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

Tuesday,
July 14, 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.
KAYLA L. KREINHEDER, 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:

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

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

CHASE T. HARRINGTON, ESQ.
JOHN M. McNICHOLS, ESQ.
T. ZACHARY HORTON, ESQ.
Torridon Law PLLC
[redacted]

ALSO PRESENT:

GRAYSON E. PHILLIPS, ESQ., Law Clerk
DECLAN HURLEY, Torridon Law summer associate
~~YUSUF~~YOUSEF YAQUB, Torridon Law

CONTENTS

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

(9:00 a.m.)

JUDGE JULIUS: We're on the record.

Today is July 14th, 2026. This is Day 10 in the matter of Schedules of Controlled Substances: Proposed Rescheduling of Marijuana, DEA Hearing Docket 26-96, DEA Docket Number 1362.

First order of business will be to have appearances stated. Mr. Lonich, appearances for the Government today?

MR. LONICH: Yes, Your Honor. For the Government, Jared Lonich, Mack Swan, Kayla Kreinheder, and David Maley.

JUDGE JULIUS: Good morning, Counsel.

And on behalf of Dr. Phillip Drum, PharmD?

DR. DRUM: Myself, Your Honor.

JUDGE JULIUS: Very good. Welcome, sir.

For Smart Approaches to Marijuana?

MR. HARRINGTON: Chase Harrington, Your Honor, accompanied by John McNichols for Smart Approaches to Marijuana.

JUDGE JULIUS: And on behalf of the Opposed States?

MR. HARRINGTON: Chase Harrington and

John McNichols for the Opposed States, and accompanied by Declan Hurley and Yusuf Yaqub of my law firm.

JUDGE JULIUS: Good morning, Counsel.

And I have, according to my notes, the parties that identified themselves as not being present today or not intending to be present were DUID Victim Voices; Dr. Finn, M.D.; Tennessee Bureau of Investigations; and the National Drug and Alcohol Screening Association. Anybody here representing those parties?

(No response.)

JUDGE JULIUS: Okay. Thank you.

Any preliminary or procedural matters before we resume testimony?

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

MR. HARRINGTON: Nothing over here, Your Honor.

JUDGE JULIUS: Thank you.

Anything, Mr. Drum -- or Dr. Drum? I'm sorry.

DR. DRUM: Yes. To present a couple copies. So do you want me to speak to that now or?

JUDGE JULIUS: If you could just tell us what you handed --

DR. DRUM: Okay.

JUDGE JULIUS: -- the court clerk.

DR. DRUM: Certainly. I -- I last night introduced and sent to counsel a copy of a new exhibit that we would like to introduce today. This is a study that came out just recently, like last week. And so we would like to be able to introduce this as an exhibit.

JUDGE JULIUS: Okay. I will mark this for identification.

DR. DRUM: Should be Number 68, if I'm right.

JUDGE JULIUS: Thank you. For identification, it will be Drum Exhibit 68.

(Whereupon, the above-referred to document was marked as Dr. Drum Exhibit No. 68 for identification.)

JUDGE JULIUS: Any objection from the Government to Drum 68?

MR. SWAN: Your Honor -- Your Honor, we have not had sufficient time to review this. We understand the Court is inclined to admit it, and

we would be able to address it in the post-hearing brief. Again, Your Honor -- again, yeah, I would have to object to this particular exhibit, Your Honor.

JUDGE JULIUS: And the basis for that was just in -- not sufficient opportunity to review?

MR. SWAN: Yeah. I haven't had an opportunity to review it sufficiently, Your Honor. It came in last night. We're -- we're working on this matter, you know.

JUDGE JULIUS: What we can do, I can leave it. I marked it as 68 for identification, and I can give you additional time to review it, and we can revisit this either later today or tomorrow before the hearing concludes.

MR. SWAN: That works.

JUDGE JULIUS: Okay. We'll mark it -- we'll leave it as marked for identification. It's not yet admitted, but I will make a note to myself to make sure we address that after you've had sufficient time to review. Okay?

MR. SWAN: Thank you, Your Honor.

JUDGE JULIUS: Thank you.

Any other preliminary matters, Dr. Drum?

DR. DRUM: No.

JUDGE JULIUS: I will note just for clarity of the record you had used a PowerPoint presentation yesterday to --

DR. DRUM: Yes, Your Honor.

JUDGE JULIUS: -- your testimony sort of followed that. Are you moving for the admission of that PowerPoint as an exhibit? Some of the other witnesses who used PowerPoints did that. I think it could be helpful in reviewing -- in reviewing your testimony to have a copy of that for the Court's purposes to -- to track what you were discussing. Are you -- or do -- did you not want to move for the admission of that?

DR. DRUM: I mean, I have no problem with admitting it. That's -- that's fine with me. I -- I don't have a problem with admitting it as evidence, if you'd like.

MR. SWAN: No objection, Your Honor.

JUDGE JULIUS: Thank you. We'll go ahead and we'll admit that as Drum 69.

(Whereupon, the above-referred to document was received into evidence as Dr. Drum Exhibit No. 69.)

JUDGE JULIUS: If you could

just -- Mr. Phillips, do we have that already? Okay. We'll just print out a copy and add that as admitted Drum Exhibit 69, okay?

DR. DRUM: Okay. No problem.

JUDGE JULIUS: Thank you.

And then, I'm sorry, anything further procedurally before we call your witness?

DR. DRUM: No.

JUDGE JULIUS: Thank you.

DR. DRUM: So, Your Honor, I -- I would like to call my witness at this time.

JUDGE JULIUS: Okay. Can we get Dr. Randall? Thank you.

MR. PHILLIPS: Is anybody going to get her?

DR. DRUM: She's online.

MR. PHILLIPS: Oh, all right. Okay.

JUDGE JULIUS: Okay. Dr. Randall, can you hear us? It looks like you may be muted. Are you able to unmute yourself?

DR. RANDALL: Okay. Can you hear me now?

JUDGE JULIUS: Yes, we can hear you. Thank you, ma'am.

DR. RANDALL: Okay. All right. Perfect. Thank you.

JUDGE JULIUS: First order of business, I will place you under oath. Please raise your right hand if you are able.

WHEREUPON,

DR. KAREN RANDALL

was called as a witness by Dr. Phillip A. Drum and, having been first duly sworn, assumed the witness stand, was examined and testified as follows:

JUDGE JULIUS: Thank you. Let me give you a few instructions about the process of testifying just for clarity of the record. You'll be asked questions. Please wait until the full question is completed before you begin your answer.

After the question is asked, pause for about a second or two to see if the question draws an objection. If you hear the word "objection," just pause. I'll address the objection, and then I'll instruct you as to whether you should answer the question or not. If you need repetition of the question at that time, just ask for repetition of the question. That's not a problem.

If at any time you get a question you don't understand, please say that you don't

understand the question, and it will be rephrased in a way that you do understand. And if you go ahead and answer a question without saying you don't understand it, we will assume that you understood the question. Does that make sense?

THE WITNESS: Mm-hmm. Yes, it does.

JUDGE JULIUS: Thank you very much. If you could just go ahead and please state your full name for the record.

THE WITNESS: Karen Randall.

JUDGE JULIUS: Thank you.

Dr. Drum, whenever you're ready.

DR. DRUM: Thank you, Your Honor.

DIRECT EXAMINATION

BY DR. DRUM:

Q Dr. Randall, what do you do for a living?

A I'm a physician in emergency medicine.

Q Where did you go to school for undergrad?

A I went to the University of Colorado and Brigham Young University.

Q And where did you go to school for medical training?

A I went to the University of Des Moines in Iowa.

Q Where did you complete a residency?

A I actually completed three residencies. I did my first residency in family practice in Arizona. Subsequently, I did an emergency medicine and peds combined residency in Detroit at Henry Ford Hospital.

MR. SWAN: Objection, Your Honor.

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

MR. SWAN: Your Honor, I can't self-assert it, but it appears that the witness is reading from something in response to the questions that she's being asked.

JUDGE JULIUS: Dr. Randall, do you have any documents in front of you?

THE WITNESS: I do. I have some notes.

JUDGE JULIUS: It would be best if you could testify based on your memory. If we need you to look at a document, either Dr. Drum or the Government, when they question you, will direct your attention to that document. Okay?

THE WITNESS: Okay.

JUDGE JULIUS: Thank you.

BY DR. DRUM:

Q So, Dr. Randall, you can use your exhibit for your CV, I believe, Number 52, if we -- we

could bring that in as evidence.

JUDGE JULIUS: Any objection to --

MR. SWAN: No objection to that.

JUDGE JULIUS: -- the CV? Okay. 52 will be admitted.

(Whereupon, the above-referred to document was received into evidence as Dr. Drum Exhibit No. 52.)

DR. DRUM: Okay. Thank you.

BY DR. DRUM:

Q So that's your CV that you -- you can go ahead and use your CV, Dr. Randall, if that helps you. How many years --

A Okay.

Q -- of training did you undergo?

A I went eight years of post-medical school training.

Q Okay. Do you have any specialized training? If so, what -- in what areas? Please clarify.

A I had specialized training in emergency medicine. Additionally, I had specialized training in pediatrics.

Q Okay. And how long have you practiced

medicine as a physician?

A For approximately 31 years.

Q Okay. Could you describe the settings in which you have worked?

A Initially, I worked in Detroit once I finished residency, and I was a training physician or a teaching physician attending at a large inner city hospital, which is a Level 1. I spent 18 years there training residents and medical students. Subsequent to that, I moved to Colorado in 2013 to take a job in a community hospital setting.

Q Okay. And did -- do you have additional training in cannabis?

A Yes. Along the way, I did do a certificate in cannabis science and medicine from the University of Vermont Medical School.

DR. DRUM: Okay. Your Honor, at this time, I tender this witness as a provisional expert in the field of emergency medicine with a specialty in pediatric medicine and a certificate in cannabis medicine and science.

JUDGE JULIUS: Consistent with the Court's preliminary order, we will provisionally accept her expertise.

DR. DRUM: Thank you, Your Honor.

Your Honor, I filed a prehearing statement identifying and submitting prospective exhibits in accordance with 21 CFR 1316.59. We did add that one additional exhibit, Number 68, last night, and counsel was sent a copy, and so we had that discussion previously. And so you -- you've allowed us to be able to discuss that exhibit, correct?

JUDGE JULIUS: Yes.

DR. DRUM: Okay. Thank you.

BY DR. DRUM:

Q Dr. Randall, are you familiar with each of the exhibits numbered 52 through 68?

A Yes, I am.

Q Have you reviewed each of them?

A Yes, I have.

Q Dr. Randall, are these true and accurate copies of the documents that they purport to be and are exhibits with -- an expert with an interest in pediatric and emergency medicine with a background in cannabis medicine and science would use these documents?

A Yes.

DR. DRUM: Your Honor, consistent with

21 CFR 1316.59, all exhibits identified in my prehearing statement were timely submitted, except for Number 68, as proposed exhibits in advance of this hearing, and Dr. Randall has confirmed the authenticity of Numbers 52 through 68 and the accuracy and reliance upon them.

So I move for the admission of Exhibits 52 through 68 into evidence.

JUDGE JULIUS: Any objection to those exhibits?

MR. SWAN: No objection, Your Honor.

JUDGE JULIUS: 50 through -- strike that. 52 through 67 will be admitted.

(Whereupon, the above-referred to documents were received into evidence as Dr. Drum Exhibits Nos. 52 through 67.)

JUDGE JULIUS: I'm still allowing the Government an opportunity to look at 68 and give me their final position with regard to that, but 52 through 67 will be admitted.

DR. DRUM: Okay. Thank you, Your Honor.

Now I'd like to ask the Court to allow Dr. Randall's PowerPoint presentation slideshow to be started.

JUDGE JULIUS: Any objection?
MR. SWAN: No objection, Your Honor.
JUDGE JULIUS: Go ahead. Thank you.
THE WITNESS: Oh. So are we --
BY DR. DRUM:
Q So, Dr. Randall --
A -- starting the --
Q -- is it up? Do you see it? Oh, there it goes.
A Yeah.
Q I think it should be up now. Okay. Dr. Randall, please begin and briefly introduce yourself.
A Okay. This is my first slide, and this is some of the topics that we'll discuss today. First, the marijuana effects seen clinically in the emergency department, and next we'll move to how the PDMP or changes in scheduling might affect the prescriber.
Next slide, please.
This is a little bit about me. We did discuss this already. I just wanted to say that the photograph in the right lower corner is the view of the Colorado fires from my deck, and for the last two weeks we've been doing fire watch.

Initially, I think that it's kind of symbolic as the fire is coming and we're concerned. I think that the fire is already here for children, especially exposed to cannabis.

Next slide, please.

Q So, Dr. Randall, can you please discuss some of the clinical presentations you have seen with marijuana in the emergency department?

A Yeah. Today I'm going to cover disclosure, harms seen in cases that I've personally seen in the emergency department. We'll talk about how the pediatric population will be and has been affected. This will include perceptions of harm, psychosis, cannabinoid hyperemesis syndrome, cannabis use disorder. And then we'll turn to discuss the prescription drug monitoring, and I'll -- I'll present a conclusion.

Next slide, please.

So whether we acknowledge it or not, the decisions that we make today in our sterile courtrooms affect children in a way that is ~~naturally~~ not actually necessary and beneficial to them, and I think we are kidding ourselves if we don't think about how children and teens can figure out how to get these products. And I think that

normalization will not only increase use, but it will increase availability.

Next slide, please.

I'd like to make this clear. I have nothing to disclose. I don't make money speaking about drug prevention. I am not being subsidized to speak today. The images that I have in my presentation were taken from free online images or my own photos.

Next slide, please.

So the first topic today will be talking about the harms, and these are cases that I've seen personally and reflect some of the consequences of cannabis exposure and use.

Next slide, please.

So when we look at some of the harms, there's a significant clinical concern that taking marijuana from a CS-III to a II will alter how the public views marijuana. It's been actively promoted as safe and healthy and natural for a lot of disease entities. But the current case reports that we have in medical literature actually supports the opposite.

Over the last decade, the potency has increased dramatically, which is leading to

increased harms, and there are more and more case reports and studies showing this. The scientific literature indicates that these perceptions are incorrect, and the use of marijuana has pronounced effects on mental and physical health, especially in children.

Next slide, please.

So this is taken from the internet. The site is cited here. It is a wheel of disease treatment, and on this site the -- there is a very big prominent sentence to think of cannabinoids like vitamins. And the average person who goes there and doesn't seek out additional information has no way to know that this is actually not the case.

If you look -- and I'm sorry, it's going to be small because they have listed so many disease elements that they treat -- but if you look, you can see that one of them is pediatric seizures. And so what we've seen in the emergency department is that parents will independently make a decision that the child has seizures and start them arbitrarily on a cannabis product.

But what we know is that using the medicine called Charlotte's Web was actually for

two rare seizure disorders, Dravet disorder and Lennox-Gastaut syndrome, and these are syndromes in children who have persistent and multiple daily seizures. These syndromes are rare and probably affects about 160,000 kids in the U.S. annually.

If you look at the American Academy of Pediatric Neurologists, the recommendation for treatment with Charlotte's Web is a fourth-line recommendation, meaning that all the previous treatments have significantly failed. Looking at the classic case of Charlotte Figi, she was diagnosed with Dravet syndrome.

She had lots of seizures, and they started her on Charlotte's Web, which is CBD with a small amount of THC. It did have some seizure control, but we know that if you read the package insert and looking at children who've had it, the efficacy rate of it is 1 in 4, so 25 percent.

And then we can see a -- a reduction in seizures of about 25 percent, but there's an 80 percent side effect profile, so it is not typically recommended as a first, second, or even third choice of drug treatment in patients. It's a fourth treatment line and basically when everything else has failed.

Next slide, please.

If we go back to the wheel, some of the disease -- diseases that are claims of cure or help, there's a few I'd like to mention. Alzheimer's disease. Typically, the Alzheimer's patient is a frail elderly person.

And what happens here is that the family will go to the dispensary, talk to the budtender. They get something from him to treat their elderly, frail patient or family member. No one checks for medication interactions, and this puts the patient at high risk for a lot of things.

If they're given indica products, they get excessive sedation and falls. If they're given high THC or sativa, it increases confusion and behavioral abnormalities. It is categorically not recommended by the Alzheimer's Association.

If we look at the claims of treatment for glaucoma, we know that these products do actually drop the eye pressure in people who have glaucoma. Unfortunately, it drops it rapidly, and then when -- when it wears off, in a short period of time the eye pressure even shoots up and sometimes even rebounds to a higher level.

So in order to get continuous control of

high eye pressure in glaucoma, you need to be using a lot, like four to six hours -- or every four to six hours. The American Academy of Ophthalmology does not recommend it because what they're seeing is it actually does more ocular damage to the optic nerve to have high and low eye pressures occurring on a frequent basis during the day.

One of the other categories on this wheel was sleep apnea, and we know it's not recommended by the American Academy of Sleep Medicine.

The next category is nausea and anorexia. I put those together. We have a medicine called dronabinol, and it was recommended for anorexia with HIV wasting syndrome. And this was a low dose, lower potency product. The high potency product has led to just the opposite, and we -- and it has led to something that we call cannabis hyperemesis syndrome, and we'll talk more about that in a little bit.

Q Dr. Randall, before you move on, would you like to discuss hypertension there on your slide?

A We know that hypertension -- it's listed as a treatment for hypertension, but we know if a person smokes or uses a product within the first

half hour, 15 minutes to half an hour, it actually has -- increases the heart rate and increases blood pressure. So we have seen cardiac disease and strokes during that time period.

And we'll do next slide, please.

So this is the first case I'd like to present to you. He was a very thin 42-year-old male who presented to my emergency department with abdominal pain, swelling, and jaundice. He stated that a few months prior he --

MR. SWAN: Objection.

JUDGE JULIUS: Hold on, ma'am. Objection?

MR. SWAN: Hearsay, Your Honor. He stated.

JUDGE JULIUS: It is, but hearsay is admissible in administrative hearings, and I think there may be some exceptions for statements made in order to obtain medical diagnosis or treatment. So overruled, but it'll go to weight.

MR. SWAN: Very well. Thank you.

JUDGE JULIUS: Thank you.

Go ahead, Dr. Drum.

BY DR. DRUM:

Q Go ahead and continue, Dr. Randall.

A These are cases that I present, and what the patient tells me goes into their medical record, which is a legal document. And I'm not presenting their medical record because it would be a HIPAA violation.

So, anyway, the patient said he was diagnosed with a form of liver cancer. He didn't know what type. He had read online that cannabis cures cancer, so instead of getting medical care, he went to a dispensary and has been using pharmacy or medical marijuana.

When he came for evaluation for us, he had diffuse metastatic cancer. His liver was riddled with metastatic disease, and he had significant ascites or fluid buildup in the abdomen. He had several blood abnormalities, and he was placed directly into hospice from emergency department, and within the week he died.

So the question here is: who's responsible for the misinformation this patient read?

Next slide, please.

So if you do an internet search, this is some of the things that you can find, and I want to be very clear. Looking at the third picture

over, the guy with the leaf coming from his head smoking a joint, I just have to say, who is this appealing to when we look at this one? Who's going to get this message? It isn't certainly adults or senior citizens, I don't think.

Next slide, please.

So in -- this is Docket Number 26-96, Exhibit Number 53, pages 7 and 8. This is an internet picture, and I think the fact that this picture could be placed on the internet really reflects normalization.

In 2020, the American College of Pediatrics wrote in a paper that a 1998 survey showed 40 percent of the public felt it was at great risk with cannabis use. And then, in 2018, the same survey was given with perception of great risk or harm, and it decreased to 20 percent.

So this is a decrease of 50 percent of people who feel like cannabis or marijuana products could be harmful. And this was occurring at a time when the usage is going up; concentration and total milligrams of marijuana are being consumed have gone up.

Next slide, please.

I don't know if anybody in this room has

actually been in a dispensary, but I did have the opportunity to tour a medical dispensary with a DA from one of the other states who was coming to visit. This is a photograph I took, and these are some of the products that we want to label medicine.

If you would look in the bottom left-hand corner, you can see a product called New York City Diesel. It is a wax product. It is 62.3 percent THC. It took me a while to figure that out, but I learned this in my cannabis science and medicine course. So that means a gram of product will have 623 milligrams of THC. This is -- so it's a significant increase in potency.

This slide is about eight years old, so we know that the potency has increased, and now there are products that are even higher potency, up to 90 percent or over.

Next slide, please.

When we look at products being advertised, this is some of the products, and -- and, believe me, our kids are seeing these. We have THC medicated ChapStick. We have THC-flavored condoms. We have on the right -- upper right-hand side, we have a key fob that is

actually a vape pen made to disguise -- made in disguise. And then we have some more ChapStick.

On the bottom you can see things that look like highlighters, and these are made for kids, and we were taking a lot of them off kids in school.

Next slide, please.

Again, there's more products available, and now in Colorado, we have touch screen kiosks where we can go show an ID card and purchase cannabis products or marijuana products from a kiosk. And I think that this is also a big mistake. I don't know that there's a way to verify identity if a 13-year-old brings someone else's driver's license.

Next slide, please.

These are what our kids are seeing. They're seeing brownies that look like normal brownies. They're seeing candy bars that, although Mr. Dankbar looks familiar to Mr. Goodbar, I'm guessing that the average six-year-old would not associate Mr. Dankbar with a product.

We now have Keef sodas, so we see THC-infused soda. And I had a 14-year-old patient

who said -- was on a sports team, and after practice, his teammate brought brownies. He said he didn't have any idea because the brownie looked like the product that you see in the upper right-hand corner.

He consumed an entire one, and usually these are segmented into 4 to 10 doses. So he came in altered and hallucinating. And when he was better and improved and ready for discharge, he said he had literally no idea that this was a cannabis brownie, and there was no way to identify it as such.

Next slide, please.

So throughout this presentation, I'm going to do some case reviews, and these are people that I have seen clinically. I would like to say that seeing these cases of people affected by cannabis are a small portion of the daily caseload, but unfortunately it's not.

And also know that every day in EDs across America, we're all seeing the same thing. Our literature is full of cannabis hyperemesis, cannabis strokes, cannabis-associated suicide, et cetera, and we'll talk about this.

My hope is to put human faces and human

stories to the legislation that we're discussing because every day that I go to work and I have to look a family in the face because their kid is psychotic, to see the desperation, I think we need to put some humans to the story.

Next slide, please.

So this case is a case of a 13-year-old that I saw. He got a prepaid Visa card-- this -- this is how our kids are getting products, and if we don't think they are, we're wrong. He got a prepaid Visa card at the grocery store. The prepaid Visa card allows you to put in whatever name you want when you go to use it. He put a name -- made up a name for the card.

He went online to a local medical cannabis dispensary. He clicked the box that said he was old enough. He ordered medical marijuana products, paid for them with the prepaid Visa, and then he had the products delivered to his backyard via Uber, and he got an ounce of marijuana. And so if we don't think our kids are getting it, they're getting it, and they're figuring out ways to get it.

Next slide, please.

This is Docket Number 26-96, Exhibit 54,

pages 1 and 2. We note here the American College of Emergency Physicians in 2022 did a study, and there is overall increased accessibility and exposure to marijuana in adolescents.

The number of adolescents who used over the age of 12 increased by 25.8 million in 2002 to 48 million in 2019. They estimate that the number of adolescents who initiate marijuana use in the past year was approximately 3,700 a day.

Next slide, please.

This is a case that I saw. I think this is one of the most profound cases because it really indicated failure in our system on so many levels. This was a 13-year-old female who presented to my emergency department with suicidal ideation. Her parents felt that it was healthy and safe and good for a lot of medical purposes, and they were both consumers themselves, and they felt it would be safe for her to start getting cannabis at the age of 11. So at 11 they started allowing her to have some cannabis.

And in the bottom right hand, it's a book, Kids of Cannabis. This is what the -- our communities are doing. We're normalizing it. The book is all about having parents --

MR. SWAN: Objection.
THE DEPONENT: -- who are --
JUDGE JULIUS: Hold on. There's an objection. Basis of objection?
MR. SWAN: Your Honor, I'm going to object to the characterization of normalization. The first time she said it, I thought that that was it. But I think this might be a theme going on in this presentation, where she's purporting that we are normalizing kids using marijuana. And I'm just going to object to the characterization of the word "normalization," Your Honor.
JUDGE JULIUS: I think it would be helpful if we could get her to explain what she means by normalization, just so that the record is clear about what -- what she means by that word.
BY DR. DRUM:
Q So, Dr. Randall, can you explain what normalization means to you?
A Normalization means that children are seeing people in their environment using the product, including their parents, including siblings and peers. And the more they see it, the more it becomes a common practice. So it is, in my theory, normalized. So, well, Joe is using it,

Mom and Dad are using it, so it must be okay.

