were to go in there and look and see that nobody else is prescribing it, and then they prescribed it. We would then contact that provider and go, Hey, Dr. X, Y, and Z are also prescribing this. Do you really still want to do it? Because I'm not going to be able to fill it. And so they would then usually say no, and then we would stop the prescription right there and say, it appears that you're getting opiates from other people, and I can't fill this prescription, right?

What ends up happening at the state level is the state is looking at this as well

electronically and seeing is somebody over-prescribing now? Is somebody over-dispensing now? They can come down on you for doing this and will come after you for over-prescribing, over-dispensing of opiates, okay? So that's how they've kind of put a kibosh then to that doctor shopping.

Right now, CS-I~~II~~ substances are not in that system. Marijuana's getting a free ride here with a hallucinogenic substance in which they're being able to dispense this, and nobody knows. And so I don't know if they're on marijuana unless the patient tells me. I'm not going to know, okay? So, if it gets made to CS-III, it should be going into the prescription drug monitoring program. And if that happens, I, as a pharmacist, you know, aren't going to be -- I can't be rung up on HIPAA violations for looking and seeing other meds that they're on, other opiates, because that's my role as a pharmacist. But is the budtender then going to have access to see that this person's also receiving -- or is receiving, you know, other C4s -- Ativan, Valium? Are they receiving Percocet or other opiates? That's what I do because I could see that, the other controlled substances that

they're receiving. Okay, so that's a concern. Next slide.

One of the things I always do as a pharmacist whenever I talk to a provider is I don't just say, oh, you know, this prescription's wrong, and throw it back at them. You always then tell them why it's wrong and how to correct it. So, I'd like to throw this out as a potential for a way to correct the way things are working now. Okay? A potential way forward. Next slide, please.

This is called REMS program, it's by the FDA. It's called Risk Evaluation and Mitigation Strategy program. Again when I came into my new position --

MR. SWAN: Objection, Your Honor.

JUDGE JULIUS: Basis of objection?

MR. SWAN: We would argue that this is not relevant to the rescheduling of marijuana.

JUDGE JULIUS: Yeah. Can you explain how this line of testimony is going to be relevant towards whether marijuana, not already in Schedule III, should be moved to Schedule III?

THE WITNESS: Okay. So we're basically going to designate it as a Schedule III as a

medication now, that now has the federal government approves that it's a medication and that this is a way to handle those other two pillars of the risk for addiction and adverse effects. What this is going to do is this is going to help regulate the dispensing amounts that we can now quickly identify the amount that they're prescribing to make sure it's an accurate amount, as well as checking for the positivity that it's working, as well as the adverse effects. And if we see this, then we can't continue to dispense the drugs. That's what a REMS program will do.

A REMS program limits the amount that the patient can receive. Right now, there's no limit on the amount that the patient can receive other than what the state says. You saw that the state amounts could be 71 times the CNS effects. A REMS program will help control that. I say start with the vape products, and let's see if we see adverse effects and efficacy. That's what a REMS program will do for you.

JUDGE JULIUS: I understand, I think, what you're saying. I think the question now is this seems like an after-the-fact sort of potentially regulatory system that would need to

be implemented.

THE WITNESS: Potentially, yeah.

JUDGE JULIUS: So, I think it's perhaps looking a little too far --

THE WITNESS: Okay.

JUDGE JULIUS: Down the road as to what we're looking at in this hearing.

THE WITNESS: Okay.

JUDGE JULIUS: Which is whether there's a commonly accepted medical use, whether marijuana should be moved from I to III.

THE WITNESS: Okay.

JUDGE JULIUS: I think this maybe I tend to agree with Mr. Swan that this seems to be venturing into sort of speculative, maybe down the road --

THE WITNESS: Okay.

JUDGE JULIUS: Kind of things if --

THE WITNESS: Understood.

JUDGE JULIUS: A certain pathway is taken.

THE WITNESS: Sure.

JUDGE JULIUS: I will go ahead and sustain the objection.

MR. SWAN: Thank you, Your Honor.

JUDGE JULIUS: Thank you.

THE WITNESS: Okay. Next slide. So this is my summary slide. Again, let's not put the cart before the horse. There's no standard FDA-approved information on the plant's activity chemicals that have been deemed necessary. We don't know what the dose is for, you know, No. 4 and what the dose is for No. 20, and adverse effects of 98, and drug-drug interactions on 67. We don't know that. Again, we've allowed public vote and legislatures to determine medical use thus far, and not the FDA.

By making it a Schedule III, it confirms its medical use status. Current risks outweigh no scientific evidence of benefit at this time. It should maintain the current status as a CS-III, and again potentially could use a program that would help to minimize the risks that we're currently seeing. Again, I think I've shown you that without federal oversight, we are seeing that we have faulty testing procedures that are happening that are putting the American public at risk. There's no prescription drug monitoring program to capture who's receiving how much and where they're getting it from, and making sure

that it's not interacting with other controlled substances, which was again causing problems. Again, one of the first guys that did this, his children were killed as a result of a person doctor shopping and receiving benzodiazepines from here, opiates from there. And so that's what the person was doing. Now, you could be getting marijuana from here, there, and everywhere, and there's no communication to anybody right now as to them receiving this.