JUDGE JULIUS: Mr. Swan?

MR. SWAN: Yes. Yes, Your Honor. Based on that follow up, we would -- we would object, Your Honor. That is not relevant to the purpose of this hearing. The purpose of this hearing is to determine or to gather information in the rescheduling of -- proposed rescheduling of marijuana. The idea that someone feels that it's being normalized because other people are using it, that has no relevance on the hearing that we are here for today.

JUDGE JULIUS: Dr. Drum, do you want to respond to the objection of how normalization is relevant to the questions of whether there's a commonly accepted medical use and whether marijuana should be rescheduled from Schedule I to III?

DR. DRUM: I -- I think, yeah, I just -- it -- it is -- the fact that we are moving it and calling it medicine is attempting to normalize the use and make the public believe that it's medicine. That's what happens when you move it from a CS I --

MR. SWAN: Objection, Your Honor.

DR. DRUM: -- to a CS III, as I talked about yesterday.

JUDGE JULIUS: Mr. Swan?

MR. SWAN: That was the narrative. You -- you asked him for clarification, and I felt that that was the narrative that --

JUDGE JULIUS: I also understand --

MR. SWAN: I -- I get it, yeah. I get it.

DR. DRUM: Yeah. I'm pro se.

MR. SWAN: I get it.

JUDGE JULIUS: He's pro se. But to the extent that she can tie it to her experience and her opinion as the purported and provisionally accepted expert, I will allow the testimony. But I -- I do think some of the testimony can veer towards being less relevant when we're talking about advertising packaging, things like that, that are moving a little bit outside of what she's been purported to be an expert on.

So the more that we can tie it to her opinion, particularly with regard to the expertise that she's been provided for, I think that would be most beneficial to the -- to the Tribunal.

DR. DRUM: Okay.

JUDGE JULIUS: So thank you, Mr. Swan.
MR. SWAN: Thank you, Your Honor.
JUDGE JULIUS: Please proceed, Dr. Drum.
BY DR. DRUM:
Q Okay. So I -- I turn back to Dr. Randall to go ahead and continue. Just be careful with using the term, I guess, normalization.
A So I'll just clarify from my point of view. When we're making the decision that we're going from a CS III to a -- or a CS I to a CS III, I think we are reinforcing the public's opinion that this is FDA approved, that safety precautions have been in place, and that this, what we want to call medicine, is being regulated and is safe.
MR. SWAN: Objection, Your Honor. It's -- it's the same thing.
JUDGE JULIUS: I understand the objection. I'll allow the testimony, but the Government can certainly argue in their closing statements the weight and to what extent it is relevant to the issues in this hearing.
DR. DRUM: Thank you, Your Honor.
BY DR. DRUM:
Q Go ahead and continue, Dr. Randall.
A Let's go to the next slide.

So this female who presented to my emergency department -- literature shows over and over again that THC in adolescent brains, and we -- I have some articles to reference that in the next coming slides, are -- have the potential to have more addiction potential than for adults.

So for this child, by the time she was 12, so this is sixth or seventh grade, she was using more than her parents would give her. And so at that point, the only thing that she consistently had of value was her body, and she was actually trading sexual favor for money and/or marijuana products.

When I saw her at 13 in the emergency department, she was depressed, unable to stop marijuana, and suicidal. And so as a clinician and as a physician, when I see these people in the emergency department, how do I get this child back to childhood? It -- even if I could find and got her the best of mental health care, she will live with the fact that she traded sex for marijuana in middle school, in sixth grade.

And so the -- the problem that we have clinically when we see these kids in the emergency department is, how do we get them back to a

childhood that's been stolen from?

Her wait time in the emergency department was a week. We could not find placement for her. We will talk about placement and facilities available in a -- in a future portion of this lecture. She was discharged home after the family became upset about the wait time, and unfortunately she was lost to follow up.

Next slide, please.

This is Case Number 4, and this indicates the behavioral difficulties that we see with adolescents using marijuana and cannabis products on a regular basis. This was a 16-year-old in foster care. He was a very large stature 16-year-old, and he had some mild developmental delay. When he came into the emergency department, his history was that he was using cannabis more and more frequently.

And because he was big, his behavior was becoming more difficult, and the foster parents felt that they couldn't safely deal with his anger outbursts and his dangerous activities, so they brought him to the emergency department. And they had tried as an outpatient to get him treatment or mental health care.

Unfortunately, they were unable to keep him in treatment, and he was back at their home. They felt there were safety issues for this child with their other children, and so they refused to take him back. This kid was in the emergency department. He was evaluated. He required medication for his behavioral control.

He was in our emergency department for six weeks -- six weeks -- before we found him care. And while in the emergency department, he suffered symptoms of withdrawal and required repeated medication.

Next slide, please.

So as I said, when we're talking about adolescents and children getting care for addiction and substance abuse, it is not uncommon in emergency departments across our country for these patients to wait for up to weeks. There are stories where patients waited over a month to get placement.

We know that marijuana abuse, especially in adolescents, can cause psychosis and violence, and when this happens, placement becomes even more difficult because a lot of our mental health and behavioral health facilities are offsite, and they

have no means to deal with a violent or disruptive patient in their congregate settings.

Next slide, please.

So if you do a quick Google search, in Colorado between 1,000 and 2,000 beds for youth psychiatric and residential treatment centers were closed over the previous decade. An AI search for Colorado mental health beds also shows there is a shortage, a significant shortage, in patient psychiatric beds for adolescents. This is true for multiple states in the country.

The two categories of beds is acute inpatient units, and these are short-term stabilization, getting them over the psychotic episode. And then there's psychiatric residential treatment facilities. These are long-term and specialized care for addiction treatment.

Next slide, please.

Again, just to look at more products of what our kids are seeing and the products that are made clearly to deceive. In the middle product with the black background, these are highlighters. They're vape highlighters, so children can use these at school and vape.

In the bottom center picture, this is

actually a vape hoodie. And if you look, you can see the strings of the hood coming down, and that's actually a built-in vape pipe. So kids can actually load up their cartridge and put it in a pocket on the inside, and they can actually vape at school.

If you look to the bottom right, you can see that Sour Patch candies and Stoney Patch candies look pretty familiar. If you're a six-year-old, I don't think you can distinguish between the two.

Let's go to the next slide, please.

These, again, are some more products. There is THC-infused tampons, tinctures, how to use a bong with wax, et cetera.

Next slide, please.

So if we talk about adolescent use, this is Exhibit Number 55, pages 1 through 8. It was a large study done in the Kaiser system of Northern California. It was done between 2016 and 2023. There were 462,000 adolescents that were surveyed. The average age of the surveyants was 14.5 years old, with a range of 13 to 17 years old. 5.7 percent admitted to past year's use, which is 26,000 children.

Again, at the average age of 14.5, they started their marijuana journey, whether long or short. And imagine if only 10 percent of the 26,000 kids in Northern California needed long-term care or mental health care or developed an addiction. You can see that it's a significant cost to the community and the healthcare system burden.

Next slide, please.

This is Exhibit 55, again, pages 1 through 8. Data was tracked in this Kaiser study, same study, 2019 to 2023. The teens who reported marijuana use were more than twice as likely to be diagnosed with a psychotic or bipolar disorder than their peers. Marijuana-using teens were 34 percent more likely to be diagnosed with depression, 24 percent more likely to be diagnosed with anxiety, and we know, again, the adolescent brain is vulnerable to addiction because the vital neural networks are still developing.

And we also know that a high-potency product will alter the dopamine reward system, and it increases the likelihood of developing a long-term problem with addiction, not just addiction to cannabis, but other substances as

well.

Next slide, please.

So if we look at these products, these are readily available products. If you're a child, there is no way to know if one is infused or not. And these are certainly hitting our market. They're readily available, and there are multiple cases to Poison Control where children have consumed these.

They are larger doses. One ~~D~~candy bar here in Colorado can contain 10 doses or 100 milligrams, and if you're a 50-pound kid and you take 100 milligrams, you will certainly be altered. The Nerd Ropes in particular contain 400 milligrams of THC. And if you were looking at these products as we're looking at them today, is there a way for anyone in this courtroom to tell the difference between an altered product and a normal product or a product that does not have THC? There isn't.

Next slide, please.

So this is the case of the Nerd Ropes. I saw two children. They were both 14. They were brought into the emergency department by ambulance. They were hallucinating and not fully

cooperative. Ultimately, they spent hours in the ED, and finally, when they were able to converse, they admitted that they shared a Nerd Rope.

They indicated to us that they got a message on Snapchat that products were available, and they purchased these from a medical dispensary. So, apparently, a Snapchat will come up, it'll tell the kids where a product is available, and in a few minutes, it goes away.

So these kids know where to go. They went to the back door of a dispensary. They thought it would be safer. And they bought -- purchased the product. This is the actual wrapper from the product they purchased. If you notice in the right upper hand corner, it says 500 milligrams of THC. These two girls shared it. They each ate half of the Nerd Rope. So they consumed what was reported to be 500 milligrams.

But if you turn the package over, and I don't think you can see it, it says 450 milligrams of THC. So either way, they consumed a large amount of THC that would probably alter every single person in this room.

Next slide, please.

They said that in their school this was

a common way for them to get products. They felt it was safer. These teens were actually released after a prolonged ED stay and blood workup and urine workup. They were only positive for THC in their urine drug screen, and they were eventually released to their parents. And this demonstrates how large the dose can be and the effects on teens and children.

Next slide, please.

So these are actually products that were taken from people in middle school. So middle school is sixth to eighth grade, 11- to 14-year-old children. One photo was from the internet, and it's a -- on the left bottom. It is a photo of the products taken from children in middle school. The photo on the right is products that when we went to school with a -- a forensic chemist who worked for the DEA, these are the products that were given to us.

The package that's on the far right side that's green and mimics one of the flavor additives for water is actually 10 milligrams of THC. If you look at the bottom of the slide, right above the silver vape pen, you can see two Ripple -- one Ripple package, and a Starbucks sugar.

You can see that the Ripple package is very similar to a Starbucks sugar package, and it contains 10 milligrams of THC. And so you can see how easily these products can slip into our communities and our children.

Next slide, please.

So this is a study that was done in 2014. It's Exhibit 56, pages 1 and then 20 through 22. At -- at this time, the products were less potent, and we know now they're more potent and more widely accepted. At that time, alcohol use and marijuana use were almost equivalent at 25 percent and 23 percent, respectively. And, once again, the perceived risk has decreased.

In 1992, 80 percent of seniors reported regular marijuana use as a great risk, so they thought it was harmful. And, in 2014, although the product potency has gone up and use has gone up, 45 percent of seniors reported that they thought it was a great risk. So it was a decrease by approximately half.

Next slide, please.

This is from Exhibit 57. It's pages 1 through 3. We know that the teen brain continues to develop and modify neuronal pathways until

about the age of 25. Marijuana use during adolescence and young adulthood is known to harm the developing brain, and sometimes these pathways are altered permanently, and we can't recover some normal functioning.

There is, we know, a significant increase in negative side effects. We see kids who have difficulty thinking, difficulty problem solving, problems with memory and learning, reduced coordination, difficulty maintaining attention, and problems with school and social life. This survey was done in schools, and, like the Healthy Kids Survey, those kids who are using or who are significant social problems will not be in school.

Colorado, last year, absenteeism rate was 28.4 percent, or 244,000 children or students were missing from school. These kids are the kids who are not taking the Healthy Kids Survey, but these kids are also high-risk kids and more likely to be abusing.

In 2022, past year marijuana vaping, 6 percent of eighth graders said they vaped; 15 percent of tenth graders admitted to vaping, and 21 percent of twelfth graders used. And this was data from 2022.

Next slide, please.

So the perception of harm has definitely decreased. It's ubiquitous or everywhere, especially in Colorado and where I live. It's in our kids' environments, and they're seeing it. They're seeing it in grade school and elementary school. But because people have been told that -- that it's -- it's healthy, it treats so many diseases, I think the perception of harm has decreased, and there's certainly articles to demonstrate.

This case is the case of an 11-month-old who was brought to the emergency department for evaluation of ongoing seizures. She had a normal birth and no medical problems. The patient and her parents had a very strong odor of cannabis in the -- in the trauma room. In the emergency department, the child continued to have seizures. She required medications to stop the seizure activity, and she was intubated and placed on a ventilator.

We did the whole workup -- CT, LP, urine drug screen, bloodwork -- because it's a young kid with new onset seizures, and everything was negative except the urine drug screen was positive

for THC.

Ultimately, due to recurrent seizures, she was flown to ICU for care at a children's hospital, and, retrospectively, the parents admitted that maybe she had gotten into their marijuana, and they thought it would be okay, and they just kept her at home for a couple of hours until she started seizing, and they brought her in for care.

Next slide, please.

This is another case where we see the perception of harm is decreased. This was a 17-year-old male. He and his friends were vaping cannabis in a truck that he was driving. His mom in the trauma room told me he had been using more and more frequently over the last several months, and he was taking more risks that she felt were serious. He had told his mother he felt better driving when he was high.

On the day he was seen in the emergency department, he was driving a small pickup truck with his friends. It was speeding. None had seat belts on. The car left the road at a high rate of speed. It rolled several times. This patient was ejected. He had multiple injuries, and he did

not survive. It was reported that they had been, by -- by other passengers in the car, that they had been smoking marijuana at the time of the injury -- or accident.

Let's go to the next slide, please.

Again, it looks like this on the internet to me --

MR. SWAN: Objection, Your Honor.

THE WITNESS: -- to say that --

JUDGE JULIUS: Hold on, ma'am. There's an objection.

MR. SWAN: It will go back to what we stated before, Your Honor. I do think that the idea that we're getting pictures off the internet, putting them in a slide, presenting it to Your Honor for Your Honor to rely on them, and then captioning it with normalization of use, I would object to the characterization of that, Your Honor.

JUDGE JULIUS: I understand. It'll go to weight. I -- to the extent that, again, we can tie this to her experience and her opinion as a medical professional, I'll allow it, but with that understanding.

MR. SWAN: Thank you.

JUDGE JULIUS: Dr. Drum, please continue.

BY DR. DRUM:

Q Okay. Dr. Randall, please continue.

A This picture speaks to me a thousand words. If -- if we put this picture up with a baby and a cigarette, we would say, oh my God, that's -- that's so bad, and people would not post that on the internet. But we see more and more of these type pictures on the internet because it's -- it's considered healthy or beneficial.

And there is all kinds of -- all kinds of internet websites where -- Ganja Mamas and other places where they talk about how to get their kids to use or how to hide their use from their OB/GYN, et cetera, and I think this picture is classic. We would not have seen this picture two decades ago.

Next slide, please.

So let's talk about some of the neurodevelopmental changes we see. This is from Exhibit Number 59, pages 2 through 4 and 39 through 43.

We know that neurodevelopmentally consequences do happen from adolescent cannabis use, and these were examined. There were focuses

on structural brain changes, cognitive impacts, and addiction vulnerability with long-term outcomes.

This comprised of 36 studies. It was a -- a global review that had 8,432 participants. Neuroimaging was done, and they said there was definitely dose-dependent changes, where they're seeing a decrease in the prefrontal cortex, hippocampal, and amygdala volumes.

And what this means radiographically, when they're looking at it, they can see that these areas on a brain imaging are actually smaller. The hippocampus and the amygdala, ultimately, changes in these are what we see when patients develop Alzheimer's or cognitive -- cognitive issues.

We also -- they also saw impaired white matter connectivity, and cognitively persistent defects persisted after prolonged adolescence in -- abstinence in adolescence. So the interpretation of this is that these changes are at least significantly prolonged, if not permanent.

The article sums it up by saying the challenge of, quote, "Soft drug perception is a

big challenge," that it's -- they do not feel it is a soft drug.

Let's go to the next slide, please.

Just for clarification, it's a definition of psychosis. We will talk about that shortly. It's a gross impairment in reality testing, so not in contact with reality. There's marked disturbance in personality, impairment in social, interpersonal, and occupational functioning. There is impairment in judgment, absent understanding of current symptoms and behavior with loss of insight, and presence of characteristic symptoms like delusions and hallucinations.

Let's go to the next slide because we'll demonstrate psychosis.

This was a patient I saw, and this was a case of adult psychosis. This was a female who came to our emergency department via ambulance. She was 40 years old. She drove up from a city approximately five hours south of where I'm living, and she came to our emergency department after being picked up at a local restaurant.

In the middle of the night, she arrived here in our city. She'd found a new friend. His

name was Ghost. She picked him up, and they decided they would go to a restaurant. They went to the restaurant. While at the restaurant, in the middle of the night, she began screaming that the police in her hometown were raping her, the whole department, and she wanted the police called. So the local police responded.

They actually -- she requested to go to the hospital. They prevented her from giving her keys to her new friend, Ghost; instead, kept them for safe keeping. When she came to our emergency department, she was agitated and combative on arrival here. Her urine drug screen ultimately was only positive for THC.

Next slide.

Oh, sorry. Can we go back again one more slide?

I do want to state that she spent hours in our emergency department. She was very combative. This was one of the times when I personally was hit by a patient because she didn't perceive us as being healthcare people. She also struck some of the techs and one of the nurses. And I guarantee you, no one in the ER wants to go to work and be hit by patients.

Next slide, please.

This is a case of pediatric psychosis, and this is the youngest patient that I've seen in psychosis with the only substance being THC positive. He was seven. He was brought to the emergency room in police custody because they couldn't control his behavior.

He had been at school, and previously at school he'd had another episode of psychotic or violent behavior, where he was acting out and hitting people. He did have, sadly, a history of recurrent cannabis use. He was addicted to marijuana. He personally told me that he loved the way it made him feel. At seven, he told me that.

This seven-year-old waited in our emergency department for over two weeks for placement. Again, because of his violence, he was very, very difficult to get placed in an inpatient treatment center. And this child was seven, and changes at this time will be persistent for a lifetime. So we derailed this child from his childhood.

Next slide, please.

This is Exhibit Number 61, pages 1

through 5 and 9. It is the earliest longitudinal study showing relationship between use and development of schizophrenia. It is a 15-year perspective. It's 50,000 entry -- or patients followed.

Those who tried cannabis by the age of 18 were 2.4 times more likely to be diagnosed with schizophrenia, and risk was noted to increase with use. And 13 percent of the schizophrenic cases could be averted if cannabis were prevented. So imagine that, 13 percent of persistent schizophrenia cases in this study could have been averted had they not been using cannabis.

Next slide, please.

This is a 14-year-old who I saw in the emergency department. He was brought, again, in police custody. He had told his mom at the start of the school year last year he was not going to go to school any longer, so he didn't. He was a large 14-year-old, and his mother couldn't force him to go to school.

On the day he was brought in, he was noted to be acting, as the family called, odd. He was talking to his picture of his grandmother. He demanded his mother get him marijuana, or he was

going to kill her. He became physically combative and escalated his behavior, and he attacked his younger brother.

At that time, the police was called. They brought him to the emergency department and -- for us to evaluate. He was clearly psychotic when he came in. It took a number of people to restrain him. Ultimately, we had to use antipsychotic medication for chemical behavioral control of this kid.

He was admitted to the emergency department. He waited for 11 days for a facility to accept him for treatment, and during that 11 days he had repeated episodes of violent behavior which required repeated medication to control behavior, and ultimately he was started on a long-term antipsychotic, and he got placed after 11 days of waiting.

And I want to just reiterate, these kids are getting it. They're having problems, and we don't have the facility to treat them.

Q Dr. Randall?

A Next slide, please.

Q Dr. Randall, what was the toxicology on this child?

A His toxicology was only positive for THC.

This is Docket Number 26-96, Exhibit 64, pages 1 and 2. If you look here, this is from the Colorado Department of Education. You can see that chronic absenteeism rate is 28.4 percent. It's defined as 10 days or more, and then chronic truancy rate is 3.6 overall.

These children are not in school, and they're not taking any surveys, and they are most likely to have social and emotional issues as well as substance abuse issues.

Next slide, please.

This is another case of psychosis. It's an 18-year-old male who was brought to the ED for evaluation. He was found running down the median of a highway, I-25. He was combative and paranoid. On scene, he was tased three times, but it had no effect. Ultimately, he was tackled, restrained by police, and brought into the emergency department

He was sedated heavily because of his combative behavior. He tested only positive for marijuana. His family did come ultimately and said he had a long history of use and had frequent episodes. He was observed in the ED for over 24 hours, and then when he woke up and became

conversant, alert, and oriented times three, as an adult, he can refuse care. He did, and he left AMA.

Next slide, please.

JUDGE JULIUS: Doctor, if you could specify what you mean by "AMA" just so the record is clear.

THE WITNESS: Oh. Again, I'm -- I'm sorry. Against medical advice.

JUDGE JULIUS: Thank you, ma'am.

THE WITNESS: You're welcome.

This is Exhibit Number 61, pages 1 through 6. It was a four-year study done on dose response relationship between self-reported cannabis use and the likelihood of reporting psychotic symptoms. Cannabis dependence at 18 predicts an increased risk of psychotic symptoms at 21.

This is a New Zealand study, 759 participants. They were assessed for risk factors, and there was a -- a clear relationship between cannabis use by 15 and increased psychotic symptoms by the age of 26.

There are studies out there that show if a child or a young adult has a first psychotic

break, and if they stop completely, they may never have another psychotic break. But if they continue to use, then the psychosis or these psychotic episodes can continue.

And the cases that I -- I've already talked about clearly represent some psychotic behavior and what we see clinically at -- on a almost a daily basis. And so if we could do some education, do some teaching, we could prevent some of these. But we can see clearly these symptoms persist.

Let's go to the next slide, please.

This is, again, Exhibit 61, pages 1 through 9, and they clearly say that evidence of regular cannabis users with psychosis will have more symptoms. They have more frequent relapses, and they require more hospitalizations. And this presents a challenge to us as healthcare workers because we don't have enough space. There's not enough rooms. These people wait for a long time in the emergency department for placement.

Given the psychosis and violent behavior, it is even more difficult to get them placed. And, finally, it's a challenge to get these people to understand that it is a benefit

to stop using cannabis. However, that being said, it is difficult for them to stop using because it really is -- and on many times I've been told that it couldn't be the -- the marijuana because they love this drug.

Next slide, please.

This is Exhibit Number 62, pages 2, 3, 4 and 5, and we're talking about psychotic disorders. This is from Canada and the Canada Community Health Services. They looked at people 12 to 19 years old with psychotic episodes. There was a study done by D'Souza, et al., in Yale, New Haven VA, and they showed that they could induce psychosis or psychotic symptoms transiently with only 5 milligrams of THC.

We now know -- I have patients who tell me they use 2,000 to 5,000 milligrams of THC a day. And so in this Canadian study they ended by saying the ED had a 77 percent past year cannabis use in those who presented psychotically.

Let's go to the next slide, please.

This -- we will turn now to talk about cannabinoid hyperemesis. This is Exhibit 63. It's -- it's a case report. Once in about the 20 -- 2000s through the 2010s for emergency

departments, when we have an unusual case, we'll call it a case report. And at one point, this was a case report where it was somebody reported that someone had acute abdominal pain, nausea, and vomiting from cannabis use.

And now, currently, it is seen every day in emergency departments across the U.S. We see it every day. It is a combination of forceful vomiting and abdominal pain, the -- being known as "scromiting" -- a combination of screaming and vomiting by emergency personnel. It is the result of cannabis use, and we know that the only treatment is cessation.

Let's go to the next slide, please.

The age range of cannabis hyperemesis patients I've seen is between 14 and -- 63 was the oldest. It is exceptionally difficult to treat. These patients don't respond to typical drugs to treat vomiting, so typical antiemetics, they don't respond.

Deaths do occur, and deaths have been reported from ruptured esophagus, severe dehydration, electrolyte abnormalities, kidney failure, cardiac arrest, anorexia, and failure to thrive. So deaths have definitely been reported

as a result of cannabinoid hyperemesis syndrome.

On July 9th, a news article described a Canadian woman who died at the age of 22. She'd been using marijuana since 14. The reference for that article is listed here.

Treatment in the ED for us is antipsychotics, IV fluids, observation, and, of course, because the patients prevent -- present dramatically, they are screaming, and they're scream vomiting, and they're very agitated. And so, as the clinician, I have to rule out bad things. So these patients get a significant work up in our emergency department.

Next slide, please.

So this is a -- a preprint article, and it just looks at the number of people who have had CHS. It was 7,034 adults. The estimation is that approximately 40 million adults use cannabis, and of those, 17.8 percent report using or having cannabis hyperemesis symptoms. This translates to 7.2 million people who have cannabis hyperemesis syndrome or symptoms. Not all of these patients do, however, come to the emergency department.

Now, it is fairly well known among users that this is something that can happen. They will

self-treat with capsaicin cream or hot showers at home and come and tell us that they can't control their symptoms.

Let's go to the next slide, please.

This is a case of a 63-year-old male who presented to the multiple -- the emergency department multiple times. He'd been seen at least 12 times in the previous month for severe vomiting and abdominal pain.

Typically, when he presented, he came by ambulance, and he presented screaming and vomiting. He was very distressed at these times. And because he was older, he would get an EKG, blood workup, X-rays, et cetera, because we have to rule out bad things that are happening. He had, on this occasion, significant electrolyte abnormalities due to his repetitive vomiting.

He did continue use of high-potency marijuana and was using multiple times a day. He felt that it would control his nausea. On his last visit with us, he had severe electrolyte abnormalities, and he was admitted to the ICU. He did not survive that hospitalization. His total number of ED visits for that year exceeded 60. His urine drug screen remained only positive for

THC.

Next slide, please.

This is another case of cannabinoid hyperemesis. This was actually probably my first experience with CHS. We were doing citywide social services rounds, and this patient's name was brought up. At the time, he was 18, but he had started using marijuana for anorexia at the age of 15.

And over the preceding three years, he increased the amount he was using and he developed recurrent protracted episodes of vomiting leading to multiple admissions, evaluations, and treatment plans, and ultimately his diagnosis was CHS, but he was early on, so it took a while to get that diagnosis.

He was using about 2,000 to 5,000 milligrams a day, depending on what he could secure and afford. He stated he couldn't stop using marijuana because it just made him feel too bad, and he had significant withdrawal symptoms. He actually understood that he would die if he wasn't going to stop using.

Next slide, please.

So despite multiple intensive

interventions with him, including inpatient treatments, inpatient behavioral health, he continued to using -- returning to using cannabis. And at the time of presentation to us, he weighed less than 80 pounds. He was 6'3 and he was dying. He was admitted directly to hospice.

His only condition on being admitted to hospice was he allowed -- be allowed to use cannabis because they said he couldn't take the withdrawal, and he died within that year from complications directly related to long-term cannabis use.

So while some may claim that there are no marijuana deaths, it is very, very clear that there are marijuana deaths. It is just not in the way that we think opioids kill people.

Let's go to the next slide, please.

Again, we call it "scromiting." It's a combination of scream and vomiting. Most patients present very dramatically. This case is a 15-year-old girl who was using daily. She was vaping, using a bong, or doing joints. She admitted to using marijuana since the age of 12. During her 15th year, it -- she had over 50 ED visits to our hospital system for CHS symptoms.

She typically came by ambulance, and because she had been seen so many times in the emergency department, her family didn't go with her, and we would have to call them to come pick her up at the end of her stay. She was admitted multiple times. She'd had multiple evaluations, including bloodwork, CT scans, hospital admissions that year.

These episodes would flare up and last for days, which she described a lot of pain, and when she was lucid enough to talk and in -- and pain-free enough to talk, she would say she could rationalize saying she knows this was bad, but she just simply could not stop using. She was actually not attending school, and ultimately, by the age of 17, she advanced to more drugs and was lost from our system to follow up.

Next slide, please.

This is Exhibit Number 62, pages 1 to 4, 6, and 7. This was a study done on the costs of -- of diagnosing CHS in a patient. The previous patient had approximately 50 visits, and even if we say at $2,000 a visit, which would only include services, nursing services, IVs, and some medications, her 50 visits would cost $100,000.

MR. SWAN: Objection.

THE WITNESS: Then there are --

JUDGE JULIUS: Hold on, ma'am. We have an objection. Basis of the objection?

MR. SWAN: Again, Your Honor, I believe this slide, going down the bullets, is purporting to get into how much cost -- how much it's going to cost in diagnosing individuals with some type of marijuana disability or problem. I think the idea that we're going to start admitting evidence regarding how much it may cost has absolutely no relevance on the rescheduling of marijuana.

JUDGE JULIUS: Would you like to respond to the objection and how this is relevant, number one, to her area of expertise, and, number two, to the issue of rescheduling?

DR. DRUM: Well, I think her area of expertise is self-explanatory. Again, she's an emergency room doctor, and she's talking about cannabis hyperemesis that she sees.

JUDGE JULIUS: But how is the cost relevant?

DR. DRUM: The cost issue is relevant because of the increase in usage that's going to go up when you move it to a CS III, and so this

is going to increase then. It's going to be even higher -- the cost -- and -- and the activities that have to be performed in the hospital are numerous to be able to rule out -- we have to rule out other cases.

JUDGE JULIUS: But how is that relevant to what this Court has to decide? I understand --

DR. DRUM: This -- this Court --

JUDGE JULIUS: -- there are lots of concerns that are out there with regard to --

DR. DRUM: Sure.

JUDGE JULIUS: -- things that go on with medical treatment. How is this relevant to what this Court has to decide --

DR. DRUM: Right.

JUDGE JULIUS: -- on the issues of rescheduling?

DR. DRUM: I think it has relevance due to the -- to acknowledge that if you're determining that it is now a medicine, by moving it from a -- from a I to a III, and that's what you're doing, that the -- there's going to be now increased usage because now the federal government has dictated that it is a medicine.

JUDGE JULIUS: Well, that's one thing,

but how is the cost of treatment relevant to this analysis?

DR. DRUM: Well, I guess we have to look at it as utilization of -- of hospital resources and -- and what we're willing to -- to fund in our society. So, to me, this is extremely important, as well as, you know, recognizing other people needing emergent services, that we are now having to treat these people.

JUDGE JULIUS: Anything further from the Government?

MR. SWAN: Your Honor, we -- we stand by that it's not relevant. If -- if --

DR. DRUM: And the numbers will increase.

MR. SWAN: I do think --

JUDGE JULIUS: Hold on, sir.

MR. SWAN: I do think that not only is it not relevant, it calls for speculation, Your Honor. All of this is, we think this is going to happen; we're going to -- we think that's going to happen. The rules of evidence are designed to keep this out, Your Honor.

JUDGE JULIUS: I -- I tend to agree that we are venturing into irrelevant territory and speculation, so --

DR. DRUM: As we've seen with marijuana usage and the liberalization of its use, moving from --

MR. SWAN: Objection, Your Honor.

DR. DRUM: -- marijuana as medicine to --

JUDGE JULIUS: Hold on. What's the objection?

MR. SWAN: The characterization of liberalization, Your Honor.

DR. DRUM: As we've opened up the ability to use more and more marijuana for other reasons, now calling it a medicine federally will lead to increased usage. That's not speculation.

JUDGE JULIUS: That's debatable, sir. That's part of -- I'm going to sustain the objection as to the issue of cost based -- I -- I don't see how that's relevant to what this Tribunal has to look at. If we want to talk about what she's seeing in the hospital, everything that she's talking about with patients, I get that. But as to the cost --

DR. DRUM: The cost has to do -- if I could clarify --

JUDGE JULIUS: I've already ruled, sir.

DR. DRUM: Okay.

JUDGE JULIUS: Please move on.

BY DR. DRUM:

Q Okay. Go ahead, Dr. Randall.

A All right. Next slide, please, then.

We are going to turn to edibles and accidental ingestions. This is Exhibit Number 66, page 1. There is a study that evaluated trends in pediatric marijuana edible ingestions of less than six years old in age. This was from 2017 to 2021.

And, in 2017, there were 207 cases reported, and between the timeframe or between that time, in 2021, the number of cases reported to the Poison Control was 3,054. And this is an increase by 13,000 -- or 1,300 percent. It's a marked increase. And what it tells us is that more products are available for kids to get into, and more kids are getting into it.

Most of the cases that come to the emergency department present as altered mental status or CNS, central nervous system, depression. Twenty-seven percent of those kids who presented were admitted. There was an increase in ICU and non-ICU admissions.

Next slide, please.

For edibles in children, it takes about 30 to 90 minutes to reach peak effect after they've eaten it. Children are smaller, and so weight based, relatively, they will have a larger dose. So a 10-milligram piece of brownie will affect a child with a smaller weight more than an adult.

Children do not appear to pay attention, especially our younger kids, to packaging or dose recommendations. And if I offer this plate on the right-hand side of candy and brownies, even if I put the marijuana leaf there, most children would still eat the cookies.

Some of the serious side effects that we see are altered mental status, hallucinations, persistent seizures, and coma.

Next slide, please.

This was a case of a 22-month-old who presented to our emergency department. Both parents ultimately stated they were on medical marijuana, but that wasn't initially forthcoming. The child was -- by report, saw some gummy candy and ate several 10-milligram doses. The child weighed 10 kilos, so this is a significant number of milligrams per kilo.

Apparently, the parents -- I'm sorry, the

parents didn't bring the kid in initially because they thought it was safe and would be safe for their kids because they had taken it without having problems. Ultimately, the child began having seizures at home, and he was brought by that time to the emergency department. He was stabilized, intubated, and given medication for seizures, and he was flown to Children's Hospital for ICU admission and care.

I believe this is third-party endangerment, believing that the product is safe. The parents did not get medical counseling about the potency or the potential problems for other people taking their medication, and they were not given appropriate care to safeguard medications. And this is indicated by the fact that the patients didn't initially bring the child in because they thought it would be safe.

Next slide, please.

If you do a quick Google search -- anybody can do it -- open your computer, do a little search that says "edibles at school," and these are all cases from exposures in the last couple of months, with one exception being in 2025.

But there are numerous reports: 4/9, students sickened by weed gummies at Pennsylvania Middle School, so these are sixth graders; 4/16, 10-year-old child hospitalized after unknowingly eating a weed gummy; 4/17, child hospitalized after eating THC gummies; 4/29, six students in an elementary school in Detroit after eating edibles; 5/1, THC-laced candy caused Minnesota students to get sick; 4/9, four middle school students sickened after ingesting THC gummies.

And we can clearly see the pattern, right? The pattern is present. There are kids who are getting these products, and the population at large may or may not know that these are really potent to children and can potentiate significant medical problems.

Let's go to the next slide, please.

Again, some more Google reports from children hospitalized after a teacher allegedly gave them gummies during school. In 5/1, THC-laced candy made Minnesota students sick. Again, 5/14, 11 students taken to the hospital in Chicago. 4/5 -- 15, a four-year-old was found unconscious after eating a gummy.

And this is the trend, and this is the

pattern, and hence the increased number of calls to Poison Control. We're not talking 100 percent. It was -- it was a 3,000 percent increase in the number of calls, and these are just a small selection of the readily available articles on exposures at school.

These kids are all like middle school, high school, and elementary school-aged children. The problem is huge, and most of these ingestions are unintentional.

Let's go to the next slide, please.

This was a case I saw in the emergency department. Two 15-year-old girls were brought to the emergency department. They got a THC vape pen. They both shared the vape. One passed out, and the other became confused and had altered mental status. They were brought to the emergency department in that condition.

Given that the child had passed out and had changes in mental status, they were both given extensive workups, including bloodwork, IVs, medications, and imaging. Both girls only tested positive for THC. One was hospitalized for further treatment, and the second child was discharged home with the family after a prolonged

ED stay.

Next slide, please.

This was just published. This would be Exhibit 68. I don't know if you want me to talk about this.

Q Go ahead, Dr. Randall.

JUDGE JULIUS: She can go ahead.

THE WITNESS: This is recently published, so it's just pretty much hot off the press. It is case reports to the U.S. poison Centers. Rates of less than six-year-olds with exposure to cannabis was relatively stable from 2000 to 2009.

However, exposures started to increase in 2010. So when you compare 2009 exposures, which was 132, this was calls to the Poison Control Center, and we look at cases -- these are kids 12 and under I -- I should add. In 2024, it was 8,430 cases, so this is an increase of 6,300 percent of cases exposed.

Next slide, please.

MR. SWAN: Objection, Your Honor.

THE WITNESS: Again --

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

MR. SWAN: The characterization of that

photo in that slide, Your Honor. I -- I think --

JUDGE JULIUS: I --

MR. SWAN: -- this is inflammatory at this point, Your Honor.

JUDGE JULIUS: It may be premature at this point. We'll see how this comes in. I understand the problem with the image, but we'll see how it -- I'll overrule it for now. Go ahead.

BY DR. DRUM:

Q Go ahead, Dr. Randall.

A These images are -- these images are taken from the internet, and I think it just supports the case. The kids are using more, and it is now a part of their life. Where you see the bottom left picture, the kids are smoking weed. So, in 2009, kids who were 6 to 12, there was 21 reports; and, in 2024, there was 2,894 reports, and that's an increase of 13,000 percent.

Next slide, please.

So we're going to turn to cannabis use disorder. This was -- is a relatively new diagnosis within the last probably 15 years. If we look at spectrum of cannabis use, we see occasional use is 16.3 prevalence; daily use, 10 percent; and, of those, 3 in 10 users will have

cannabis use disorder.

Warning signs that we see in cannabis use disorder are loss of control, neglecting responsibilities, so schoolwork, jobs, et cetera, time spent in getting high, and withdrawal symptoms. So it definitely has withdrawal symptoms associated.

Let's go to the next slide, please.

From a mental health perspective, a person is unable to stop using cannabis despite social or physical harms. This is the definition of cannabis use disorder. Almost all the previous cases that I have discussed where people tell me they cannot stop using would fit the criteria for cannabis use disorder, and the criteria include failed quit attempts. So they tried to quit, but they couldn't. It drew them back.

Relationship or issues and conflicts regarding use of cannabis, neglected obligations like we talked about, not going to work, not going to school, not performing what they should be doing.

And, additionally, there's a thing called tolerance. So tolerance usually happens when someone is addicted, and it means that in

order to get the high that I got when I first started using, I need now to take more of the same. And that's called tolerance.

And withdrawal symptoms and cravings are also listed as cannabis use disorder.

Let's go to the next slide, please.

So we talk about marijuana and overdose and death. Opioids kill people by affecting the brain stem. So the opioids, we have receptors in our brain stem that -- that opioids, heroin, fentanyl will cover, and when this happens, our brain stem doesn't tell us to breathe. And so when people overdose on opioids, this is why they die. They have respiratory depression and suppression and then death because they're not breathing.

But unlike opioids, there's no reversal agent for marijuana. Opiates, we can give Narcan. And marijuana does not have receptors in the brain stem, or it doesn't have very many receptors in the brain stem, so you can consume a large quantity without actually having respiratory depression.

That being said, death does occur in other ways. It's accidents, it's prolonged seizures, it's electrolyte abnormalities as we've

seen with CHS, and suicide, as well as pulmonary issues, cardiac arrest, and MIs.

There are cases where people consume an inordinate amount of THC. There's a YouTube video out there that shows a guy who smokes 35,000 milligrams of THC in a bong, and he does pass out, and that's referred to as a greenout. So we know that people do have symptoms when they use too much.

JUDGE JULIUS: Just so the record is clear, ma'am, could you explain what "MI" means after cardiac arrests on the second-to-last bullet point?

THE WITNESS: I'm sorry. That's a myocardial infarction.

JUDGE JULIUS: Thank you. Please proceed.

THE WITNESS: Thank you.

Marijuana is the number one associated substance in completed pediatric suicides in the state of Colorado.

Let's go to the next slide, please.

This is taken from Colorado Vital Statistics. It is Exhibit Number 64, page 2, and these were the parameters that I looked at. It's

from Colorado Vital Statistics looking at suicides in the state, completed suicides from the time period of 2013 to 2024. I specifically selected out ages 10 to 18 and where toxicology was available.

Let's go to the next slide, please.

BY DR. DRUM:

Q Dr. Randall? Dr. Randall, why did you select 2013 to 2024?

A 2013 is when we legalized in Colorado.

So this is what that graph looks like, and in that time period, there were 719 deaths. Of those, 620 had toxicology available; 99 did not. Of the 620 toxicology reports, we see that 23.7 percent of those children who committed suicide in our state during that time period had THC. Compare that to alcohol, which was only 10 percent, and compared to opiates at the same time period was 5 percent.

Let's go to the next slide, please.

So if we look at this again, 23.7 percent of completed suicides in children was associated with a positive toxicology for marijuana. The death rate in that time period was approximately 70 kids per year. And 13.7 percent had no

toxicology reported, and I'm not sure of why that wasn't done, and I don't know how that would alter the numbers inevitably.

Let's go to the next slide.

This is the same exhibit. I changed the time range from 2004 to 2012, children aged 10 to 18, and we can see that the total number of suicides for that time period was 360. Toxicology was available for 322 of these completed suicides, and 38 percent had no toxicology available. Once again, cannabis was present in -- present in 17.4 percent. Compare that to 4.7 percent of opiates in completed suicides.

During the time period when we were looking at these tables, we note that there was a decrease in suicides per year of approximately 45 to 50 percent compared to the most recent of 2013 to 2024.

Let's go to the next slide, please.

This was a case of a patient that I saw in the emergency department. He was brought to the emergency department by EMS. He had declared himself suicidal and was found to be sitting on an overpass to the highway.

A crisis team was dispatched to the

scene, and just prior to their arrival, he jumped off the bridge into highway traffic. He had multiple injuries and was pronounced shortly after arrival to the trauma room. His urine toxicology was only positive for THC.

Let's go to the next slide, please.

I just put this in for reference. Colorado has the marijuana MED. So these -- this department tracks retail and medical operations in marijuana retail stores and medical marijuana stores. There are a total of -- see, there's a total of 943 marijuana dispensaries, which means that if every single employee was out doing surveys, would mean 19 stores per person, and this would -- is requiring them to check products for contamination, quality, licensing, et cetera. So it -- it's kind of a shortage in personnel actually overseeing or supervising the regulation of these products in Colorado.

Next slide, please.

I'd like to do a case wrap up at this point. We're talking about the pediatric harms of marijuana, and they're numerous, and I didn't cover all that we're seeing.

There are several cases presented today,

but it is, again, not inclusive, and what we discussed is the perception of harm, which over the last decade has decreased dramatically, especially in children.

We talked about addiction, and clearly for our kids, in adolescence, it's addictive, it's dangerous, it leads to depression. Getting treatment is very difficult. So we're putting in a substance that we want to ~~in~~decrease the CS level to III, which means it will be more available, and more kids will need treatment, and we don't have a spot for them, and so these kids get sent home, which provides long-term disabilities for them.

We talked about edibles. They're readily available. If there's anyone in this room that thinks kids aren't getting edibles, they're wrong.

We talked about psychosis and what it looks like and how difficult it is to treat and that it could be persistent.

We also talked about cannabinoid hyperemesis. Again, very difficult to treat, very present, increasing in numbers, and we also talked about accidental exposures.

Next slide, please.

So here we talk about some of the

conclusions. We did talk about kids are definitely getting product. They know how to get it. They get it via Snapchat. They get it via prepaid Visa cards from other kids at schools, from parents. There is literally no way to solidly protect our children.

The public perception of harm has rapidly, again, decreased. The product's potency has increased in the same time period. I presented only two cases where the parents thought it was okay to let their kids have marijuana. However, in clinical reality, this is happening so frequently. If the DEA determines that this drug has met the criteria to be --

MR. SWAN: Objection.

THE WITNESS: -- a CS III --

JUDGE JULIUS: Hold on, ma'am.

MR. SWAN: Speculation. She said "if the DEA." I would -- I would argue that that's speculation, Your Honor.

JUDGE JULIUS: I'll allow it, and it goes to weight based on her -- her provisional expertise and her opinion, but I -- there is an element of speculation in there, but go ahead.

BY DR. DRUM:

Q Go ahead, Dr. Randall. Continue.

A Clearly, as we've seen, and some of the reports I presented showed that the public perception of harms will and has decreased, and I feel it will only decrease further because the public will view this now as being a safe, regulated medication with controls and safeguards.

Q Dr. Randall, how does the Prescription Drug Monitoring Program work for providers? Can -- can you explain that?

A Next slide, please.

So this is called the Prescription Drug Monitoring Program, and I would just like to take this time to tell you how it affects us as prescribers. It's -- we call it, abbreviated, the PDMP, and this -- I'll briefly describe how it's used, and I will describe how it's changing for the practitioner if we indeed do this change.

Let's go to the next slide.

The PDMP is a really important tool for me. On almost every case where I prescribe a scheduled drug, whether it's a benzo or a narcotic or some kind of scheduled drug, I look up in the patient's chart, the PDMP, and now because we know it's so important, it's actually tied to our

medical records, so we can easily open it up and access.

When I look at the PDMP, I can see several important features. One is the name of the patient. Next is the medication that's prescribed, how much was prescribed, who wrote it, so the prescriber, the person who is writing the prescription, and are there refills, and if so, how many times? And I can also see things like the patient is getting scripts from different people.

I can also see if they're getting prescriptions for medications that in combination present increased harms, like an opiate given with a benzodiazepine, which would increase sedation, so be harmful for the patient. And if I can look at this and then I know that these are what's happening, then I may or may not prescribe an additional medication for this patient. So we rely heavily on the PDMP.

Sadly, what we see is the patient is prescribed -- prescribed marijuana. I can't -- I can't see that. That's not in our PDMP. It is -- it's not. So we're calling it a medication. It is currently Schedule I, and I cannot see in

the PDMP that it is -- a patient is getting marijuana, nor can I see the quantities or the person who's prescribing or writing for him.

The problem is is that when prescribing opioids or other medications, even some things like blood thinners, there's an interaction with the medication, and I can't see this. So as a prescriber, I have no idea, and the information is oftentimes, I would say probably most of the time, not forthcoming from the patient. So I may inadvertently prescribe a combination of medication when used with marijuana that may potentiate sedation or other side effects that would be harmful for the patient.

Let's go to the next slide, please.

So we'll talk first about the chart on the right. These are basic cannabis plants. There's sativa, a hybrid, which is sativa and indica, and ruderalis. Just basic information, sativa is the cannabis that people talk about making them creative. It's kind of an upper. It makes them active. A hybrid is the combination. And indica is what they term "in-de-couch," so it's a sedative. It's a -- it's a slow-you-down type thing. Ruderalis is probably closer related

to hemp, although it has approximately three percent THC and it has more CBD.

So if we are making recommendations for treatment, I don't believe that the person or the prescriber making recommendations actually recommends a -- a variety or a specific species of the plant. They may get something that's not actually prescribed.

So if you talk to recommending physicians, they don't know what strain the patient is getting. They don't know how much the patient is using. They don't know actually where the medication is being purchased. They don't know quality control or contaminants, and they don't know who's making the medical decision for the treatment pathway. And this could be somebody like the budtender who's making a medical decision.

As we saw with the Alzheimer's patients, when the family goes to the dispensary to get medication for their Alzheimer's because they've seen online that it helps, I, as their physician, would have no idea what the patient is taking.

Additionally, where and how the product is -- is made is typically unknown to the

prescriber, and it's really important because this plant is a soil scrubber, so it will pick up elements from the soil that could be harmful, such as lead or cadmium, et cetera. And these things, lead, cadmium, arsenic, they're not cleared by the human body, so they kind of tend to build up.

And the place where we've seen that they build up is in the amygdala, and that, again, is the center that keeps us alive and keeps us thinking. And so when you have a problem with your amygdala, these are people who present with dementia.

So, also, we don't know purity or contaminants.

So let's go to the next slide, please.

So in contrast is your atypical blood pressure medication because I really need for everyone to understand what the difference is. When I prescribe a medication for, say, a disease process like blood pressure, this is metoprolol. The patient -- I will personally sit down and review the patient's chart.

I prescribe it for specific indications. It's prescribed for blood pressure, it's prescribed for some cardiac diseases, and there's

a few other uses that it can be used for, but primarily for blood pressure and cardiac disease. So I've already reviewed this chart. I've looked, and I thought metoprolol would be an adequate medication.

I then review the medications that the patient is taking because I don't want there to be a medication interaction. So if the patient is taking metoprolol and I see that he's taking another beta blocker that he got from another physician, then I would not prescribe it. So I check for interactions.