Again, without an FDA-approved indication in that package insert that we in medicine need, I don't know that we should be moving forward. Let's do what we did with CBD. With CBD, we approved the drug by the FDA and had the package insert. Then we moved it from the CS-V to a non-controlled substance. That concludes my talk.

JUDGE JULIUS: Thank you, Dr. Drum. I think I heard you say early on that your opinion, your views are based upon your understanding of the CSA definition of marijuana.

THE WITNESS: Correct.

JUDGE JULIUS: Did I hear that correctly?

THE WITNESS: Yes.

JUDGE JULIUS: Okay. I just wanted to confirm.

THE WITNESS: Yes.

JUDGE JULIUS: Thank you. Mr. Swan, I don't know, it's now 11:33. I don't know if you have a sense of how long cross-examination may take. Do you want to --

MR. SWAN: Can I get a minute to confirm with the team?

JUDGE JULIUS: Sure. We could either do that before lunch. We could take early lunch, come back. Just confer, let me know how you'd like to proceed.

MR. SWAN: Thank you. Yes, Your Honor, we can take an early lunch now because my understanding there's another witness this afternoon.

JUDGE JULIUS: My understanding, from court staff, is that your second witness is not available until -- as scheduled on the original published schedule -- until tomorrow.

THE WITNESS: That's correct.

JUDGE JULIUS: So Dr. Drum will be the only witness today.

MR. SWAN: Okay. Can I have a minute,

Your Honor?

JUDGE JULIUS: Of course.

MR. LONICH: Yeah, you're right.

MR. SWAN: Your Honor, we can go.

JUDGE JULIUS: Okay.

MR. SWAN: Yeah.

JUDGE JULIUS: Mr. Swan, whenever you're ready.

CROSS-EXAMINATION

MR. SWAN: Thank you, Your Honor. Good morning, Dr. Drum.

THE WITNESS: Good morning.

BY MR. SWAN:

Q Have you received any of the proceedings, the transcripts in this matter?

A As a designated party, I have, yes.

Q Okay. Did you get an opportunity to review them?

A No.

Q Okay.

A We were informed not to read other witnesses' materials.

Q Okay.

A I mean, I did review what was sent to me -- you know, that were the non-witness issues,

right? Because we were instructed not to read the witness.

Q What exactly did you review?

A I'm unclear of your question.

Q You testified that you did review some materials that were sent to you, correct?

A Yes. They were the ones that gave me directions as to how to send in information, my exhibits, et cetera.

Q Thank you. Dr. Drum, you'd agree with me that the study of marijuana is a complex subject, correct?

A No, not really.

Q So, it's not complex?

A No, it's like any other substance, it should be treated like any other substance. The complexity comes with what's being attempted, where we're attempting to say that we need all 100 cannabinoids and all terpenes and all that. That's where the complexity comes in, if I understand the question right.

Q You would agree with me that there are different methods of studies and ethical considerations that come into play in the study of marijuana, correct?

A That's kind of complex. Can you break it down?
Q Sure. There's different methods to study marijuana, correct?
A Different methods? Sure, scientific and non-scientific. Absolutely.
Q Doctors study marijuana, correct?
A Sure.
Q Pharmacists like yourself study marijuana, correct?
A Under guidelines, yes.
Q Researchers, academia study marijuana, correct?
A Yes.
Q Different considerations come into play, correct?
A I don't understand what you mean by considerations.
Q The individuals that are studying it at the time --
A Yes.
Q -- they're considering different things, correct?
A Correct.
Q Okay. And you would agree with me that

those professionals may have different of opinion in the study of marijuana, correct?

A Have a difference of opinion? If they're studying certain disease states, sure. You know, they may be looking for certain efficacy, and it's different.

Q And you would agree with me, amongst those studies, whether it's two doctors or two pharmacists, they may have different of opinions, correct?

A Sure.

Q Okay. Now, you testified briefly about your corresponding responsibility. Can you explain a little bit about that?

A Corresponding responsibilities mean that I have to assess the amount of product that a patient receives and, especially with regards to opiates, that I have to calculate how much opiate that they're receiving, and I have a corresponding responsibility to be able to stop that prescription because it exceeds what's recommended for a daily amount. So for example, we commonly use a 90 milligram equivalent of morphine and we have a corresponding responsibility, meaning even though the physician recommends it, we have a

responsibility to say that we're not going to fill it. That's our corresponding responsibility, that we do not have to fill a prescription if we feel it's out of the realm --

Q Okay.

A -- of appropriateness.

Q And based on your testimony, is it safe to say that marijuana is dangerous?

A Is marijuana dangerous? I believe it is. I believe that as far as we know, it has no proven medical use.

Q Sir, I didn't ask you that part. Is it safe to say opioids are dangerous?

A Yes, but in a different manner.

Q Ketamine is dangerous?

A Yes, it's a controlled substance.

Q So it's safe to say all controlled substances can be dangerous, correct?

A Yes.