When the patient goes to the pharmacy and he has a prescription for 50 milligrams of metoprolol, he will get 50 milligrams of metoprolol, and that is consistent. And there's also checks for product purity and, again, consistency.

The patient will also -- his prescription is typically reviewed by the pharmacy or the pharmacist who's filling the prescription. And also, if you've ever gotten a prescription, you see those white sheets that are stapled to the outside of your bag. Those are precaution and warning labels. And these are drug -- drugs also

being monitored for impurities, and -- and recalls can occur.

So let's go to the next slide, please.

Now, if we say that we want to make this a recommendation. So same case. John Doe comes to me, and he has a problem with his blood pressure, and it's high. So I agree, and I make a recommendation, and I say, "You need to go down and get some blood pressure medication." I send him to the local dispensary or convenience store and ask him to speak to the clerk, who's likely not a pharmacist or a physician. They let him look at a variety of pills, and John Doe picks the one he wants.

No one checks to see if he has medication interactions or contraindications. Then John Doe can select the one he wants and take as much as he wants when he wants. And I, as the recommending provider, I don't see this. I don't see my patient at follow up. I don't see that the medication has been efficacious, and I don't know what medicine he chose.

Next slide, please.

This was a picture done by myself in a medical dispensary. On the right-hand side, you

can see Elephant Purple. It's 65.6 percent THC. It's a wax, and it's meant to be smoked. So that means a gram of this wax will have 65 point -- or 656 milligrams of THC.

The -- the syringe next to it is clearly a syringe made for injecting, and when we asked -- when I asked the dispensary owner, I said, "Is this injectable?" Because at that time it was illegal, and I don't know now if it still is, but I think so.

And he said, "No, this is for rectal insertion," when clearly this is a syringe.

If you look to the left side, you can see that medication is advertised as candy bars. You can see the doses and you can see the prices, and it's being advertised with aliens.

Next slide, please.

This is from the inside of a dispensary. If -- if you guys haven't been, I recommend you go and you look at the products that are available. If you look at the far right-hand side, the bottle is for energy, and that's sativa. The next one is relax, and that's a combination or a hybrid. And the final one, the one on the right-hand side, is for sleep, and that's indica.

If you look on the left-hand side, you can see that there are a variety of medications available. And if you look in the middle, you can see medications available, how they're available. And also noted when I -- here was that the second shelf from the bottom was medications for your dog.

Let's go to the next slide, please.

This was on a tour I took, again, with a DA from another state. We arrived in a sheriff's van, so it wasn't like our identity was hidden or covert. This was in the inside of a dispensary.

MR. SWAN: Objection, Your Honor.

THE WITNESS: They won't let you --

JUDGE JULIUS: Hold on. Basis of the objection?

MR. SWAN: Your Honor, I -- relevance, Your Honor. The witness has given the credentials of a expert in --

DR. DRUM: Cannabis science and medicine.

JUDGE JULIUS: And pediatrics.

MR. SWAN: Trained in pediatrics and she has her certificate in cannabis science and medicine. She's reporting evidence that is touring different facilities. I think that's

outside the scope of her proposed expertise at this time.

JUDGE JULIUS: Anything more on that?

MR. SWAN: Nothing more.

JUDGE JULIUS: Any response?

DR. DRUM: I -- I think her expertise in cannabis science and medicine speaks to this, and she's explaining what she's seeing.

JUDGE JULIUS: I -- I tend to agree with Dr. Drum on that. I'll allow her to testify. If there are more specific objections, you can make them.

MR. SWAN: Thank you, Your Honor.

JUDGE JULIUS: Please proceed.

THE WITNESS: So this -- we often don't get to take pictures, but they allowed us to take pictures. And I put this picture in because I specifically want to say the -- the counter on the right -- or the left-hand side, which is covered in red, that was for retail marijuana. The counter in -- on the right-hand side that is green was medical marijuana, and the products in between the two were identical.

So, really, the only change was the green color. There is no difference between retail and

medicine.

Let's go to the next slide, please.

So as a physician, I often prescribe accessories for my patients to use their medication. Sometimes it's an IV, sometimes it's a liquid, sometimes it's an oral tablet, and here were the medication accessories in the medical dispensary.

The first one is butane at five times the concentration. The next one is blowtorches, so you can light your pipe up. And the final one is pipes that you can smoke in, and I'll have you note that the middle one is Pickle Rick.

So if I'm going to make a -- a prescription or a recommendation, I'm really, as a physician, not sure how to do this. Do I tell the patient to get two ~~nubs~~nuggs, put it in Pickle Rick, blowtorch it, and smoke it? So there's my question.

And let's go to the next slide, please.

Here's a -- a prescription written by me and the elements of a prescription. It's John Doe. His name's on there. It's the date that I wrote it. It's the -- the medication, the milligrams that are indicated. It's the quantity

that he will get for this prescription. And the sig, or the signature, is how will the patient take it. That means he will take one every day.

If you look down, you can see that it can be refilled five times. I sign my name. I will print my name. My office phone number will go on the bottom. And if it's a scheduled medication, I will put my DEA number.

So it's very clear. These are clear instructions to the patient. It will be translated from the pharmacist after review to the patient and has very clear instructions.

Let's go to the next slide, please.

This is Purple Kush. This is a medication?~~.~~ So as a physician, also I have a certificate in cannabis science and medicine. And as -- as a proposed prescriber of a new Schedule III medicine, I'm just wondering, how do I prescribe this? And what's the dose? And what will the dose be next time? And what's the consistency of the milligrams of THC in each product? And -- and how do I ask the patient to consume this?

I don't think that I will ever ask a patient to smoke anything because the harms of

smoking are clearly known. And, also, oftentimes if we're making an extract like wax, shatter, or dab, there's this solvent used to extract it, and this also presents problems to the patient.

So let's go to the next slide.

So this is a prescription that, as a Schedule III, I assumed that we would be writing, and this is the same prescription for John Doe, dated 7/14/2026. It's for Purple Kush, the plant we just saw. Dispense -- I don't -- I don't actually know how to dispense. How do I dispense this? The signature -- do I ask him to vape? How many times a day do I vape? Do I ask him to smoke two ~~nubs~~ nuggs three times a day? I -- I don't know.

And I don't know about refilling it. It's a Schedule III. So there's so many questions from a prescriber's point of view that -- how do we handle this? What do I tell my patient to do?And -- and I'm going to tell you that most prescribers don't understand this. This is why I got my cannabis science certificate because I needed to have a better understanding.

Also, we wouldn't know if a patient is looping, and looping is a big thing in Colorado. So when you get a medical license, you can go into

a store and buy a certain amount. Initially, what would happen was people would take their license, go into a store, buy a certain amount, and then go to the next dispensary, buy a certain amount, take it to the next, and it's called looping, where the patient can get way more than they were prescribed.

Now the Marijuana Enforcement Division, MED, does follow some of this, but it is still hard for them to follow completely because a lot of these systems are -- have faulty systems. They aren't connected, and they're not followed. So we know that looping is -- is happening.

If we said the patient couldn't loop with opioids, the -- the translation would be, so a Schedule III opioid, I would -- the patient would go to pharmacy X and get 30 Norco tablets. They would go to pharmacy B and get another 30. They would go to pharmacy C and get another 30.

And the thing that prevents this from happening is the PDMP. So the pharmacist can look it up, and I as a physician can look -- look it up. And so we can prevent that kind of thing from happening. But currently, here in Colorado, there is no placement of medical marijuana in our PDMP,

so there is no way for me to know what's happening.

And then, finally, as -- if I'm a prescriber and I'm prescribing this medication, ultimately I'm taking the responsibility for the harms that occur to the patient and actually don't know all the harms that can occur.

So let's go to the next slide.

BY DR. DRUM:

Q So -- so, Dr. Randall, do you have any closing remarks?

A I do. In closing, I would like to say thank you for the opportunity to speak. I would also like to say, over the years that I've done this, I'm not paid. I have offered to have senators, representatives, judge, lawmakers, et cetera spend a day with me in a shift. Just one day. Come and spend 12 hours in the emergency room to see what happens down the line with these consequences.

We're making rules, and we're seeing the endpoint of legalization or -- or legislation that you guys don't see. And I see this every single shift. Every ER doc is seeing it. We're seeing the results of bad decisions, poor legislation, and a substantial increase in drug use.

And it's very difficult to handle these patients knowing that, on the back end of that, we don't have a place to put them, and we don't have treatment facilities, et cetera. So it's a very difficult position to walk in, and I recommend that everyone in this courtroom spend a day in an ER so you can see what it looks like from our point of view.

We worry about cell phones and guns and gender issues and kids, but we're allowing a very potent hallucinogen with no potential -- or with a known potential to alter children for the rest of their lives. And these are significant consequences, and it can happen to adults as well. And in the medicine world, the side effects of psychosis, DHS, et cetera, this would be a black box warning.

So if my metoprolol in the previous prescription had a history of causing psychosis or cannabis use disorder, it would be a black box warning, or it would be pulled from the market. But that's not so with the cannabis or marijuana products.

We are truly seeing the endpoint of legislation. We're the front line in the

emergency department. I highly recommend that you come visit us.

The cases that I discussed, they're not the -- they're not the one-offs. I can't say that the 13-year-old with addiction was a one-off. It happens all the time. All the time. You can go to any emergency room, pull aside an ER doc that you know and talk to them. It happens all the time, and our kids are really being hit hard.

And a portion of the kids that we are hitting will develop lifelong crippling addictions or medical issues that will derail them from childhood and a lifetime of -- of healthy living.

Let's go to the next slide, please.

In discussion of the harms, I did only discuss a few of them. There are many more that we didn't discuss, and for time's sake, I did not want to discuss them. But they're certainly available, and there's plenty of literature available.

We know it's addictive. Most notably, it's addictive for the developing brain, which means children and adolescents and young adults to the age of approximately 25. We know that the potency and dangers increase, and the perception

of harm is markedly decreased.

Our children are very creative in finding ways to get marijuana, and if we don't think they are, talk to your kids. They are finding ways to get it.

Multiple medical problems -- medical problems occurs as a result of marijuana use. And if we lose a child to addiction, as I said before, it is a lifelong problem, and it is a lifelong problem for society as a whole.

Treatment, again, is not available. So changes in the PDMP would be substantial and should not be undertaken quickly or lightly.

Next slide, please.

Again, I'd like to thank you for the opportunity to speak, and I would just like to say that for every action, including laws, there's an equal and opposite reaction. As -- according to Sir Isaac Newton, there are reactions to the laws we're making, and I advise you guys to take it seriously and under consideration.

Thank you.

DR. DRUM: Your Honor, that concludes our testimony. Thank you very much.

JUDGE JULIUS: Thank you very much,

Dr. Drum.

We've been hearing testimony for quite a while. I think it's a good time to take our break for everyone's benefit.

Mr. Swan?

MR. SWAN: Your Honor, if I could propose something, Your Honor. As you indicated, we have taken testimony for about two hours.

JUDGE JULIUS: Yeah.

MR. SWAN: Can -- I would propose either a longer comfort break so I could have a more in-depth conversation with my team, or an early lunch so that I can still have -- I don't think 15 minutes at this point to -- to regroup with the team would be sufficient.

JUDGE JULIUS: Okay.

DR. DRUM: Your Honor, if I may?

JUDGE JULIUS: Yes. Go ahead, Dr. Drum.

DR. DRUM: I do have a flight that I need to get to.

JUDGE JULIUS: Okay.

DR. DRUM: And I understand that I have to be here for any type of conversation with Dr. Randall, and so I would still propose a 15-minute break, maybe 20 at most, but not to take

an -- an hour-long break.

JUDGE JULIUS: Okay. And you would also have an opportunity for redirect --

DR. DRUM: Correct.

JUDGE JULIUS: -- after cross-examination. So --

DR. DRUM: Right. And I need to be here for that.

JUDGE JULIUS: All right. Mr. Swan, just let me know when you're ready.

MR. SWAN: Your Honor, I believe Dr. Drum is scheduled to be here 'til 1:15. I'm sorry, 2:15.

JUDGE JULIUS: When is your flight, Dr. Drum?

DR. DRUM: I believe it's, like, 3, 4:00. I've -- I've had to change my flight three times.

JUDGE JULIUS: Okay. Well, I mean, sir, you -- you did apply to be an interested party in this.

DR. DRUM: Right.

JUDGE JULIUS: We published the schedule weeks ago.

So after Dr. Drum will be the Opposed States. I think their first witness is scheduled

to begin at 2:45. Is that correct?

MR. HARRINGTON: That's correct, Your Honor.

JUDGE JULIUS: All right. We have a little bit of time to play with. How about -- I'll split the difference. How about we do a 25-minute break? Let's come back at 11:20. We'll do cross-exam, see how long that takes, and then we'll look into whether you want to do redirect before lunch, after lunch. We can shift our lunch break to accommodate Dr. Drum's schedule.

DR. DRUM: Thank you.

JUDGE JULIUS: I think we'll still probably end up with a longer lunch break. It may just be a little later, and then we would resume at 2:45.

But for now, let's plan to come back at 11:20, and we'll see where we go from there. Okay?

DR. DRUM: Thank you.

JUDGE JULIUS: Dr. Randall, please feel free to use the restroom, get some water, stretch your legs. Just don't discuss your testimony with anyone during our 25-minute break. Okay?

THE WITNESS: Okay. Thank you, sir.

JUDGE JULIUS: Thank you very much.

We'll be in recess for 25 minutes. See you back here at 11:20.

(Whereupon, the above-entitled matter went off the record at 10:56 a.m. and resumed at 11:20 a.m.)

JUDGE JULIUS: Just a couple of matters before we proceed to cross. Make sure we get Dr. Randall back. Dr. Drum, did you want to move to admit Dr. Randall's PowerPoint presentation the way you did yours?

DR. DRUM: Certainly.

JUDGE JULIUS: Okay.

DR. DRUM: Yes, that'd be fine.

(Whereupon, the document referred to was marked as Drum's Exhibit No. 70, for identification.)

JUDGE JULIUS: Any objection to the PowerPoint?

MR. SWAN: No objection, Your Honor.

JUDGE JULIUS: We'll admit that as Drum Exhibit 70, and it'll be admitted.

(Whereupon, the above-referred to document marked as Drum's Exhibit No. 70 was received into evidence.)

-- DR. DRUM: Thank you.

JUDGE JULIUS: Thank you.
MR. SWAN: Your, for the record, we do not have that PowerPoint, Your Honor.
JUDGE JULIUS: So if you could now^
DR. DRUM: I think that was placed on the JEFS system, Your Honor.
MR. SWAN: We can't see the JEFS system.
JUDGE JULIUS: Oh, JEFS is just for the court's upload purposes.
DR. DRUM: Oh, I'm sorry.
JUDGE JULIUS: Sure. If you could --
MR. SWAN: Not right now, but at some point we would like to get a copy of it.
DR. DRUM: Can the JEFS send it over? Because again, you do have it, Grayson? No?
JUDGE JULIUS: No. At some point --
DR. DRUM: Okay.
JUDGE JULIUS: Either today or -- coordinate maybe it with Mr. Harrington, who's gesturing to you-
DR. DRUM: Right.
JUDGE JULIUS: If you could just share a copy of that PowerPoint with the government.
DR. DRUM: Great.
JUDGE JULIUS: That would --

DR. DRUM: No problem.

JUDGE JULIUS: Be good.

DR. DRUM: Thank you.

JUDGE JULIUS: And I just have one question to ask Dr. Randall before we proceed. I've been asking all of the preliminary experts the same question. So ma'am, are you familiar with the Controlled Substances Act definition of marijuana at Title 21 U.S. Code?

THE WITNESS: Yes, I am.

JUDGE JULIUS: And how, if at all, does your opinion change if limiting it only to marijuana as defined in 21 U.S.C. § 802(16)(A)?

THE WITNESS: Well, your definition contains only sativa, and most of the products out are a combination or hybrids of sativa, indica, and as I said, ruderalis. So I think that that would definitely change the definition, or it doesn't meet the definition if you're saying the product is indica.

JUDGE JULIUS: Okay. So for our purposes of our hearing, we're only looking at the potential rescheduling of Cannabis sativa L. How, if at all, does that change the opinions that you, or testimony that you have given this morning, if

limited to just the federal definition under the Controlled Substances Act?

THE WITNESS: Well, I'm not sure if you're just limiting it to that product, how that would actually translate into a product from the consumer because again, there are so many hybrids. There's so many compounds with indica that it would be very difficult to separate out just sativa. I believe that people, as you saw in my presentation, people are using indica as a medication for sleep or sedation properties. So where does that fall in your definition? And if I'm having a plant, so the purple Kush plant that I showed, how do we know that that's just sativa? And how do we know that the next batch would just be sativa? So we don't know. So it makes the big question in product availability.

JUDGE JULIUS: Okay. Thank you very much, Dr. Randall.

THE WITNESS: You're welcome.

JUDGE JULIUS: Mr. Swan, cross-examination from the government whenever you're ready, sir.

CROSS-EXAMINATION

MR. SWAN: Thank you, Your Honor. Good

morning, Dr. Randall.

THE WITNESS: Good morning.

BY MR. SWAN:

Q Can you bring up that PowerPoint again?

A It's under Grayson's control.

MR. SWAN: Grayson? Thank you.

JUDGE JULIUS: Yes. Mr. Phillips will bring it up on the screen. Thank you.

MR. SWAN: Okay. Dr. Randall, have you received any of the transcripts in this proceeding before your testimony today?

THE WITNESS: No, I haven't.

BY MR. SWAN:

Q Okay. Did you read or review any of the transcripts of the previous testimony in this proceeding?

A No, sir.

Q Okay. Did you speak with anyone about your proposed testimony prior to taking the stand today?

A I've been communicating about the procedures and process with Dr. Drum, but otherwise, no.

Q Thank you. Grayson, can you go to the next slide? No, I'm sorry. I was not provided

with this PowerPoint, so we're going to have to go through it just so I can see it. Next slide, please. Next slide, please. Next slide, please. Drawing your attention to this slide, do you see it, ma'am?

A I do.

Q What does the last bullet point say?

A Images were taken from an online or free images, so not copyright-protected images.

Q Next slide, please. Next slide, please. Next slide, please. Next slide, please. Next slide, please. Next slide, please. I'm drawing your attention to this slide. Do you see it, ma'am?

A I do.

Q Was this your particular case?

A All these cases that I presented were my cases, yes, sir.

Q Okay. In this particular matter, it says that he read that marijuana causes cancer online, and he opted for that treatment plan.

A He read that marijuana cures cancer online.

Q Okay.

A And he told me that's the treatment plan he opted to go with.

Q Okay. And what did you do?
A Brought him in the emergency department.
Q I'm sorry?
A I got blood work. Gave -- with regards to treating him in the emergency department? Is that what you're asking me what I did?
Q Yes.
A Okay. I drew blood, gave him IV fluids because he was clinically dehydrated. He was also coagulopathic and he had significant ascites, which is fluid buildup in the abdomen with associated with liver failure, and I did a paracentesis, which is a procedure to put a needle in the abdomen and draw the fluid off to make the patient more comfortable. It also helps if the patient's abdomen gets so distended they can't breathe well because their diaphragm doesn't work, so it helps with that, so I did that.

I also had the social worker come see him because clearly his case was advanced and he had several abnormalities, and we discussed whether he would want to be placed in the emergency department or hospice. During his emergency department stay, we had the social worker see him, we had hospice nurses come in to interview the

patient, and he was placed on hospice at his request.

Q So it's safe to say he was not under the influence of marijuana?

A He was alert, oriented, and appropriate for me.

Q If you look at the third bullet, you indicate that he read that marijuana causes cancer. What was --

JUDGE JULIUS: Counsel, the word is cures.

THE WITNESS: The third bullet?

MR. SWAN: I'm sorry.

THE WITNESS: Cures.

MR. SWAN: What did I say? I'm sorry.

JUDGE JULIUS: You're saying causes?

MR. SWAN: Oh, I'm sorry. My apologies, my apologies. What was the purpose of putting that bullet in this slide?

THE WITNESS: Because that's what the patient told me. When he told me he had liver cancer, typically you ask who's their oncologist so that we can connect with them to see if there's anything in particular they would like us to address during their emergency stay. He told me

that he read that it cured cancer and he opted to go with that treatment plan, and he had not been seeing any oncology professionals.

BY MR. SWAN:

Q Was he a doctor?

A No.

Q So he just had this opinion that it cures cancer?

A Correct.

Q And he had no medical training?

A I didn't ask him if he had medical training, but he didn't present himself as such.

Q He indicated that he got that information from online, correct?

A Correct.

Q Safe to say that's not medical training?

A I would say, correct, yes.

Q Next slide, please.

JUDGE JULIUS: Just for the record, the last line of questioning related to case 1 at the top -- just so the record is clear as to what we were looking at.

MR. SWAN: Thank you, Your Honor. Do you see the next slide, ma'am?

THE WITNESS: I do.

BY MR. SWAN:

Q The first picture, it reads, Don't worry, don't cry, smoke weed and fly. Is that correct?

A It is correct.

Q Where did you get that picture from?

A Again, as I've stated previously, all these images were taken from unprotected online searches. So these images are not protected. Free images.

Q So, the term Don't worry, don't cry, smoke weed and fly that did not come from a medical journal, is that correct?

A I would hazard a guess it did not, yes.

Q Okay. to your knowledge, that did not come from a medical professional, is that correct?

A Correct.

Q The next one is a picture of^well, can you describe the next one?

A It looks like it's an astronaut or a scuba diver who has smoke coming out, holding either a joint or a pipe, and it says, time to get high 4:20.

Q Okay. I'm going to ask you again: where did you get that from?

A Again, online. Internet search.

Q That did not come from a medical journal, is that correct?
A It did not.
Q The term time to get high, is it safe to say that did not come from a medical professional?
A It is.
Q Okay. Can you describe the third picture?
A The third picture is a cartoon character with leaves smoking a joint.
Q Where did you get that picture from?
A Online.
Q Okay. What site?
A I don't know. I could go back and reference it for you, but I don't have that here right now.
Q So you just went on a random website, took a picture, and put it in this slide to present to the Court?
A And the purpose for doing that is so that we can see what the general public can see.
Q That was not my question, ma'am. The purpose for --
A Okay. Yes, I did.
Q Okay. What does the next picture say?

A Marijuana, hey, at least it's not crack.
Q Where did you get that picture from?
A Again, online.
Q Okay. Is it safe to say that did not come from a medical journal?
A Yes.
Q Is it safe to say that the term marijuana, hey, at least it's not crack did not come from a medical professional?
A I would hope it didn't, yes.
Q Okay. Next slide, Grayson, please. Do you recognize this slide, ma'am?
A I do.
Q Is there a picture in the slide?
A Yes, there is.
Q Can you describe the picture?
A The picture is of a toddler smoking from a bong.
Q Whose toddler is that?
A I don't know.
Q Where was that picture taken?
A From a Reddit subgroup.
Q What location was that picture taken? Not where you took it from, but where was that picture taken?

A Oh, I don't. I don't know where -- I don't know where it was taken.

Q When was that picture taken?

A That picture is several years old.

Q And can you describe it? You said several years old?

A I think it's been around. I've had it for several years, yes.

Q Okay. And where did you get it from? You said Reddit?

A A Reddit subgroup, correct?

Q Can you describe for the Court what is a Reddit subgroup?

A Reddit is an online chat internet, and there's all bunch of subtopics. And this topic or sub -- I don't know how to say it -- a subgroup is called Ganja Mamas, and it is something worth looking at if you haven't. It's all about how moms who use and prefer marijuana products live and navigate through their daily lives, including how to avoid having urine drug tests when you're pregnant, et cetera.

Q Is there any qualifications that require someone to submit a picture on Reddit?

A I don't believe so.

Q So anyone could have put this picture there, right?
A Correct.
Q Is it safe to say it didn't come from a medical journal?
A Yes.
Q Is it safe to say you don't know if this is real?
A Yeah, I guess so.
Q Are you familiar with AI? Artificial intelligence.
A Yeah. I think this was, like I said, this was several years ago, so I don't think the AI was prominent at that time.
Q Are you familiar with artificial intelligence?
A Yes, I am.
Q Is it possible that this picture could be artificial intelligence?
A As I said, I don't believe so because this picture is several years old.
Q But you also testified you don't know who took the picture, correct?
A Correct.
Q You don't know where the picture was

taken, correct?

A Correct.

Q You do not know the name of the baby in the picture, correct?

A Correct.

Q How do you know that's a real baby?

A I guess with your line of questioning, I don't.

Q But yet you submitted it to the Court, so the Court can make a decision in this hearing, correct?

A I did submit it to the Court for the purpose of demonstrating that --

MR. SWAN: Next, Grayson, next slide please.

THE WITNESS: This stuff is happening.

BY MR. SWAN:

Q Wait, I'm sorry. Can you go back, Grayson? You said, say that again, ma’am.

A I submitted it to the Court to demonstrate that this is happening.

Q Ma’am –

A And if you choose not --

Q Ma’am -- ma’am.

A -- to look at it.

Q Excuse me, ma'am.

A And choose not to accept it, it's happening.

JUDGE JULIUS: Go ahead, Mr. Swan. How do you know it's happening if you don't know if this picture is real?

THE WITNESS: Because I see these things in my emergency department, that people come in, so I see the endpoint of this kind of behavior. So I know it's happening, and I tried to present those cases to you during this hearing.

MR. SWAN: Next slide, Grayson, please.

THE WITNESS: It is happening.

BY MR. SWAN:

Q Next slide. Next slide. Ma'am, can you describe the picture on the left of this slide?

A That's a juice drink. It's a liquid hybrid of 10 milligrams of THC.

Q Where did you get the photo from?

A Online.

Q Is it safe to say it did not come out of a medical journal?

A Correct.

Q Okay. And what is the text on the packaging?

A Drink two joints in the afternoon. Sublime.

Q Is it safe to say that that did not come from a medical professional?

A I would guess, yes.

Q Okay. Next slide. Next slide. Next slide. Ma'am, can you describe this slide, please?

A This is a slide indicating a case I saw where a 13-year-old got cannabis online using a prepaid Visa card.

JUDGE JULIUS: Just for the record, it's listed as Case 2 at the top of the slide.

MR. SWAN: Oh.

THE WITNESS: Oh, sorry. Yeah.

BY MR. SWAN:

Q Why did you include this slide?

A I included this slide because I think it's actually very important. If we want to legitimize this as a medicine, it should not be as easy for kids to get a prepaid Visa card and order medical marijuana products delivered to their house via Uber. That's why I included it. I think it's a tale of caution here. This is what's happening.

Q In your professional role, are you familiar with the term diversion?

A I am.

Q What is diversion?

A It means that a product is being taken away from a legitimate line.

Q Would you describe this as diversion?

A Correct. I would describe it as diversion, and the issue that I see in the emergency department and the issue that reflects the fact that more kids are getting^or more calls are going to Poison Control indicates that we do have a substantial diversion problem, and it's as easy for kids who are -- she was in middle school.

MR. SWAN: Next slide, Grayson.

THE WITNESS: To figure out how to work the system and get product.

BY MR. SWAN:

Q Ma'am, can you describe this slide, please?

A This slide is Exhibit No. 54. It is the slide discussing a Journal of the American College of Emergency Physicians and indicating increased accessibility or diversion, as you would say, and exposure to marijuana in adolescents.

Q So it's safe to say that this slide is describing diversion, correct?

A I would say, unless you have families intentionally giving their children products, which has happened.

Q Next slide, Grayson, please. Next slide, Grayson. Next slide, Grayson. Next slide, Grayson. Next slide, please. Can you describe this slide, ma'am?

A This slide describes adolescent mental health facilities in Colorado in particular.

Q And can you read the first bullet point, please?

A A Google search shows that Colorado closed between 1,000 and 2,000 beds for youth in psychiatric and residential treatment over the last decade.

Q What exactly did you search to get that hit?

A If you search Colorado and adolescents or youth mental health treatment facilities.

Q And why did you go to Google?

A Because it would give me a global look at Colorado in general. Probably five years ago, I did a lecture, and when I looked up the numbers,

the state of Colorado between 2009 and 2018 had closed 1,008 beds particularly directed for youth and children. And that information otherwise from the state of Colorado is somewhat difficult to obtain. So this was my way of getting this information for this lecture.

Q Ma'am, given your line of work, is it safe to say you have access to different medical journals?

A I do.

Q And is it safe to say that you routinely review different medical journals?

A I do.

Q And you did not try to get this information from a medical journal?

A I did, and in subsequent topics we talk about the shortage.

Q Is it safe to say in your profession the professionals in your profession rely heavily on medical journals, correct?

A We do.

Q And that's because it's for the most part reliable, correct?

A Correct. But these are also available online.

Q Ma'am -- ma'am.
A Just so we understand that.
Q Is a Google search reliable as a medical publication?
A It depends on the search that you do and I felt that this information was fairly reliable given that I had looked it up previously and also clinically what I see when we're holding patients for up to months at a time waiting for placement.
Q So, it's your testimony today that a Google search has just as much reliability as a medical publication?
A Well, you're making that sound like a generalized broad statement, and that's not my statement. My statement is in this case, it helped me look up numbers of beds closed to give me an approximation of how many beds that the state of Colorado has closed in the previous decade, indicating that we have a serious shortage of inpatient psychiatric beds and treatment beds for adolescents. That's the purpose of this slide.
Q Next slide, Grayson, please. Next slide, please. Next slide. Ma'am, can you describe this slide for me?
A This slide discusses a Kaiser system

study done in Northern California from 2016 to 2023, indicating that 5.7 percent of those children, of 26,000 children, indicated past year use.

Q Okay, and is it safe to say that this is all about diversion?

A I don't know that you can make that conclusion, but I guess if they're adolescents and they haven't reached the required legal age to purchase product, then it ultimately is diversion.

Q Next slide, please.

A And as you can see, a large amount is being diverted.

JUDGE JULIUS: Counsel, just make sure she completes her answer before asking Mr. Phillips to advance the next slide, just so that we don't have crosstalk.

MR. SWAN: Very well. Sorry, Your Honor.

JUDGE JULIUS: Thank you.

MR. SWAN: Ma'am, can you describe this slide for me, please?

THE WITNESS: This slide describes the same Kaiser study conclusions. They conclude that teens who reported marijuana use were twice as likely to be diagnosed with psychosis or bipolar

than their peers who did not use. Marijuana-using teens were 34 percent more likely to be diagnosed, based on their review of their system and diagnoses, with depression.

They were 24 percent more likely to be diagnosed with anxiety. And the reason why this is a particular problem for adolescents is because they're vulnerable to addiction because vital neural networks are still developing, and the high-potency products alter the dopamine reward system and increase the likelihood of developing a lifelong addiction in children and youth.

BY MR. SWAN:

Q Is it safe to say that this is completely diversion?

A I guess that you would be asking me to guess. It doesn't say where these children got their marijuana products. There are products that allow marijuana for children or young adults, so 18.

Q So you did not include that in this slide, did you?

A No.

Q Where they got it from?

A It wasn't included in this study, so I

didn't make the guess. Yes.

Q Given that it's teens, is it safe to say that this is diversion?

A Well, that would be an assumption.

Q Okay. Next slide, Grayson. Next slide, Grayson. Next slide, please. Next slide, please. Ma'am, can you describe this slide for me, please?

A This is a slide of products taken from children in middle school.

Q Where was this picture taken from?

A The picture on the right-hand side was taken approximately two years ago.

Q Where did you get it from?

A I had the opportunity to go do some drug education teaching in a middle school, and these were products that were given to us by students in the middle school.

Q Next slide, please. Next slide, please. Ma'am, can you describe this picture for me?

A This is a picture of a baby smoking a pipe.

Q Okay. What is the baby's name in that picture?

A I don't know. This image was taken from the internet again.

Q Do you know who took the picture?
A I do not.
Q Do you know the substance that's purported to be inhaled by the baby?
A I don't know, but it appears to be a leafy green or a leafy substance.
Q Do you know if this is real?
A I don't know.
Q And it's my understanding you're purporting it to^you're offering it to the Court so the judge can make a determination using this piece of evidence. Is that correct?
A I am. Once again, this is what's happening. This is what people are seeing on the internet, and we can say it's AI, or we can say it's images, but they're present, and to ignore them is a fallacy. These images are present. It didn't take me long to find these, and they're present, and so consumers are seeing them, and kids are seeing them, and other moms are seeing them. These images are there.
Q Next slide, please. Next slide, please. Next slide, please. Next slide, please. Ma'am, can you describe this slide for me, please?
A This is a case report, case No. 9, a

seven-year-old who was brought to the emergency department in police custody for evaluation of psychotic and violent behavior.

Q Is it safe to say because the adolescent was seven, this is a form of diversion?

A Seven years old isn’t adolescence, he's a child.

Q I'm sorry. Is it safe to say because he's seven years old, this is a form of diversion?

A I would say yes.

Q Next slide, please. Next slide, please. Ma’am, can you describe this slide for me, please?

A This is Case Number 10, another case of pediatric psychosis. It describes a 14-year-old male who was brought to the emergency department while I was working, in police custody, having evidence of altered behavior, aggressive behavior, and he was combative.

Q Is it safe to say, because he's a 14-year-old male, this is another form of diversion?

A Yes.

Q Next slide, please. Next slide, please. Next slide, please. Next slide, please. Next slide, please. Next slide, please. Next slide, please. Next slide, please. Next slide, please.

Next slide, please. Ma'am, can you describe this slide for me, please?

A This is Case Number 14. It's a case of scromiting. It's the case of a 15-year-old girl who reported to our emergency department frequently for what was ultimately determined to be cannabinoid hyperemesis syndrome.

Q Is it safe to say, because the study started when she was 15 and completed by 17, that this is a matter of diversion as well?

A Well, it wasn't a study. This is a case review, and it started when she was 12, and she was coming till she was 17. And yes, I guess it would be a case of diversion by your definition.

Q Next slide, please. Next slide, please. Ma'am, can you describe this slide for me?

A This is a slide. It's Exhibit No. 66, edibles and accidental ingestions for children less than six years old. The timeframe was 2017 to 2021. And the cases -- it shows the number of cases in 2017 compared to the number of cases in 2021, which shows a substantial increase in percentage of cases.

Q Would you agree that an accidental ingestion is diversion?

A Yes, but as I presented in my cases, I don't think all these were accidental. I think some the parents purposely would give their children cannabis products because they thought they were safe or thought it would be okay to give it to their children. So, but yeah, it's certainly diverting.

Q Next slide, please. Next slide, please. Next slide, please. Ma'am, can you describe this slide for me?

A This is a Google search done, and the search words I used were edibles at school. And these are the results. They're all newspaper articles.

Q Ma'am, why did you not go to a medical journal to get such information?

A Well, you can go back to a couple previous slides where I show you that the Poison Control calls increased by 3,000 percent, which would indicate some of this. And the reason I put this in is because, again, if we don't look at it and we ignore that this is happening, problems are going to continue. This is happening, whether we get this information online, because most of these are not^it happens so often, most of these are no

longer case reports. It's just something that the media noted, and the media has commented on, saying, these kids, wow, we have a whole class of kids come in with an intoxication which turned out to be cannabis. So these are reports from that type of media, and there are a lot of them.

Q Is it safe to say that this Google search is not as reliable as a medical journal?

A In this context, I don't think so, because, as I said, this happens so frequently that it is no longer a case report. It's no longer special, and it is just an occurrence that we know is happening. And if you look, these are a very few -- it's a very short time period where we see all these cases, and these are just the ones that the media has found out about and reported.

Q So it's your position that this Google search is just as reliable as a medical journal, correct?

A That's not what I said, did I?

Q Next slide, please. Ma'am, can you describe this slide for me?

A Again, it's the same as the slide you asked me about previously. It's a Google search about articles on children getting sick with THC

products at school.

Q The first bullet that references the date of the article?

A It does.

Q Who wrote the article?

A I can look it up for you, but in the interest of time, I didn't put the news source that I got it from. So these are from media sources. Local newspaper or local news channels.

Q You would agree that's not as reliable as a medical journal, correct?

A Correct.

Q Next slide, please. Can you describe this slide for me, ma'am?

A This is a case of two 15-year-old girls. Number 16, they got a THC vape pen. They were vaping at school. One passed out. The other one had altered mental status. They were brought to the emergency department for a fairly extensive workup, and both were only positive for THC.

Q Given the age of the girls, is it safe to say that this is a matter of diversion?

A It could be, yes.

Q Next slide, please. Next slide, please. Ma'am, can you describe this picture for me,

please -- I'm sorry, this slide for me, please.

A Which one?

Q The slide. My apologies.

A This slide is changes in exposure of children. This is age 6 to 12. It's a number^in -- or 2009, there were 21 cases. And in 2024, there were 2,894 cases reported. This is an increase of 13,000 percent.

Q And can you describe the picture on the right for me, please?

A The picture on the right is a baby wearing a weed hat smoking a joint, who obviously looks high.

Q Where did you get that picture from?

A Same place that you've asked previously multiple times. It's from the internet.

Q What site? I mean, what site?

A I don't know. I could look it up and reference that to you and send you an email.

Q When was this picture posted to the internet?

A I don't know.

Q Okay. And is it safe to say it didn't come from a medical journal?

A We kind of established that previously.

Yes.

Q Ma'am, can you answer the question that I asked? Is it safe to say that this --

A I just said yes.

Q Okay.

A We established it previously, and the answer is yes.

Q Okay.

JUDGE JULIUS: Ma'am, I'm just going to alert you that he has to do his job and ask you questions about each image. So please --

THE WITNESS: It --

JUDGE JULIUS: -- just take that into consideration with the tone.

THE WITNESS: I will. And it seems like it's repetitive.

JUDGE JULIUS: But each image is separate, ma'am, so the record needs to be clear.

THE WITNESS: Okay -- okay.

MR. SWAN: Ma'am, can you read the text in the picture?

THE WITNESS: My baby smokes weed.

BY MR. SWAN:

Q Is it safe to say that that didn't come from a medical provider?

A I would hope not.

Q Next image -- I mean, next slide, please. Next slide, please. Next slide, please. Next slide, please. Next slide, please. Next slide, please. Next slide, please. Next slide, please. Next slide, please. Next slide, please. Next slide, please. Ma'am, also included in this PowerPoint was presentation of what appeared to be the similarities of packaging compared to candy. Is that correct?

A Correct.

Q What was the purpose of putting that in this slide?

A Well, it's not in this slide. Did you want to look at a --

Q I'm sorry.

A Different slide?

Q No, I'm sorry. This PowerPoint -- not this particular slide. Well, do you know exactly which slide it is? I don't have it in front of me. I don't have the number. So do you know which slide?

A I don't have it easily available, but I understand what you're talking about. It's pictures of candy, and the reason I put that in

there is because these candies, like I showed in the slide of the dispensary, are being sold as medicine. But if you're a child and you're six years old and you look at that, the packaging is so similar to common candies that are available, the children don't know the difference, and they're going to eat it. And they're not going to just eat one or a part. They're going to eat the whole thing because they don't know that there's dosing.

Q Ma'am, you gave a lot of testimony regarding those images. Is that correct?

A Correct.

Q Is it safe to say you're worried about the packaging of the products?

A Yeah.

Q Is it safe to say that you're worried about diverting the product?

A Yes.

Q Is it safe to say you're worried about normalizing the use of the product?

A Well, I think you objected to the term normalization, so I don't know what you want -- what are you indicating when you say normalization?

Q The way you used it, your term, how you believe it.

A Okay. Yes. I think that we are -- products are available ubiquitously in the environment. Kids are seeing adults use, like they in the past saw their adults drink or smoke cigarettes. The harms are present. Everybody around them is using, so why not? And we know more kids are using than ever before.

Q Is it safe to say it could be a parenting problem?

A Not necessarily all the time. I don't know if you have teenage kids, but the decisions I would make for them and the decisions they make themselves are not necessarily always the fault of the parent.

Q You would agree with me that any controlled substance consumed outside of the medical supervision can be harmful, correct?

A Correct, and I think the cases here reflect that.

MR. SWAN: No further questions, Your Honor.

JUDGE JULIUS: Thank you, Mr. Swan. Dr. Drum, you have an opportunity to ask any follow-

up questions or see if there's any clarification based on Mr. Swan's questioning. Yes, Mr. Harrington?

MR. HARRINGTON: Your Honor, can I just request a five-minute recess just so I can confer with my friend, Mr. Drum, before he begins his redirect?

JUDGE JULIUS: Any objection?

MR. SWAN: Yeah, Your Honor, I would actually object to this. These are two separate parties. This is not a strategy meeting. I don't see what the conversation would be about that would be directly tied to my cross-examination of this particular witness.

JUDGE JULIUS: I am a little concerned by the fact that he is a pro se party, and this would essentially be what I would perceive as advice from an attorney to him. I've explained what the purpose of redirect is. I don't like potential shadow representation. Unless you're going to enter an appearance for Dr. Drum, I am concerned about consultations.

MR. HARRINGTON: That's all right, Your Honor.

JUDGE JULIUS: Okay. Thank you. It's

fine. Any follow-up questions for redirect, Dr. Drum? Whenever you're ready, sir.

REDIRECT EXAMINATION

DR. DRUM: Yes. Thank you very much, Your Honor. Dr. Randall, are there states that have allowed youth to receive medical marijuana?

THE WITNESS: Yes, there are.

BY DR. DRUM:

Q And so in some of the cases that you presented, could some of those cases have been medical marijuana cases?

MR. SWAN: Objection. Leading.

JUDGE JULIUS: Could you rephrase it in a more open-ended way, Counsel?

DR. DRUM: Pro se.

JUDGE JULIUS: I understand, but if you could try to -- to do a little more, to get the testimony out of her as opposed to a yes or no question. Sometimes who, what, where, when, how, those types of questions are more open-ended, and we get the testimony from her as opposed to built into your question. If you need to take a moment to think about how to rephrase it, I can give you flexibility there.

DR. DRUM: So, to ask a who, what, where,

when is what you're saying?

JUDGE JULIUS: Those are generally --

DR. DRUM: One of those?

JUDGE JULIUS: More open-ended.

DR. DRUM: Okay. Like, so I can't ask a yes or no question?

JUDGE JULIUS: You can, but it may draw an objection for being leading.

Dr. DRUM: Okay. So you've testified that youth could have received a medical marijuana prescription, correct?

THE WITNESS: Yeah, at 18 they can get a prescription.

BY DR. DRUM:

Q How about under 18?

A I think there are some states that allow that under 18. But what we find here in Colorado is that an 18-year-old is a senior in high school; they get prescriptions, and they share with their friends.

Q Okay. Is it safe to say that you're concerned about the appearance of the products?

A Yeah, very concerned.

Q And why is that?

A Very concerned. They're appealing.

They're appealing to children, and younger children don't know the difference. We're talking about large dose products in a small child, which means that the effects will be magnified.

Q Okay. I'd like to refer back to -- unfortunately I don't have the slide numbers -- but it's the one that you showed with regards to the Google search of the edibles at school. Do you remember that slide?

A I do.

Q Okay. And you were asked about whether this could have been found in a journal article, correct?

A Yes.

Q And why you did not use a journal to report these cases, correct?

A Correct.

Q And so what were the dates of those edibles, and would you have expected to see them in a journal?

A Well, the dates were really recent. I wanted to get them the most up to date, and so I would not expect them to have time to actually become a journal because it takes months to have it reviewed and peer reviewed and then submitted

for publication. So I would not have expected them to be in a journal.

Q Correct. Okay, so it's kind of bringing up what we see happening today, correct?

MR. SWAN: Objection, leading, Your Honor.

THE WITNESS: Correct.

JUDGE JULIUS: It is, but I'll allow the question.

DR. DRUM: Thank you.

THE WITNESS: It is. It's reflective of what we're seeing today. And in the articles that I showed, the increase in poison control calls, it's a serious problem. We can call it diversion, but there are supposed to be guardrails in place currently in Colorado, and we know that our kids are both diverting more than ever. And it's as easy as going to get a prepaid Visa and purchasing online. And if our kids can figure that out, they're going to figure out how to get product. Whether we call it diversion or not, they're getting product. They're getting product from people who are selling out of dispensaries from the back door, as easy as a Snapchat. So if we pretend that this is all diversion and we can fix

it, why hasn't it been fixed here? Because our kids are more and more accessing this.

BY DR. DRUM:

Q And Dr. Randall, is there any other thing that you would like to comment on after your cross-examination?

A Yeah.

MR. SWAN: Objection, Your Honor.

JUDGE JULIUS: Hold on, ma'am. The basis of the objection?

MR. SWAN: I think that was outside the scope of the, I mean, the cross-examination.

JUDGE JULIUS: Anything? Maybe a way? Is there anything she'd like to follow up on or clarify based on her answers to the cross-examination^

DR. DRUM: Yeah.

JUDGE JULIUS: Just to keep it within the scope?

DR. DRUM: Right. So based on your cross-examination, would you like to comment any further on how you answered?

THE WITNESS: Yes, I would.

BY DR. DRUM:

Q Go ahead, please.

A When we talk about the photos that I used, those are used primarily in there for illustrative purposes. Clearly, no medical journal is going to post a picture of a baby with a weed hat saying, does your baby smoke weed? It would be medical fallacy to do that. But those, whether we acknowledge them or not, they're present on the internet in an extraordinary amount, and the cartoons are present in an extraordinary amount.

A cartoon figure of a guy with leaves coming from his head smoking a joint. That is not meant to reach anybody in this courtroom. It's meant to reach kids and youth. Or maybe some adults, I guess, I don't know. So to say that just because it came from the internet that it doesn't exist or it's fake, the reality is those images are out there, and they're out there in abundance. And our kids are on social media, and they're seeing them. Every time they see them, they're seeing a happy guy smoking a joint, a baby high, a baby smoking a bong. And in their mind it's like everybody's doing this, so why not? We see at the end of every shift or the beginning of every shift, we see the harms in these kids every

single day.

Once again, I invite everybody in this courtroom to come spend a day, come spend a day with me. I'll take you to our emergency department, and if you leave saying, hey, this is such a good idea, I would be super happy, but I doubt that. 12 hours. Our country has a significant problem --

MR. SWAN: Your Honor,

THE WITNESS: With substance abuse.

MR. SWAN: Objection. At this point, Your Honor, I think this is going to a narrative where there wasn't really a direct question that would elicit specific testimony, Your Honor. She went on a while. It was regarding my cross-examination. Now she's entering my country or this country to something like that. That is beyond the scope of my cross-examination, and I don't see how that would be permitted at this point.

JUDGE JULIUS: I understand the objection. She was still talking a little bit about what the effects that she's seen from the proliferation of the images that were a subject of the cross-exam. So I'll give a little bit of

leeway here.

MR. SWAN: Thank you.

JUDGE JULIUS: Overruled. Understood. Go ahead. Please continue, ma'am.

THE WITNESS: I kind of -- anyway, what I was saying is that all these exist. They exist in abundance, and our children and our youth are seeing them. And that when they decide to take up a habit, especially for cannabis, it could be lifelong and life altering, and we derail yet another kid from childhood.

DR. DRUM: I think, Your Honor, that concludes our rebuttal. Thank you.

JUDGE JULIUS: Okay. Thank you very much, Dr. Drum. Thank you very much, Dr. Randall, for your testimony. I hope you and your loved ones stay safe from those wildfires that you discussed earlier today.

THE WITNESS: Thank you.

JUDGE JULIUS: You're free to log off^

THE WITNESS: Yeah, me too.

JUDGE JULIUS: Whenever you would like, please go enjoy the rest of your day. Okay?

THE WITNESS: Okay. Thank you so much. I appreciate your time.

JUDGE JULIUS: Sure. Before we adjourn for lunch and let Dr. Drum rush off to the airport, have you had any opportunity to look at ex^

MR. SWAN: No.

JUDGE JULIUS: You're still waiting on that?

MR. SWAN: I did not, Your Honor.

JUDGE JULIUS: Okay.

MR. SWAN: During the 15 minute or 20-minute break, we were discussing --

JUDGE JULIUS: You had other things.

MR. SWAN: Yeah.

JUDGE JULIUS: I understand. So we'll still leave that as marked for identification. Just let me know sometime^

MR. SWAN: Yes.

JUDGE JULIUS: Before we close the record for evidence with --

MR. SWAN: I'll review it now during lunch.

JUDGE JULIUS: Perfect. Safe travels to you, Dr. Drum.

DR. DRUM: Thank you.