Q Okay and it’s safe to say that all controlled substances, if not used properly, can lead to harms, correct?

A Correct.

Q Okay.

A Specific harms that have to do --

Q Sir, sir, sir, as -- just please --
A Or can I finish my --
Q You will get the opportunity.
JUDGE JULIUS: You'll have an opportunity for what's called redirect, and you can --
THE WITNESS: Okay.
JUDGE JULIUS: Add to or --
THE WITNESS: Okay.
JUDGE JULIUS: Clarify any of your answers to --
THE WITNESS: Okay.
JUDGE JULIUS: The questions that Mr. Swan --
THE WITNESS: Okay.
JUDGE JULIUS: -- is asking.
THE WITNESS: Okay.
MR. SWAN: Part of that corresponding responsibility is that you, as a pharmacist, can deny any prescription, correct?
THE WITNESS: That's correct.
BY MR. SWAN:
Q If a patient comes to you wanting to fill a prescription, and if you're not comfortable with it, as you testified on direct examination, you can say, I'm not going to be able to fill that?

A Correct.

MR. SWAN: Okay. No further questions, Your Honor.

JUDGE JULIUS: Thank you, Mr. Swan. Dr. Drum, as I explained, you'll have an opportunity at this time to do what's called redirect.

THE WITNESS: Okay.

JUDGE JULIUS: If you had an attorney, that would be your attorney's opportunity to ask you follow-up questions or to clarify anything regarding Mr. Swan's questions.

THE WITNESS: Yeah, I just --

JUDGE JULIUS: At this stage, I'll just let you --

THE WITNESS: Okay and it was the issue about the special, what was it again? I tried to jot it down really fast. Special types of harms. With regards to that, you know, each drug has special types of harms and so yeah, marijuana has special types of harms. Opiates have special types of harms. I know the industry likes to try and claim that opiates will kill you, and our product will not.

I'm also aware that it does lead to other types of harms and risks. So, when a coroner

writes that somebody that commits suicide by jumping off a building, that that is --

MR. SWAN: Objection, Your Honor.

THE WITNESS: -- that's a risk.

JUDGE JULIUS: Hold on. We have an objection. Basis of the objection?

MR. SWAN: I think we're starting to get beyond the scope of my cross-examination. I understand he's talking about the risks --

THE WITNESS: The harms.

MR. SWAN: But he's incorporating now hearsay of what a coroner may testify to or propose to the court. So I guess it's one of those things where I understand that there is a lot of rope with my redirect, so to speak, but I think we might be getting too far. And maybe it's premature, I'll sit down if Your Honor --

JUDGE JULIUS: I understand where you're coming from with your objection. I think he's using this as an illustrative example to make a point. I'll allow him to continue with his answer. If ultimately it doesn't go where I imagine it's going, then we'll revisit.

MR. SWAN: Thank you, Your Honor.

JUDGE JULIUS: Please continue, Dr. Drum.

THE WITNESS: Sure. So it has to do with, again, what's already in the package insert, the risk of suicide ideation is in there. And so that's a risk and potential harm that someone could experience as a result of using marijuana products, THC and CBD in particular, Because it's in the package inserts, as I showed you. There are different risks and harms that, yeah, you may not stop breathing like what an opiate causes with the central nervous system, but it does raise the risk of a suicidal ideation. That's clearly in the package insert. That's clearly associated with marijuana. That clearly has resulted in many deaths.

JUDGE JULIUS: Anything else you'd like to say?

THE WITNESS: I think that's really it.

JUDGE JULIUS: Okay. Thank you very much, Dr. Drum. Any other procedural matters before we recess for the day?

MR. LONICH: Nothing from the government, Your Honor.

JUDGE JULIUS: Thank you.

MR. MCNICHOLS: Not for us, Your Honor.

JUDGE JULIUS: Thank you, Counsel. You

are excused, Dr. Drum. I understand you'll be back with us tomorrow.

THE WITNESS: Correct.

JUDGE JULIUS: You'll be asking questions of your witness.

THE WITNESS: Correct.

JUDGE JULIUS: And she'll be appearing remotely, I understand.

THE WITNESS: Correct.

JUDGE JULIUS: Okay.

THE WITNESS: And she will have -- because I asked for that as well -- that she'll be using a PowerPoint presentation as well.

JUDGE JULIUS: Sounds good. All right. Thank you very much for your testimony.

THE WITNESS: You're welcome.

JUDGE JULIUS: We will be in recess until 9:00 a.m. tomorrow morning. Everyone have a good afternoon, and we will see you back here bright and early. We'll be in recess until then. Thank you.

(Whereupon, the above-entitled matter went off the record at 11:43 a.m.)

C E R T I F I C A T E

This is to certify that the foregoing transcript was duly recorded and accurately transcribed under my direction; further, that said transcript is a true and accurate record of the proceedings; and that I am neither counsel for, related to, nor employed by any of the parties to this action in which this matter was taken; and further that I am not a relative nor an employee of any of the parties nor counsel employed by the parties, and I am not financially or otherwise interested in the outcome of the action.

James Cordes