JUDGE JULIUS: We will be in recess for lunch. I understand, Mr. Harrington, I think your

witness is not available until 2:45, is that right? That's correct, Your Honor. Okay. Let's just come back at 2:45. I'm sorry, 2:30. Okay. We'll come back at 2:30, and we'll be in recess for lunch until then. That's a nice two-plus-hour lunch for everyone. Be well, and we'll see you back here at 2:30.

(Whereupon, the above-entitled matter went off the record at 12:17 p.m. and resumed at 2:30 p.m.)

JUDGE JULIUS: Just one procedural check before we start with the opposed state's opening statement. Government, I don't know if you had an opportunity during the lunch break to take a look at proposed Exhibit Drum 68 for identification?

MR. SWAN: I did, Your Honor.

JUDGE JULIUS: Any objection to it?

MR. SWAN: There's no objection.

JUDGE JULIUS: Okay. We'll go ahead, and we'll admit that as unopposed. Thank you very much for taking a look at that.

(Whereupon, the above-referred to document marked as Drum's Exhibit No. 68 was received into evidence.)

MR. SWAN: Thank you.

JUDGE JULIUS: Counsel, if you want to do your opening statement unless you have any preliminary or procedural matters before then.

MR. HARRINGTON: Your Honor, the only preliminary matter would be to have our demonstrative brought up on the screen.

JUDGE JULIUS: Okay.

MR. HARRINGTON: Our computer is set up just whenever Mr. Phillips is ready.

JUDGE JULIUS: I think Mr. Phillips will take care of that. Thank you. Feel free to do your opening statement whenever you're ready, Counsel.

MR. HARRINGTON: Thank you. This proceeding concerns what could become the most important rescheduling decision in the history of the Controlled Substances Act. Congress placed marijuana in Schedule I when it passed the Controlled Substances Act in 1970. That determination has been repeatedly revisited in the years since.

Over nine times, the Department of Health and Human Services and the Drug Enforcement Administration have considered and rejected

recommendations or petitions to move marijuana out of Schedule I. Each time, the government has concluded that marijuana lacks a currently accepted medical use and has a high potential for abuse.

Today, the government is asking this tribunal to reach a different conclusion. That requires more than just a different policy judgment. It requires evidence that meets the specific factors that Congress provided in the Controlled Substances Act for transferring a dangerous drug to a less restrictive schedule. The evidence provided by the government thus far has not established that these criteria are met.

To change course now and reschedule marijuana, DEA would need to demonstrate that there has been a sea change in the epidemiologic and scientific evidence surrounding marijuana. The states would submit that they have not done so. The states of Nebraska, Idaho, and Indiana will focus on two subjects of particular importance to these statutory factors.

The first will be the mental health consequences surrounding marijuana use. The second will be criminal diversion. The mental

health evidence matters because psychosis imposes enormous costs on my clients, the states. Individuals suffering psychotic episodes often require emergency medical care. They can require psychiatric hospitalization, publicly funded treatment. Children whose lives are destroyed by marijuana can become dependent on the state. It requires intervention by law enforcement and first responders. These costs are real, recurring, and borne largely by state governments, and our witnesses will demonstrate that these consequences have only increased since the last time the government considered rescheduling marijuana.

Indeed, concern over marijuana's psychiatric effects in the past determination about marijuana was central to the government's analysis. If you'll look at this first slide, and I understand we have shown you this slide before but I think it bears repeating that in 2015, when HHS did its analysis of marijuana, it devoted at least seven paragraphs to the psychiatric consequences of marijuana, specifically a discussion of psychosis and schizophrenia. In the 2023 scientific review supporting rescheduling, that discussion disappeared entirely.

The government's own presentation left these critical questions unanswered. I noticed during its case in chief that there was a sharp tension between the presentation or the testimony of Dr. Chiapperino and Dr. Burchman with respect to these psychiatric considerations. Dr. Chiapperino testified that HHS found insufficient scientific support for using marijuana to treat conditions like PTSD and anxiety. Yet Dr. Burchman testified that he has recommended marijuana in his writings and in his speeches for precisely those conditions. Also, in his testimony, Dr. Burchman acknowledged he is not a psychiatrist, despite having given that recommendation of using marijuana for some of these mental health conditions. Specifically, if you look at this slide, he says, well, today I'm presenting myself as a domain expert in pain management. I am not a psychiatrist. He also was not aware of the Department of Veterans Affairs contrary position for indications like PTSD, even though he had recommended marijuana for that condition.

While Dr. Chiapperino agreed that the American Psychiatric Association concluded that

marijuana was more likely to worsen psychiatric illness, Dr. Burchman testified he was unfamiliar with the American Psychiatric Association's position, that his domain is not psychiatry. He's not familiar with the statements that the body of experts in that field have issued with respect to that particular issue. When asked about psychosis, likewise, Dr. Burchman begged off the question. He could not offer an opinion with respect to the effect of marijuana on psychosis and schizophrenia. "Not being a psychiatrist, I can't comment on that question. I'm sorry."

When asked about the mental health risks from chronic marijuana use, Dr. Burchman also explained, "Not being a psychiatrist or studying psychiatric illness, I can't really answer that question." And when asked about psychosis from stopping marijuana use, Dr. Burchman also once again explained, "I'm not a psychiatrist or an addictionologist. It's not really the sphere in which I deal with."

Today, the states intend to answer some of those questions. Our first witness will be Dr. Deepak D'Souza of the Yale School of Medicine. He is the first psychiatrist to testify in this

proceeding. Dr. D'Souza has spent decades studying the effects of THC on the human brain, and he is widely recognized as a pioneer in the field of marijuana's effects on the human brain and body.

Additionally, Dr. D'Souza has the notable distinction of being the only expert in this proceeding who is both quoted by the 2023 HHS recommendation that gives rise to this proceeding, as well as the Drug Enforcement Administration's own eight-factor analysis that was prepared by Dr. Akinfire-Ssoye, who also relies on Dr. D'Souza's testimony. Dr. D'Souza will explain that marijuana has a high potential for abuse and that the evidence linking marijuana to psychosis and schizophrenia is substantial, consistent, and scientifically robust. He will explain that this evidence is getting stronger as the THC content in marijuana goes up.

He will also explain that marijuana lacks a currently accepted medical use. He will explain that marijuana is a highly variable product, where concentrations of THC ranging from 3 percent in low-dose cigarettes to 90 percent in dabs and shatters. He will further explain that these

well-established risks outweigh the limited, marginal, and often inconclusive evidence of potential therapeutic benefits for marijuana.

The states will also present evidence on an issue uniquely within their sovereign responsibility -- diversion. Earlier in this hearing, there was a discussion of the Faces of Fentanyl exhibit downstairs. There's also a wall of honor commemorating DEA agents who gave their lives in the fight against drug trafficking. Among them is Special Agent Enrique “Kiki” Camarena, who was tortured and murdered while investigating major marijuana and cocaine trafficking organizations. That history is a reminder that marijuana trafficking has long been intertwined with organized criminal enterprise.

Now, advocates for rescheduling or for loosening or relaxing the restrictions on marijuana will often make the argument that by lightening controls, you will also cut against the illicit market of marijuana. The evidence, however, will show the exact opposite. The state's second witness will be Sheriff William Honsal of Humboldt County, California. You may ask why are the states calling a law enforcement

officer from California rather than one of their own officers? The answer is simple: Humboldt County has lived with the consequences of marijuana deregulation more than almost anywhere else in the country. Sheriff Honsal will testify that he comes from what's called the Emerald Triangle, one of the first three counties that began to see the upsurge in marijuana production, that his county was responsible for the production for much of the marijuana that was illicitly sold throughout the United States in the ‘90s and early 2000s. He will testify that weakening legal controls has not displaced the illicit market. Instead, it has fueled illegal cultivation, organized crime, human trafficking, and violence.

The states' evidence will demonstrate that the scientific concerns regarding marijuana's psychiatric effects remain compelling and that the practical realities of diversion and criminal enterprises remain substantial. And at the end of the day, the evidence will demonstrate that marijuana has a high potential for abuse that is consistent or commensurate with other Schedule I drugs, particularly other Schedule I hallucinogens, and also that it does not have a

currently accepted medical use. And thus, the evidence does not justify transferring marijuana out of Schedule I. Thank you, Your Honor.

JUDGE JULIUS: Thank you, Counsel. Are you ready to call Dr. D'Souza --

MR. HARRINGTON: I am ready.

JUDGE JULIUS: Using Zoom virtually?

MR. HARRINGTON: What time is it?

JUDGE JULIUS: It is 2:41.

MR. HARRINGTON: 2:41. Before we call Dr. D'Souza, just one brief housekeeping item in order, Your Honor. If you'll open up the binder that we provided to the Court and just look at the table of contents, we noticed in preparation that some of the states' exhibits are duplicated. Dr. Finn already admitted into evidence several of these exhibits, so I have taken the liberty of just interspersing Dr. Finn's exhibits in the place where we had corresponding documents. So periodically throughout my examination of Dr. D'Souza, I might say, Turn to tab 15, what was state 15. It's going to be, however, I think Dr. Finn Exhibit No. 48, and I'll just make that clear as we go through.

JUDGE JULIUS: Thank you, Counsel.

MR. HARRINGTON: All right. And with that, I'm ready to call Dr. D'Souza.

JUDGE JULIUS: Okay. Dr. D'Souza, can you hear us? It looks like you may be muted on your end.

DR. D'SOUZA: Yes, I can hear you.

WHEREUPON,

DR. DEEPAK CYRIL D'SOUZA,

was called as a witness by Opposed States and, having been first duly sworn, assumed the witness stand, was examined and testified as follows:

JUDGE JULIUS: Very good. If you would, sir, if you're able, would you please raise your right hand in order to be placed under oath? Do you swear or affirm that everything you say in these proceedings will be the truth, the whole truth, and nothing but the truth?

DR. D'SOUZA: I do.

JUDGE JULIUS: Thank you very much. You may put your hand down. Before we proceed to questioning, I'll just give you a few brief instructions or comments about the process of testifying just to make sure we create as clear a record as we can.

Please wait until the entire question is

asked before you begin your answer. After the question is asked, pause for a second or two to see if the question draws an objection. If you hear the word objection, just pause. I'll address the objection with the attorneys, and then I will instruct you whether you should or should not answer the question. If at that point you need the question repeated, you can ask for a repetition.

DR. D'SOUZA: Thank you.

JUDGE JULIUS: And if at any time you get a question that you don't understand, please state that you don't understand the question before you try to answer it. We'll make sure the question is rephrased in a way that you understand and can answer. If you go ahead and answer a question without saying that you don't understand it, we'll assume that you understood that question. Does that make sense?

DR. D'SOUZA: Yes, thank you.

JUDGE JULIUS: All right. Mr. Harrington, direct examination whenever you're ready, sir.

DIRECT EXAMINATION

MR. HARRINGTON: Good afternoon, Doctor. Would you please state your full name for the

record?

THE WITNESS: Deepak Cyril D'Souza.

BY MR. HARRINGTON:

Q In preparation for your testimony today, have you read or has anyone read to you any of the transcripts of testimony from prior witnesses in this hearing?

A No.

Q And would you please confirm that you don't have notes or aids off-camera, that you're just focused on the screen with me and not looking at any exhibits yet?

A No, but I should say that I'm giving this testimony from my office at the VA hospital. I have a screen of my VA computer next to me, and I can't control the number of emails or messages that I get. So, if my attention is diverted, it's only for a second because messages are coming in.

Q Doctor, what do you do for a living?

A I'm a psychiatrist.

Q What is a psychiatrist?

A A psychiatrist is a physician who specializes in treating people with mental illnesses.

Q Where do you practice?

A I wear two hats. I'm a staff psychiatrist at the Department of Veterans Affairs in the VA Connecticut Healthcare System in West Haven, where I've practiced since 1992. I'm also a professor of psychiatry at Yale University School of Medicine.

Q How many patients would you say that you see in a given year?

A I am ultimately responsible for approximately 2,500 patients. I direct the clinical service at VA Connecticut Health Care System that provides care to veterans with serious mental illness, including schizophrenia, bipolar disorder, depression, and other disorders. And the numbers vary from year to year, but it's somewhere in the range of 2,500.

Q With respect to your role at the Yale School of Medicine, what responsibilities do you have?

A As a professor in the School of Medicine, I am involved in teaching trainees at different levels. I also conduct research, and most recently I was appointed the inaugural director of the Yale Center for the Science of Cannabis and Cannabinoids.

Q What is the work of the Yale Center for the Science of Cannabis and Cannabinoids?

A Our goal is to generate the highest quality scientific information about the risks and benefits of cannabis, and that's the goal of science in general, to generate information that people can then use in whatever decisions they need to make.

Q What influenced you to study the connection between marijuana and psychiatry?

A Actually, it goes back to when I was in medical school. I went to medical school in India, and I had a colleague who was a year ahead of me who was a really smart guy, well-adjusted and he started using marijuana. And it culminated in a significant psychotic break, which fortunately he recovered from, but as a young medical student, it had a profound impression. It created a profound impression on me how somebody who was previously well-adjusted could undergo such changes because of drug use.

Q Doctor, where did you go to medical school?

A I went to medical school at St. John's Medical College in Bengaluru, India.

Q And after medical school, did you pursue any fellowships?

A I came here to the U.S. in 1986 and did a residency in psychiatry at the State University of New York Downstate Medical Center in Brooklyn. And then in 1992 I came to Yale, I did a fellowship in psychopharmacology, and that's my training.

Q Are you licensed to practice medicine?

A Yes, in the state of Connecticut.

Q And when were you first licensed?

A 1992 in Connecticut.

Q Do you have any board certifications?

A Yes. The American Board of Psychiatry and Neurology.

Q Do you hold any patents?

A I have a pending patent for the use of a certain psychedelic drug in the treatment of major depressive disorder that drug is called DMT or dimethyltryptamine. I have another pending patent on the use of another psychedelic drug, psilocybin, in the treatment of headache disorders. Those are patents that are held jointly by me, the Department of Veterans Affairs, and Yale University School of Medicine. Sorry, I misspoke. The patents are not held; they're

pending.

Q Thank you. And are you familiar with the process of preparing and submitting peer-reviewed research?

A Yes. I'm also the principal editor of the international journal called Psychopharmacology, and in my capacity as an editor, I have to review papers submitted to me. And then as a researcher myself, I have to submit papers to journals, so I'm very well aware of the peer review process.

Q How many peer review articles have you published?

A I would say over 200 papers, books, and chapters.

Q What books have you published?

A I'm one of the co-editors, actually the principal editor, of the third edition of The Book Marijuana and Madness. I was also the editor of the second edition of that book, and that's a book that basically covers everything anyone would want to know about the relationship between cannabis and mental illness.

Q Doctor, do you also conduct research studies?

A Yes. I've been conducting research since 1992. I conduct human clinical research. I don't do any animal research.

Q What kind of research do you do?

A I would say I do three different kinds of research. As you know, we don't have really good animal models of psychiatric disorders. You know, you can't get a monkey to tell you he's depressed, or you can't get a rat to tell you he's hearing voices. But what we can do, and the reason I came here to Yale, was one can use certain drugs to induce certain symptoms that resemble the symptoms of the illness that we might be interested in. So, for example, there are drugs that can reliably induce anxiety in a person. There are drugs that can reliably induce hallucinations in a healthy normal person. And by studying those phenomena in healthy individuals, that could tell us a lot about the reality of depression or anxiety disorders. So that's one line of research -- acute laboratory studies.

The second line of research at the other end of the spectrum is the development of treatments for psychiatric disorders, and I've been involved in developing drugs for the

treatment of schizophrenia, bipolar disorder, major depressive disorder, cannabis use disorder. And then I also conduct observational studies using technologies such as EEG, where we measure brain waves, and positron emission tomography. That allows us to measure the numbers of receptors that we might be interested in the brain.

Q Who provides funding for these studies?

A Most of my funding over the last three, four years has come from either the National Institute of Health, the Department of Veterans Affairs, and then a number of foundations that support this line of research. Most of my research has come specifically from the National Institute on Drug Abuse, or NIDA.

Q And just to focus on a subset of your research, about how many randomized, double blind, and placebo-controlled trials have you participated in?

A I would estimate that I've participated in approximately more than 100 clinical trials over the last three, four years.

Q All right. Could I ask the Court to turn to tab 20 or States' Exhibit 20, and can I also direct Dr. D'Souza to also turn to States' Exhibit

20?

A That's my CV?

Q That was my next question.

A Oh, okay.

Q So you have identified this document as your CV, correct?

A Correct.

MR. HARRINGTON: Your Honor, I would move this into evidence.

(Whereupon, the document referred to was marked as Opposing States' Exhibit No. 20, for identification.)

JUDGE JULIUS: Any objection?

MR. LONICH: No objection, Your Honor.

JUDGE JULIUS: Opposing States' Exhibit 20 will be admitted without objection.

(Whereupon, the above-referred to document marked as Opposing States' Exhibit No. 20 was received into evidence.)

MR. HARRINGTON: Doctor, have you previously testified as an expert in court?

THE WITNESS: Yes, I have.

BY MR. HARRINGTON:

Q What was the nature of that expert testimony?

A That was a medical malpractice suit. It's not over as yet. It's ongoing and I was testifying on behalf of the Department of Justice.

Q In the medical malpractice case, or in a separate matter, you also testified on behalf of the Department of Justice?

A No, in the medical malpractice case.

Q Okay. And is that the only time you've testified for the United States?

A Yes, I believe so.

Q Okay. Have you ever testified before state legislatures?

A Yes. I testified quite extensively at the Connecticut State Legislature when there were discussions about legalizing medical and recreational cannabis use. Yes. I was also invited by Senator Takano and some -- another Congress person who's in charge of the Department of Veterans Affairs for a closed-door hearing about what kind of research the VA might conduct on cannabis to meet the needs of veterans.

Q Are you being paid anything for your appearance here today?

A No.

Q Do you receive any remuneration from

cannabis producers, retailers, interest groups, or opponents of legalization?

A No. I don't receive any compensation from either proponents or opponents of cannabis.

Q Do you have any financial ties to a pharmaceutical company?

A No, I don't.

Q What are your sources of income?

A I get paid mostly from the Department of Veterans Affairs, and then a small portion of my salary from Yale University School of Medicine, and then some speaking engagements and other sundries.

MR. HARRINGTON: Your Honor, at this time, we would tender Dr. D'Souza as a provisional expert in five areas: First, the pathophysiology of psychotic disorders; second, conducting clinical trials; third, peer review process for medical research; fourth, uses of marijuana for medical purposes; and fifth, effects of marijuana on the human brain and body.

JUDGE JULIUS: Consistent with the Court's preliminary order, we will accept the provisional expertise subject to challenge and argument in the closing statements, but --

MR. HARRINGTON: Thank you, Your Honor.

JUDGE JULIUS: Accepted for now.

MR. HARRINGTON: Dr. D'Souza, prior to your testimony today, have you had the opportunity to review States' Exhibits 1, 3 through 9, 11 to 14, and 18 to 19?

THE WITNESS: Yes.

BY MR. HARRINGTON:

Q Do you have a copy of these exhibits with you as you testify today?

A I do.

Q And are these true and correct copies of the published articles, reports, and documents they purport to be?

A Yes.

Q Were these articles, reports, documents published by authoritative sources regularly relied on by psychiatrists and public health specialists on cannabis?

A Yes, and they were published in highly reputable journals.

Q Are these the kind of materials on the effects of cannabis on the brain and body that experts would rely upon in forming their opinion?

A Yes.

Q Do these materials bear on whether marijuana has a currently accepted medical use?

A Yes.

MR. HARRINGTON: Your Honor, the States would like to move into evidence Exhibits 1, 3 through 9, 11 through 14, 18 through 19.

(Whereupon, the documents referred to were marked as States' Exhibit Nos. 1, 3 through 9, 11 through 14 and 18 through 19, for identification.)

JUDGE JULIUS: Any objection from the government to the admission of those exhibits?

MR. LONICH: No objection, Your Honor.

JUDGE JULIUS: Okay. So I want to make sure I got these numbers correct: 1, 3 through 9, 11 through 14, and 18 through 21.

MR. HARRINGTON: 18 through 19 at this time, Your Honor.

JUDGE JULIUS: Sorry, 18 through 19. Thank you.

MR. HARRINGTON: We separately admitted Exhibit 20, and then we'll come to Exhibit 21 in due course.

JUDGE JULIUS: Got it.

MR. HARRINGTON: Thank you.

JUDGE JULIUS: Thank you, Counsel.

MR. HARRINGTON: Thank you.

JUDGE JULIUS: Those will be admitted without objection.

(Whereupon, the above-referred to documents marked as States' Exhibit Nos. 1, ~~2~~3 through 9, 11 through 14, and 18 through 19 were received into evidence.)

MR. HARRINGTON: Dr. D'Souza, would you please go to what was previously States' Exhibit 15 and what is marked in this hearing as Dr. Finn Exhibit 48? The Court can find --

THE WITNESS: I'm sorry.

BY MR. HARRINGTON:

Q This at tab 15 in the binder, yeah.

A 15, you said.

Q Yes.

A Yeah. Yes.

Q Do you recognize this paper?

A Yes, I do.

Q Could you please turn to page 2? Let me know when you're there.

A Okay. Hold on one second. Yes, I am there.

Q In the upper right-hand corner, there's

a glossary of terms. Do you see that?

A Yes.

Q Could you please read the definition of cannabis in that glossary?

A Cannabis, the plant, (Cannabis sativa) that produces cannabinoids, including THC. Legally, plants with less than 0.3 percent THC can be called hemp.

Q When you use the word legally, are you referring to a federal legal distinction between marijuana and hemp?

A Yes.

Q And are your opinions today based on the federal definition of marijuana?

A Correct.

Q For purposes of this examination, can I use cannabis or marijuana interchangeably to refer to botanical Cannabis sativa L.?

A Sure.

Q Has Congress' exclusion of hemp from the federal definition of marijuana in 2018 changed any of the opinions you've expressed in your published work?

A No.

Q And does excluding hemp from the federal

definition change your assessment of marijuana's abuse potential or medical utility?

A No.

MR. HARRINGTON: Your Honor, I'm holding in my hand right now Government Exhibit 3. This is the HHS recommendation. Dr. D'Souza has not seen this document, but I'd like him to comment on something that I will read to him. But I just want the court to know where I'm at. I'm on Government Exhibit 3, specifically page 19.

JUDGE JULIUS: Thank you, Counsel.

MR. HARRINGTON: Dr. D'Souza, would you agree that cannabis is a highly polymorphic species?

THE WITNESS: Yes.

BY MR. HARRINGTON:

Q And would you agree that it is known as, I'm going to quote language here, Cannabis sativa L., with the other two previously reported species listed as Cannabis indica and Cannabis ruderalis?

A Yes.

Q I'm going to keep reading. Let me know if you agree with the following: Plants previously believed part of the latter two species are generally recognized as varieties or

subspecies of Cannabis sativa L.

A My understanding is that there are three subtypes: indica, sativa, and ruderalis. The ones that are most relevant to, I suppose, this hearing would be indica and sativa and not ruderalis, which has very low quantities of THC.

I think the distinction, though, is a little semantic because these days that distinction between indica and sativa is no longer relevant since these plants have been so cross-bred. You really don't get pure sativa plants or pure indica plants. And then to take it another level, at the end of the day, what's driving the effects of whether it's Cannabis indica or sativa is really the principal active constituent of cannabis, which is delta-9 THC. And delta-9 THC exists in both plants, both species. So, it doesn't really matter. I think it's more of semantic interest.

Q Approximately how many chemicals are in marijuana?

A Over 500 chemicals. And of those, there are several hundred cannabinoids. Another group of compounds are terpenes, which impart cannabis its distinct aroma, and then flavonoids. But

amongst the cannabinoids, the two that are of greatest interest and that drive most of the psychoactive effects of cannabis are obviously delta-9 THC, and some of the effects of delta-9 THC might be offset by cannabidiol, which is sometimes referred to as CBD.

Q What is the principal psychoactive constituent of marijuana?

A Delta-9 tetrahydrocannabinol, or THC.

Q And if I say THC or CBD, you know that I'll be referring to delta-9 tetrahydrocannabinol or cannabidiol?

A Correct.

Q What effects does THC produce?

A THC drives most of the psychoactive effects of cannabis, which includes alterations in perception, alterations in mood, typically a reduction in anxiety, psychomotor effects, and so on and so forth. In contrast, cannabidiol or CBD does not have any of those psychoactive effects, though in studies looking at the interactions of CBD and THC, including studies in my lab, there's some evidence that CBD might reduce some of the effects of THC in some studies.

Q Has genetic engineering of cannabis

affected THC concentration?

A Yes, I think there's been a systematic effort to increase the THC content of cannabis, and that's been fairly successful because at one time, natural cannabis had only about three to four percent THC, and now most of the plants have been genetically engineered to produce up to 30 percent THC and sometimes even a little more.

Q Has the potency or the concentration of CBD changed as well?

A There's some indication that maybe the CBD content of cannabis may have declined over time. That said, just to clarify, one way to look at the different kinds of cannabis are THC-rich cannabis, CBD-rich cannabis, and balanced, where there's a balance of THC and CBD.

Q And in your three decades of study, to what extent has the THC concentration changed in marijuana?

A The THC concentration of cannabis has changed quite substantially over the last three or four decades from being in, you know, close to between four and seven percent to now closer to 20 percent. And you can definitely buy cannabis at dispensaries where the THC content is close to

35 percent, and some states are capping the THC content at around that. So yes, there's been almost, you know, 5 to 10 time increase in THC content over the last few decades.

Beyond just cannabis, there are cannabis-derived products like cannabis oils and vaping fluids, which have a THC content of up to 95 percent, which would be 20 times greater than the THC content of cannabis that people were smoking in the 1960s and 1970s.

Q I'd like now just to pivot to discuss the endocannabinoid system. Could you briefly explain what the endocannabinoid system is?

A Sure. So approximately around 1988, scientists at the National Institute of Drug Abuse discovered a receptor in the brain to which THC binds. A receptor is basically, the best way I can describe that to you would be imagine a lock and a key. The lock being the receptor, the key being THC. And when the key goes into the lock, it opens the lock, and then downstream, there's a cascade of events that occur after that. Now, rats, mice, dogs, hamsters, rabbits, and humans have cannabinoid receptors in their brain. Those receptors are not there to get us high. Those

receptors and that system, the endocannabinoid system, are present in the brain because it's involved in many normal physiological functions.

Another way of putting this would be back in the 1970s, we discovered endorphins. Endorphins are chemical substances that the brain makes that are similar to exogenous opioids. We now know that the brain makes endogenous cannabis-like substances, which we call endocannabinoids. These endocannabinoids have been identified. One is called anandamide, which is named after the Sanskrit word meaning bliss. The other is 2-AG. We know that there are two receptors in the brain. We now know a lot about the machinery involved in how these chemical compounds are synthesized, how they're degraded. And it looks like the endocannabinoid system plays an important role in a number of important functions, including appetite, sleep, the regulation of stress, and it plays a very important role in adolescence, while the brain undergoes perhaps its greatest changes during adolescence. The endocannabinoid system plays a very important role there.

Q Thank you very much. When was the endocannabinoid system discovered?

A So probably in late 1988, I think, was when the first cannabinoid receptor was discovered.

Q Is the scientific understanding of the endocannabinoid system still progressing?

A Yes. It's quite nascent. We are still learning a lot more about the system. It's only been, you know, 40 years or so.

Q I believe earlier you characterized cannabinoid receptors as akin to a lock. What are the cannabinoid receptors?

A There are two cannabinoid receptors. The CB1 receptor is the one that's present mainly in the brain. And activation of CB1 receptors is what probably drives all the psychoactive effects of cannabis. And there's a CB2 receptor, which is present mostly in the periphery, and it's located on immune cells and may play a role in inflammation and immune responses.

Q And I think in your prior answer, you may have touched on this, but just so that it's clear in the record, could you describe what the normal function of the endocannabinoid system is?

A Sure. The endocannabinoid system seems to be involved in regulating appetite, and this is

why people get the munchies after they smoke cannabis. And this is also why pharmaceutical companies developed an anti-cannabis drug, which was quite effective actually as a weight loss drug. The problem is that it made people depressed, and so it was withdrawn from the market. So one area is appetite. Another area is sleep, regulation of sleep. Third area is circadian rhythms. So these are the normal body rhythms that all of us have.

I also mentioned neurodevelopment. The endocannabinoid system, especially in adolescence and in utero, seems to play some role in brain development. And I think I may have also mentioned the regulation of stress.

Q Where are the CB1 receptors located?

A They're distributed all over the brain, but they have a very high density in specific areas of the brain. And it's very interesting, and it makes sense because these are also the areas of the brain that are involved in most of the actions of cannabis. So the high density of receptors, for example, in the hippocampus, which is that part of the brain that's critical for memory.

There’s a high density of cannabinoid

receptors in the basal ganglia, and that's an area of the brain which may be involved in reward and also addiction. The high density of cannabinoid receptors in the cerebellum, which is that part of the brain that seems to control psychomotor function, and so the kinds of functions that might be involved in, say, driving or operating heavy machinery.

There's high density of cannabinoid receptors in the prefrontal cortex, which is involved in planning and execution. And so these brain areas overlap nicely with the known effects of cannabis.

Q Does the concentration of CB1 receptors explain marijuana's potential for abuse and dependence?

A Not really, it doesn't explain. But what we do know is that one common way that the brain responds to being bombarded by a substance is that the receptor system, we use the word scientific term, down-regulates, meaning if the brain is constantly bombarded by, let's say, cannabis, the numbers of cannabinoid receptors actually go down. And that's a kind of protective or compensatory mechanism that the brain has.

We did some studies, some of the first studies in living human beings, where we invited heavy cannabis users. We took pictures of the cannabinoid receptors in their brain using a technology called positron emission tomography. For those of you want to try and understand that, what we do is we take a chemical that's known to bind to cannabinoid receptors, and then we tag that chemical with a radioligand, which then shows up, which we can take pictures of. So we took pictures of the number of cannabinoid receptors in the brain in people who were using cannabis regularly versus healthy controls, who are not using cannabis. And we found that they, cannabis users, had about a 15 percent reduction in the numbers of cannabinoid receptors relative to age and gender-matched controls. This provided some of the first in vivo evidence of, or in the living human being evidence, that chronic use of cannabis results in changes to the endocannabinoid system.

Q Let's take a look at your earlier testimony about CB1 receptors in the basal ganglia, I believe. And you said that might explain the connection between marijuana and reward and addiction. Could you elaborate on

that?

A So, like most drugs of abuse, including cocaine, heroin, nicotine, cannabis has the potential to increase the release of dopamine, which is basically we can call it a reward chemical. Cannabis can cause an increase in the release of dopamine in the basal ganglia, which is common to most drugs of abuse.

Q Thank you. Can you explain to the Court how does THC affect the endocannabinoid system?

A Okay. So first, let me tell you a little about how the normal endocannabinoid system works. The normal endocannabinoid system is a peculiar system, and I don't know whether I should go into detail here and bore you with details, but let me put it this way, what happens when neurotransmitters are released, there is an on-demand synthesis of these endocannabinoids that I referred to, anandamide and 2-AG. These chemicals are synthesized on demand, and they're released in a very, very, very small area. They then bind to cannabinoid receptors, activate those cannabinoid receptors, and are destroyed almost immediately.

So, forgetting about all these details, the two important things to remember are, number

one, that these endocannabinoids are released in a very tiny area -- very, very small area, number one. And number two, they are inactivated almost immediately. As soon as they bind to the receptors, they're inactivated. In contrast, when you smoke weed, when you smoke cannabis, THC present in cannabis floods the entire brain, number one and number two, it activates cannabinoid receptors in an indiscriminate way. There are differences between the natural endocannabinoids that the brain produces and the effects of THC.

There are some important implications of that. We know that the endocannabinoid system plays an important role in brain development. Just for argument's sake, we are all born, let's say, with 100 billion neurons. The brain undergoes its greatest change during adolescence. And during adolescence, the brain removes connections that are unnecessary and strengthens connections that are necessary. So we go from, I'm making up this number, 100 billion neurons to 60 billion neurons. The endocannabinoid system seems to play some role in that neurodevelopmental pruning process. When that normal pruning

process, that the endocannabinoid system is involved in, is disrupted by THC present in cannabis, you could imagine how there could be long-term implications related to that. We are accumulating evidence now that exposure to cannabis in adolescence may be associated with a number of long-term changes in the brain and in the development of psychiatric disorders.

Q Is the fact that the body has cannabinoid receptors that respond to THC mean that marijuana is safe?

A No.

Q Does the fact that the human body contains receptors that respond to THC establish that consuming marijuana could be medically beneficial?

A Not in and of itself.

Q And when researchers study THC in controlled lab settings, are they able to administer known doses of THC?

A In the laboratory setting, yes.

Q What are the pharmacokinetics of THC?

A It really depends on whether a person is smoking, vaping, or consuming an edible. So when a person smokes cannabis or vapes cannabis, THC reaches the --

Q Actually, Doctor --
A So --
Q I think it -- it might be useful if I backed up a second. Could you define for the Court the term pharmacokinetics?
A Okay. I'll do my best. Pharmacokinetics involves the absorption, distribution, and elimination of a drug in the human body.
Q Thank you. And now to return to my prior question about the pharmacokinetics of THC. Could you please continue?
A Sure. When cannabis is smoked or vaped, THC that's released is absorbed by the blood vessels in the lung, and it goes to the brain almost within a few minutes. And the effects, therefore the psychoactive effects, emerge very quickly. The peak of those effects occur around 15 to 20 minutes, and they may last for about an hour, and they slowly dissipate after that. But when a person consumes an edible or such, or a brownie or some other product that they take orally, it has to go through the stomach and then through the liver and the small intestine -- not the liver. Goes through the intestine, gets absorbed, then it goes to the liver, where it gets

metabolized. And so it takes a lot longer for the effects to emerge. The effects emerge typically between 45 minutes and 60 minutes after consuming an edible. And furthermore, the effects last a lot longer than when someone smokes or vapes cannabis. The third issue is that there's much greater variability in the levels of THC if someone consumes an edible or a brownie versus smoking or vaping cannabis.

Q Are you familiar with different routes of administration for medicines?

A Yes.

Q Are you aware of any medicine that's designed to be inhaled using combustion?

A No. Of course, there are drugs that are commercially available that are used as inhalers, like asthma inhalers, et cetera, but those don't involve combustion.

Q I'd like now to talk about brain development. Does the endocannabinoid system play a role? I think you've testified yes, but I want you to speak to this question ~~discreetly~~discretely here. Does the endocannabinoid system play a role in normal adolescent brain development?

A Yes.

Q Can THC disrupt adolescent brain development?

A Yes, as I testified earlier.

Q And are those changes short-term, long-term?

A That's a good question. There is some data suggesting that some of those changes could be long-term. I think we still need a lot more research to nail that down, but there is some concerning evidence from one of the most expensive studies funded by the federal government called the ABCD study, which looks at the impact of drugs on child brain development.

Q And now let's talk about your own research. Dr. D'Souza, do you conduct original research into the effects of cannabis?

A Yes, I do.

Q And how long have you been working on that?

A I began my work with THC back in 1997.

Q Have you personally designed and conducted controlled human laboratory studies involving THC?

A Yes, I have.

Q Have those studies generally been

prospective clinical trials conducted under carefully controlled conditions?

A Yes, most of the laboratory studies that I've conducted are double-blind, randomized, placebo-controlled, and crossover design.

Q I want to talk about each of those components. So why is randomization important?

A Randomization is important because it allows us to interpret the results and removes the possibility that, you know, that there are alternative explanations for the findings.

Q Why is it important that a study be double blind?

A So we all bring our biases, both as patients and as researchers; we might bring biases to the experiment. So for example, if a researcher is anti- or pro-cannabis, those unconscious biases might interfere with their assessments if they know that the person did or did not receive cannabis or placebo. And likewise, participants in research might bring their own expectations and biases to studies. So for that reason, a fundamental aspect of controlled clinical trials is that those studies have to be double blind, so both the researcher and the patients should not

know what they were assigned to.

Q Why is it important that the study be placebo-controlled?

A Because that's the best way to compare a drug against a blind state, so to speak.

Q Are any of the studies that either you've designed, participated in, or are relying on informing your opinions today funded by companies that manufacture cannabis products?

A No, not companies that manufacture cannabis products, but I have conducted studies with a drug that blocks the enzyme that breaks down the brain's endocannabinoid. Let me try and explain this to you. So as you know, there are no FDA-approved treatments for cannabis use disorder, and as we are concerned about the increasing rates of cannabis use disorder, we need to have drugs, or we need to have treatments that will be effective for cannabis use disorder.

We came up with the idea that could we increase the brain's own cannabis-like substance? And if we were able to increase the brain's own cannabis-like substance, perhaps people who are addicted to cannabis would not feel the desire to use cannabis. Many years ago, the company Pfizer

developed a drug that blocked the enzyme that broke down anandamide, the principal endocannabinoid in the brain. And they tested that drug as a painkiller for people with osteoarthritis, and unfortunately, the drug failed in that drug study. But they were willing to give us the drug, and we conducted a study at Yale where we invited heavy cannabis users, and we gave them -- they either got placebo or they got this drug. And we kept them on an inpatient unit where they were not allowed to leave, and so they weren't able to have access to cannabis. So we forced them into withdrawal, so to speak. And this drug had some very curious effects. It blocked the withdrawal symptoms that are well known to occur when someone who's using cannabis regularly stops using cannabis abruptly. When we discharged them from the hospital, they tended to use less cannabis than the group that received placebo.

That study was funded by the National Institute on Drug Abuse, but the drug was supplied to us by the company at the time, Pfizer. So yes, I have done some work in partnership with the industry, with the pharmaceutical industry.

Q And I think you've mentioned there's no

FDA treatment that's approved for cannabis use disorder. So is that drug that you just described that's not available right now?

A Not available, no.

Q Okay, specific to studies involving marijuana, can you describe some of the methodological challenges that researchers face?

A One is that if you want to study the effects of THC one important aspect of that is to be able to study dose response. That is to give different doses of the drug and to observe the response, and that allows us to make some important interpretations, and one, it gives us greater confidence in the data. Another issue is that, like I said to you earlier, we found that people who use cannabis on a regular basis have about a 15 percent reduction in the number of cannabinoid receptors in the brain. So, putting that in a different way, the degree of cannabis exposure has a strong influence on the effects of THC in the lab. That is to say, if someone has been using large amounts of cannabis and they take part in a study, they are going to have blunted responses to THC in the lab. Conversely, if someone has not used cannabis at all, they are

going to have more robust responses to cannabis in the lab.

Measuring cannabis exposure is very hard to do because, as you know, joints can come in different shapes and sizes. The THC content of cannabis can vary considerably. So that is one of the challenges that we face as researchers.

Q Doctor, could you -- could you -- I'm sorry. Please finish your answer.

A And just the third issue is that which we touched upon being able to blind studies, is really -- making studies double blind is really critical, and that is a challenge that has faced a number of cannabis researchers.

Q Could you please turn to States' Exhibit No. 7?

A 7. Okay, yeah.

Q Does this study relate to the subject you were just testifying about?

A Yes.

Q Could you please explain?

A Sure. This is a mega-analysis where we took all laboratory studies with intravenous THC and looked at a specific outcome that we were interested in, and that is psychosis-like

outcomes. And this paper involved, I believe it was about 10 studies. Some were from my lab, and others were from colleagues and researchers in the United Kingdom. And the paper reports the magnitude of psychosis-like effects produced by intravenous THC in the laboratory relative to placebo.

Q Could you just -- to make sure we're on the same page, could you please read the title of the article you're looking at?

A Oh, sorry. Oh, sorry. My bad.

Q No problem.

Q No. Let's go to Exhibit 7.

A Yes. Okay. Seven is characterizing psychosis-relevant phenomena and cognitive function. Is that the one you're referring to?

Q Yes. There we are.

A Okay. Yes.

Q Could you describe for the Court the population that you examined in this study?

A Yeah. So just a little bit of background on this. When conducting epidemiological studies about the consequences of any drug use, one of the problems researchers run into is that people who use -- for example, if you want to study the long-

term -- do an epidemiological study looking at the effects of alcohol, people who use alcohol may also use other drugs, including tobacco, et cetera. So it's very hard, whatever finding you then have, it's hard to attribute that finding specifically to alcohol because of these other confounders. And so likewise, in studies looking at the effects of cannabis, epidemiological studies, one of the challenges to those studies is that people who use cannabis may also use other substances that might contribute to the findings.

I was trying to think about how I would be able to study the isolated effects of cannabis. And I stumbled upon a group based in Central America. They have a very interesting interpretation of the Old Testament. And I don't remember the exact psalm that they refer to, but in that psalm there's reference to grass for the sake of humans and they interpret grass as -- or the herb as cannabis, and they believe that cannabis is a sacrament. And so they use large amounts of cannabis.

They also have a very conservative interpretation of the Bible. So where the Bible says, and drink is forbidden, they don't drink

alcohol, they don't smoke cigarettes, they don't use any drugs. So in some ways, they are the ideal subjects to study the long-term effects of cannabis.

Q As I was reading --

A So I –

Q Well, I'm sorry.

A Yeah, go ahead.

Q As I was reading this study, I was wondering, are these Rastafarians?

A I prefer not to give them a label.

Q Fair enough.

A That was one of the conditions of the study. Anyway, we compared that group to a similar group that has conservative views but who don't use cannabis from the same area with many of the same belief systems. And we found that those who were using cannabis scored higher on measures of schizotypy, which is a measure of psychosis-like phenomena. We also found that they performed worse on a number of cognitive tests, including tests of memory, attention, and executive function relative to the control group.

Q And, Doctor, now I think let's go to States' Exhibit 4. I think you might have been

speaking about this earlier. Let's go to number 4.

A Of 4. Yeah, got it. The meta-analysis.

Q Could you again just summarize the design and findings of this study?

A Yes. We looked at all the studies conducted with intravenous THC, where the outcome was psychosis. And, as you know, a common method to confirm findings that may have been evident in small sample studies is to then conduct meta-analysis or mega analyses. So I think this study, this paper, covered 10 studies. Some of them were from my lab. Some were from colleagues in the UK. And we looked at measures of psychosis relative to placebo, and we found that there was a significant effect of THC in increasing psychosis-like phenomena in healthy individuals.

Q And how did you determine that?

A So in these laboratory studies, we collect measures of psychosis at baseline before a person has received THC and then several times after they've received THC. And then just as a reminder, these are double-blind, randomized, placebo-controlled studies. So each person got THC and then on a separate day also got placebo.

And so, we had the capacity to compare within an individual what their scores on this measure of psychosis were on the placebo condition versus the THC condition.

Q All right. Thank you. Doctor, would you please turn or pull up on your computer what has been marked as States' Exhibit Number 21?

A Is that the one, the clinical trial, the German clinical trial?

Q I believe the one I'm referring to is authored by a person with the last name of Karst. It was published in --

A Yeah.

Q May of 2025. Let me know when you have that.

A Yes.

Q Available.

A Somehow I don't have it in this, but I know the paper that you're referring to.

Q I see.

A Yeah.

Q And have you --

A Is it?

Q Have you seen the document that's marked States' Exhibit 21?

A I have seen it in a previous email that you sent me.

Q I see. Okay. Your Honor, the States would like -- actually, no, never mind. Not yet. Could you please describe the Karst article, Dr. D'Souza?

A That was a very large double-blind placebo-controlled study using an oral form of a compound referred to as VER-1, I believe. It was a whole cannabis extract in individuals with chronic lower back pain. The study involved a sample of more than 800 individuals, I believe. And the study showed that there was statistically significant differences between the active compound and placebo on the main outcome measure of pain. The scale that they used goes from 0 to 11, and the difference between placebo and the active drug was roughly one point or so. So while there was statistically significant differences between placebo and the active drug in the standard blind placebo-controlled studies, these effects were relatively modest.

Q Dr. D'Souza, has the FDA ever approved a new drug application for a botanical substance?

A Not to my knowledge, at least in

psychiatry. I'll restrict my comments to psychiatry.

Q Are you at all aware of the FDA approval progress of the drug you were just discussing, VER-1?

A I'm unaware of the development of that, but in terms of botanicals, if I may --

Q Please.

A The tradition in modern medicine is to extract the principal active constituent of a plant, purify that, standardize its production, and then make it into a medicine. So for example, opioids come from the opium plant, and doctors don't prescribe the opium plant if someone goes to them with pain. They prescribe an isolated opioid that's standardized. Likewise, if you have congestive heart failure, your cardiologist will prescribe digoxin, which comes in a tablet, and not the foxglove plant from which digitalis is derived. So the tradition in modern medicine is usually to isolate the principal active constituent and then go from there.

Q Are there any differences between VER-1 and medical marijuana that's available for sale today?

MR. LONICH: Objection, Your Honor.

JUDGE JULIUS: Hold on, Doctor. We have an objection. What's the objection?

MR. LONICH: I believe it's outside the scope of this witness' expertise. He already testified he's not super familiar with this substance. He hasn't been tracking its progression, and also his own statement is he's going to limit or restrict his comments to psychiatry. I believe we're getting into now opioids and pain management and those things.

JUDGE JULIUS: Mr. Harrington, do you have a response?

MR. HARRINGTON: A few, Your Honor. He is tendered as an expert on marijuana, marijuana for medical purposes. His CV demonstrates that he's involved and has testified with respect to the state medical marijuana program at the State of Connecticut. He testified, I believe, that he's not familiar with the FDA approval progression of VER-1, but he did not -- he's read the Karst paper and said he was familiar with its contents, and so I think he can describe the nature of that particular drug and compare it with state medical marijuana as it is conventionally

available.

JUDGE JULIUS: Did you have anything further, Mr. Lonich?

MR. LONICH: No, Your Honor.

JUDGE JULIUS: I do. Because he has been provisionally accepted as an expert on the uses of marijuana for medical purposes and has familiarized himself with this particular article, I will go ahead and overrule the objection.

MR. LONICH: Yes, Your Honor.

JUDGE JULIUS: Thank you. Please go forward.

MR. HARRINGTON: Yeah. Dr. D'Souza again, are there any differences between VER-1 and marijuana you might get for medical purposes at a dispensary?

THE WITNESS: Can I just respond to something else for the moment? And so I am the principal investigator of the largest --

MR. LONICH: Objection, Your Honor.

JUDGE JULIUS: Hold on, sir. We have an objection.

MR. LONICH: This isn't really --

THE WITNESS: It's relevant to the –

MR. LONICH: It’s not responsive to the

question, I believe it's responsive to my objection.

JUDGE JULIUS: Hold on, sir. Hold on, sir. We have an objection.

MR. LONICH: So I would object.

JUDGE JULIUS: I agree. If we could get an answer to Mr. Harrington's question and then if there's a follow-up question that he can answer. There was no real question pending, or however you would like to proceed, but he was responding to something that was not Mr. Harrington's question.

MR. HARRINGTON: Dr. D'Souza, let me withdraw the pending question and let me ask, is there anything you would like to comment based on the colloquy that I had with the Court?

MR. LONICH: No, Your Honor, objection again.

THE WITNESS: So I am the principal investigator.

JUDGE JULIUS: Hold on, hold on. Number one, we have an ambulance or something outside. I can barely hear, and we also have an objection. Pause one moment while this passes. Thank you. Mr. Lonich?

MR. LONICH: I would object to the

characterization of the colloquy with the Court. It was in response to an objection, and I understand Your Honor overruled that objection. However, we would object to the phrasing of that question. It's not directing the witness to answer anything specific.

JUDGE JULIUS: Sustained. If you'd like to formulate your question a little more open-endedly to address the topic.

MR. HARRINGTON: Dr. D'Souza, is there anything that you would like to share before I ask my next question?

MR. LONICH: Your Honor, again, I object. It's not directing the witness to anything specific, and that's calling for a narrative.

MR. HARRINGTON: I can narrow the question if you'd like, Your Honor.

JUDGE JULIUS: Thank you, Mr. Harrington.

MR. HARRINGTON: Dr. D'Souza, is there anything about your current role at the Yale School of Medicine that you would like to share before I ask my next question?

THE WITNESS: Yes. I am the principal investigator of what could be the largest federally funded study to look at cannabis

derivatives for pain. So, while I'm not an expert in pain, I am managing and leading the largest federally funded study that will compare THC, CBD, the combination of THC and CBD in chronic neuropathic pain amongst veterans. So I'm familiar with some of the methodology for clinical trials designed to investigate the effects, the safety, and efficacy of cannabinoids in pain.

BY MR. HARRINGTON:

Q And then to go back to the prior question, differences between VER-1 and medical marijuana products?

A I'm not familiar with any differences.

Q All right. Dr. D'Souza, I'd now like to ask you specifically about what does the term abuse liability mean in medicine and pharmacology?

A Did you say abuse or use liability?

Q Abuse liability.

A Abuse liability. Abuse liability refers to the concept of -- or the likelihood that a drug will be used in excess of what it was intended for. And that's a term that's used in psychiatry to assess the likelihood that someone will abuse either a prescribed drug or a street drug.

Q Based on your research and your review

of scientific literature, how would you characterize the abuse liability of botanical marijuana?

A I believe cannabis has abuse potential. I think that studies that were done looking at abuse potential of cannabis in the 60s and 70s and 80s suggested that only 1 in 10 people would get addicted to cannabis. And when I say addicted, I'm using the same criteria that the Diagnostic and Statistical Manual 5, DSM-5, uses to describe addiction to any drug, whether it's cocaine or alcohol.

It's basically first a person losing control of the use of the drug where they spend too much time, effort, money acquiring the drug, getting high on the drug, recovering from the drug, or trying to quit the drug. And that the use of the drug impacts their social, occupational, and academic life. So to that extent, more recent studies using more sophisticated epidemiological techniques have shown that 3 out of 10 people who are regular cannabis users will develop cannabis use disorder. We know that, for example, in brain imaging studies, there are biological correlates of

repeated and heavy cannabis use that we see in the endocannabinoid system and the dopamine system. We also now know that, and this was previously not recognized, that when a person who uses cannabis on a regular basis stops using cannabis, many of them may experience a withdrawal syndrome, which is characterized by disturbances in sleep, appetite, mood. And it's often a reason why people go back to using cannabis and are unsuccessful to remain quit. And so, yes, there's no question that with the available evidence that cannabis has abuse potential.

Q Earlier, Doctor, I think you mentioned that you have pending patents on two hallucinogenic substances. Is that correct?

A Correct.

Q Would you say you're generally familiar with the pharmacology of other hallucinogens besides cannabis?

A Yes.

Q In terms purely of addictiveness, how would you compare cannabis and psilocybin?

A Okay. May I just respond to something that you said earlier? I think you may have referred to marijuana as a hallucinogen, and I

just want to clarify something if I may.

Q I'll construe what you're saying as a preface to answering the pending question, if that's all right. But yes, clarify the --

A Yeah.

Q Whether marijuana is a hallucinogen in your understanding?

A Right. Among psychopharmacologists, marijuana or cannabis would not be considered a hallucinogen. I know that's how the federal government may have written it in the earlier descriptions. But whereas hallucinogens like LSD, psilocybin, mescaline and DMT reliably induce hallucinations when given acutely, cannabis does not. So, at least in my book, I don't think of cannabis as a hallucinogen. That said, at high enough doses and in certain individuals, cannabis can induce hallucinations.

But to answer your question about abuse liability, I think there's pretty compelling evidence that hallucinogens in general, the likelihood of abuse is relatively low and low in comparison to cannabis.

Q So, if you had to compare cannabis with LSD on the subject of addictiveness, what would

you say?

A I would first preface it by saying, to my knowledge, there are no direct comparisons looking at the abuse liability of LSD and cannabis that I'm aware of, but I would rate cannabis higher than LSD in terms of abuse liability.

Q And MDMA?

A Again, MDMA is not really a hallucinogen, but MDMA may be somewhere in between LSD and cannabis. There are people who use MDMA more than misuse MDMA. Yeah.

Q Doctor, could you define a narcotic?

A Oh, okay. A narcotic? I suppose there are many different definitions of it. My understanding of a narcotic would be a chemical substance or a drug that has some abuse liability. That would be one characteristic of it. Narcotics can also be, for example, sleeping pills. Sometimes that’s described under that definition. So it's quite a broad definition.

Q All right. Thank you. If you could please turn to States' Exhibit 13, let me know when you're there, Doctor.

A Yes, is that receptor availability after cannabis abstinence?

Q Yes.
A Yes.
Q Could you just summarize your conclusions from this study?
A Yeah. That was a study where we compared the numbers of cannabinoid receptors in regular cannabis users versus age and gender-matched controls, and we found that at baseline there was a 15 percent reduction in the numbers of cannabinoid receptors in cannabis users. When we asked them to abstain for 28 days, there was some recovery of this cannabinoid receptors over time.
Q Was there full recovery?
A I don't -- our study was only 28 days long, so the abstinence period was 28 days long. But in those 28 days, there wasn't complete recovery.
Q Earlier, you testified about the nature of cannabis withdrawal symptoms. Are there any psychiatric consequences during cannabis withdrawal?
A Yes, cannabis withdrawal is one of those syndromes that's somewhat variable in its expression. And what I mean by that is there are some people who experience very disturbing

withdrawal symptoms, and there are others who have a very mild withdrawal syndrome. But the withdrawal symptoms typically include disturbances in sleep, appetite, and mood. Those are the three main features. And some of those withdrawal symptoms are severe enough to force a person to go back to using -- to cannabis after they've tried to quit.

Now, there is some emerging data, I think we still need replication, from a group in the UK, suggesting that patients with schizophrenia who use cannabis, who stop using cannabis, may experience a withdrawal psychosis, and they end up back in the hospital. But that's, again, that's one study that needs replication.

MR. HARRINGTON: And Your Honor, I'm about to start one topic, and then I think we'll be ready to take a break once I conclude the next topic.

JUDGE JULIUS: Okay.

MR. HARRINGTON: Dr. D'Souza, how long have scientists been considering whether cannabis has a relationship to mental health concerns?

THE WITNESS: The earliest that I'm aware of is almost 200 years ago by the French physician,

Moreau de Tours, who published a book in French that studied people who were using hashish. And he described in exquisite detail symptoms of psychosis that occurred in these hashish users that if you showed them to a psychiatrist in today, they would say, oh yeah, this is a psychotic reaction, or this seems very schizophrenia-like. It was described almost 200 years ago by this physician, but there was a lot more work done in my country of origin, India, where when the British colonized India, they actually had a hemp commission back in the late 1800s, where they began to recognize that, “the native Indians who were using a lot of marijuana were ending up in” at that time, they were referred to as, “lunatic asylums.” And so they and they concluded that the heavy use of cannabis was sometimes associated with “mental instability.” So yeah, this is not a new observation. It's been around a long time, but it's gathering steam in part because there are converging lines of evidence that seem to support this relationship between cannabis and mental illness.

Q Dr. D'Souza, could you briefly define psychosis?

A Yeah. Psychosis refers to a break in reality, and it includes a constellation of symptoms such as delusions, paranoia, ideas of reference, hallucinations, disorganization of speech and thought. Those are the typical psychotic symptoms.

Q And schizophrenia, how would you define that?

A Schizophrenia is a psychotic disorder, and the hallmark feature of schizophrenia is the presence of psychotic symptoms. Though schizophrenia, there are many other symptoms that go along with schizophrenia. So maybe one way of explaining that would be the relationship between chest pain and a heart attack, psychotic symptoms and a psychotic disorder. And schizophrenia is a prototypical psychotic disorder.

Q What effect does schizophrenia have on a person's ability to function?

A It's perhaps the most tragic of mental illnesses because it strikes usually between the age of 15 and 25, before a person has reached their full potential, before a person can complete college, before a person can get married, before a person can own a home. And so schizophrenia

affects almost every aspect of functioning. And many of my patients have never been married, don't have families; some of them are homeless. Many of them are wards of the state and rely on the state for food and for housing. Yeah.

Q What types of scientific evidence have researchers relied upon to study the relationship between marijuana and psychosis?

A Epidemiological evidence, laboratory studies and some genetic studies. These are the main lines of evidence that seem to support the relationship between cannabis and psychosis.

Q What did your controlled laboratory studies demonstrate regarding the effects of THC that might have bearing on a connection to psychosis?

A In laboratory studies, we're able to control many of the shortcomings of epidemiological studies because we know what dose we are giving people. We can compare it to a placebo. We can measure outcomes and --

JUDGE JULIUS: Oh, hold on. I think we're getting some interference.

THE WITNESS: Yeah.

JUDGE JULIUS: Dr. D'Souza, we didn't get

your last response. Would you mind repeating your last answer? There was an internet connection issue.

THE WITNESS: Sure. Sorry. I'll repeat myself. So laboratory studies allow us to address the main shortcomings of epidemiological studies and observational studies. It allows us to do double blind randomized placebo controls, you know, studies. It allows us to measure our outcomes of interest in real time and not retrospectively. It allows us to measure those outcomes over, you know, prospectively. And it allows us to look at many outcomes of interest. In our studies, we examined the extent to which THC, the principal active constituent of cannabis, could replicate some of the symptoms associated with schizophrenia in people who are healthy. So we invited healthy volunteers who have been carefully screened for any psychiatric disorder and we administered THC versus placebo at different doses. We found that THC could induce a number of symptoms resembling the symptoms of schizophrenia, including paranoia, disorganization of thought and speech in some cases, ideas of reference, and so on and so forth.

In addition, THC disrupted memory and attention, which are well known to be impaired in schizophrenia, and THC also mimicked some of a third domain of symptoms reported in schizophrenia referred to as negative symptoms. All those findings were then reanalyzed in, I think, one of the exhibits we've already discussed, number 7, I think, the mega-analysis.

MR. HARRINGTON: Thank you, Doctor. Are you familiar with the Bradford Hill factors?

THE WITNESS: Yes.

BY MR. HARRINGTON:

Q Could you describe to the Court what they are?

A Sure. In the 1950s, doctors and the lay public were really unconvinced that smoking cigarettes caused lung cancer. So, we owe it to Sir Bradford Hill, who was a physician in the UK, who came up with a series of criteria to establish causality. And it is really the work of Sir Bradford Hill that convinced physicians and then later regulatory bodies and the public that there was a causal relationship between smoking tobacco and lung cancer.

I don't think I have time to go over all

the 10 criteria, but I could name some of them. And those include a dose response, as in the more you're exposed to that environmental factor, the greater the likelihood of that outcome. So in the case of cannabis, it would be the more cannabis a person is smoking, the greater the risk of developing psychosis, or the more potent the form of cannabis they're smoking, the greater the likelihood, that would be dose response.

Another temporal relationship would be that which came first? Did the schizophrenia come first or the cannabis come first? The lung cancer come first, and the smoking come second. So that's an important piece, and that is what we can address in laboratory settings, because in laboratory settings, we have people who are fine one minute. We give them THC in the lab, we induce these symptoms, and then by the end of the day, they're back to the normal. So we can fairly establish a temporal relationship. Some of the others include biological plausibility. I think I provided testimony early on that the endocannabinoid system plays a role in neurodevelopment. And, as you know, schizophrenia is also an illness which is which is considered by many a neurodevelopmental

illness, an illness that may be related to aberrant pruning. And I mentioned earlier how cannabis can have an impact on pruning.

There are many other criteria. I don't know if you want me to continue on those criteria, but Sir Bradford Hill's criteria were really critical in establishing the idea that smoking contributed in a causal way to the development of lung cancer.

Q Dr. D'Souza, would you say that smoking marijuana contributes in a causal way to the onset of schizophrenia or psychosis?

A Yes. I just want to point out, you know, there's some parallels between smoking and lung cancer and cannabis and psychosis, and that is that not everybody who smokes cigarettes develops lung cancer, and not everybody with lung cancer smokes cigarettes. So smoking cigarettes is neither necessary nor sufficient. But all of us would agree that smoking is clearly identified as the number one causal contributor to the development of lung cancer.

To that extent, not everybody who smokes cannabis or uses cannabis develops psychosis. Not everyone with psychosis has used cannabis. But

cannabis seems to be a contributing factor interacting with other factors, such as genetic factors, to confer a greater risk in the development of psychosis.

Q And comparing marijuana to other Schedule I substances, such as psilocybin or MDMA or LSD, how does marijuana compare with respect to as a risk factor for schizophrenia?

A So I don't think -- I certainly haven't done any studies comparing these drugs. There are some studies that most of them have come out of Scandinavia. So I think there are studies from Denmark and Finland suggesting that the risk of developing schizophrenia seems to be highest with cannabis relative to other drugs. And that's a paper I forget the first author's name, but it's published paper from Denmark.

Q And you certainly have no reason to doubt that that is a sound epidemiological conclusion, correct?

A With all the caveats that epidemiological studies have, yeah.

MR. HARRINGTON: Correct. All right. Your Honor, I think now is a good time for a break.

JUDGE JULIUS: Okay, are you thinking 15?

How long are you thinking?

MR. HARRINGTON: 10 minutes should be fine.

JUDGE JULIUS: Okay. Let's come back at let's say 4:25, just to make it a round number. I don't like coming back on weird --

MR. HARRINGTON: Yeah. Thank you.

JUDGE JULIUS: Weird times. So it'll be a little bit more than 10 minutes. Let's come back at 4:25. I'll see you back here then. During the recess, Dr. D'Souza, please don't discuss --

THE WITNESS: Yes.

JUDGE JULIUS: Your testimony or review any documents. But if you need to check those emails that may have been coming in while you were testifying, you can do that. Just don't talk to anybody about your testimony or review any documents associated with it.

THE WITNESS: And should I log off -- should I log off?

JUDGE JULIUS: No, you can stay on. We can mute you.

THE WITNESS: Okay.

JUDGE JULIUS: And you can have some privacy there as well. But we'll bring you back

at 4:25 Eastern. Thank you. We'll be in recess until then.

(Whereupon, the above-entitled matter went off the record at 4:13 p.m. and resumed at 4:25 p.m.)

JUDGE JULIUS: Dr. D'Souza, can you hear us still?

THE WITNESS: Yes --

JUDGE JULIUS: Excellent.

THE WITNESS: Your Honor.

JUDGE JULIUS: Thank you. Mr. Harrington, if you'd like to resume whenever you're ready.

MR. HARRINGTON: Dr. D'Souza, if you would please go to the document that is marked as SAM Exhibit 7. Meanwhile, I believe my colleague has copies he can provide to the government and to the Court, if that's convenient.

JUDGE JULIUS: Thank you, Counsel.

MR. HARRINGTON: Let me know when.

THE WITNESS: I'm sorry. Could you repeat that?

BY MR. HARRINGTON:

Q This is SAM Exhibit Number 7.

A Okay. Oh, okay, yes.

Q Yes. Could you turn to what's marked in the bottom right-hand corner, page 11 of 106?

A Yes.

Q And it says, Marijuana: Scientific and Data Review as it Relates to the Controlled Substances Act. Do you see that?

A Yes.

Q All right. And have you had a chance to take a look at this document and peruse it at all?

A Yes, briefly.

Q And could you please turn to page 27 of 106?

A 27, yes.

Q I'm looking at the third paragraph on this page, the one that starts with alterations of certain brain biomarkers. Do you see that?

A Yes.

Q Your work is cited in this paragraph, saying that your work has demonstrated lower hippocampal density in individuals with cannabis use disorders. You see that?

A Correct.

Q Could you just describe that research and the association of cannabis use and lower hippocampal density?

A Okay. So we have the capacity now at Yale and a number of other centers to study the number of synapses in the brain. And for those of you who are not familiar, synapses are basically the connections, the electrical junctions in the brain, and we have the capacity now to actually measure the number of receptors in the living human brain, when previously the only way to study that was to do post-mortem studies, so it wasn't possible.

This technology allowed us to study the number of synapses in the brain of cannabis users versus controls. We were specifically interested in the hippocampus because that is an area of the brain that has a very high density of cannabinoid receptors and it is memory, with which cannabis seems to have effects on. So we studied, in a very small study funded by the National Institute on Drug Abuse, we looked at the numbers of synapses in the hippocampus related in cannabis users compared to controls. We found approximately a 15 percent reduction in the numbers of synapses in the hippocampus.

Furthermore, in those same individuals, we studied their memory using paper and pencil

tests, and we found a tight correlation between the numbers of synapses or the synaptic loss in cannabis users and their impairments in memory. That study was published, I think, five years ago or so, and we are now following it up with another study to look at whether, when people stop using cannabis, whether there's recovery of the synapses.

Q And could you turn to page 56?

A 56. Yes.

Q And you see the second paragraph on this page says that per Ganesh and D'Souza in 2022, available evidence supports that marijuana causes psychosis and that the risk for conversion of psychosis to schizophrenia is highest when the psychosis is marijuana induced. Could you summarize for the Court the research that this paper is citing for that proposition?

A I'll start with the second piece of it, where the conversion of psychosis to schizophrenia is highest when the psychosis is marijuana induced. That is not my work. Just, I just want to be clear. That is work by a Finnish researcher, Niemen Pietari. And in their study, they showed that, you know, there are many drugs that can cause

psychosis, cannabis being one of them, including stimulants, such as cocaine, and also hallucinogens. But what they looked at was if someone experiences psychosis induced by these drugs, what is the rate of conversion to a chronic psychotic disorder such as schizophrenia. And it seems like it was highest for cannabis relative to the other drugs that are known to induce psychosis.

Q Thank you. Now, I want to talk now about the effects of marijuana on cognition generally. So, how does marijuana affect cognition during intoxication?

A Yeah. So, we have collected an enormous amount of data over the last almost 30 years on the effects of cannabis and cognition. We find that one of the most reliable effects of cannabis in our lab is an impairment in short-term memory and working memory acuity. Cannabis also impairs -- has effects on impairing attention and, to a lesser extent, executive function.

Going beyond that, we find that cannabis can also impair EEG or electrophysiological indices of cognition. So, we hook people up to electrodes. We place electrodes on their scalp,

and that allows us to measure their brain waves just as electrodes are placed on the chest to measure an EKG. And we are able to analyze the EEG data before they get THC, while they're getting THC, and after they get THC. And we find that THC can impair these electrophysiological indices of information processing. Information processing is just another fancy word we have talking about cognition.

Q Dr. D'Souza, could you please turn to what's marked as States' Exhibit 5? Number 5.

A 5. One second.

Q Which, I believe, is titled Dose-Related Modulation of Event-Related Potentials to Novel and --

A Yes.

Q Yes. You have it?

A Yes.

Q Could you summarize the conclusions, the findings of this study?

A Yeah. So, this was what I was just speaking about. We did a study where we collected EEG data in a double-blind, randomized, placebo-controlled crossover study where people receive placebo, a low dose of THC, and a medium dose of

THC. And then we recorded EEG while they were participating in some very simple attentional tasks, and we find that THC in a dose-dependent manner impaired attention and this and this electrophysiological index of attention. I would point you to figure 1 in this paper if you'd like to see the images. Sometimes the images speak much louder than words.

Q Is this?

A As we found --

Q This is on page 6, Doctor? Figure 1.

A Page 6 of 15. Correct.

Q Thank you. Yeah. Continue, please.

A So, if you can see there, there are two panels. The first panel is waveforms, and the waveform that we were particularly interested in was this waveform called the P 300, which is 300 milliseconds after a certain stimulus. And we're showing there the difference between the placebo on the far left, the low dose of THC in the center, and the medium dose of THC on the far right. And you can see that with each dose of THC, the separation between the blue line which is the pre-infusion or the baseline, and the green line, which is the post-infusion, which is the effect of

THC. So what this shows here is that THC in a dose-related manner is reducing this waveform, and we believe this waveform is an important biological measure of attention processing which we have shown clearly in this study in a dose-related way.

Q Can repeated marijuana use also produce longer-term cognitive consequences?

A Yes, though the data on the long-term cognitive effects of cannabis are not as clear and robust as the acute effects, there are some studies suggesting that there indeed are long-term impairments in memory and attention, and even IQ in heavy cannabis users even after they quit. And there are other studies suggesting that there are no differences or the differences are relatively small.

Q Dr. D'Souza, do you still teach students about cannabis and marijuana?

A Yes, I do.

Q And do you only teach medical students, or do you teach a wider range of students?

A I teach a wider range. Just this morning, I was invited at Yale to speak to adolescents about cannabis -- and yeah.

Q How did that go?

A I think they slept through most of the my talk.

Q Well, I'd like to talk to you about the effects of cannabis on adolescents now. So I think earlier you explained the importance of the endocannabinoid system during adolescence. Do you remember that testimony?

A Yes.

Q Why does that make adolescent marijuana exposure especially concerning?

A Because, as I mentioned, the biggest change that occurs in the brain occurs during adolescence. And this is the biological process that underlies us going from being children to adults where connections in the brain that are necessary are preserved, and connections that are unnecessary are removed or pruned. We call this -- there's this pruning process that occurs during adolescence. And we believe that -- not we believe -- there's evidence that the endocannabinoid system appears to play some role in this pruning process and the neurodevelopmental changes that are occurring during adolescence.

Adolescence is also the time when people

begin to experiment with drugs, including marijuana. And so there is concern that exposure to cannabis during adolescence is going to lead to long-term neurodevelopmental changes, some of which may contribute to the development of psychiatric disorders such as schizophrenia.

Q How does adolescent exposure relate to cannabis use disorder?

A I'm not sure I --

Q In terms of susceptibility to cannabis use disorder, does it matter what age you are?

A Yes. Clearly, the younger a person starts using cannabis, the more likely they're going to be addicted to it. That's fairly well known.

Q And your susceptibility to psychosis, does it matter what age you're first exposed?

A Yes. There is pretty good epidemiological evidence that the earlier in adolescence a person starts using cannabis, the greater their risk. And conversely, the later that they start using cannabis, the lower their risk.

Q And what about cognitive impairment? Does early exposure, adolescent exposure to

cannabis have bearing on your cognitive impairment?

A Yes. So are you referring to acute effects? So clearly, you know, cannabis impairs precisely those functions that are necessary for scholastic life acutely. But if you're talking about regular chronic cannabis use, yes, there's some evidence that the earlier that a person starts using cannabis, the greater the chances of long-term cognitive impairments in some studies.

Q What is the most widely used illicit drug by adolescents?

A I would think it's close between alcohol and cannabis.

Q If I change the question to most widely used illegal drug?

A Illegal. Oh, cannabis.

Q And Dr. D'Souza has research also examined marijuana exposure during pregnancy?

A Yes.

Q How does THC exposure in pregnancy affect the pre-born child?

A It's still a topic of fertile research. I think we still have a lot of questions, but the available evidence would suggest that exposure to

cannabis during pregnancy is associated with long-term negative consequences in children born to mothers who were using cannabis during pregnancy. Of course, this is a hard question to answer because we obviously cannot do experimental studies. And so, for example, that's where conducting animal research becomes really important in trying to answer some of these questions.

Q Do you think it's dangerous for pregnant women to take marijuana?

A Absolutely.

Q In just simple layman terms, how come?

A I think that any drug that has the potential to impact the development of the unborn child is problematic. And we know that the endocannabinoid system, you know, can be perturbed by exposure to exogenous THC. And we know that from some epidemiological studies that there are negative consequences that have been observed in children who were born to mothers who were knowingly using cannabis, including, you know, including changes in the structure of the brain on MRI studies, including on measures of cognition and also on measures of scholastic achievement

too.

Q Thank you. Mr. Phillips, can I get a read on time? How much time do I have left?

MR. PHILLIPS: 16 minutes, 20 seconds.

MR. HARRINGTON: Thank you very much. All right. Doctor, I want to harken back to that large pain study I think that you mentioned earlier, maybe in response to an objection. Can you describe this study that is looking at the effects of marijuana vis-à-vis pain?

THE WITNESS: The VER study?

BY MR. HARRINGTON:

Q No. I the one that you mentioned that you are writing.

A Yes. This is a study that will recruit approximately 300 individuals that will compare THC alone, CBD alone, the combination of THC and CBD versus placebo. This is a double-blind, randomized, placebo-controlled study with many other checks and balances in place. Our hope is that the design of the study will address many of the limitations of previous studies looking at cannabinoids and pain, both in terms of the sample size also in terms of the methodology. Yeah.

Q What is the end point of that study?

MR. LONICH: Objection, Your Honor. I don't see the relevance to this line of questioning. This study hasn't been completed yet. It's still in the early stages or still in the works, so to speak. So I just don't see the relevance of what may happen or the methodology of a study has any bearing on what we're doing here today.

JUDGE JULIUS: Mr. Harrington, do you wish to respond?

MR. HARRINGTON: Your Honor, as he was describing the nature of this study, it's to fill a gap in the existing body of clinical research, and so he's explaining why the current evidence about marijuana, as a therapeutic for the pain treatment has lacking data. He's trying to fill in that data. He's explaining the limitations of the other studies. He's trying to correct those. It seems squarely on point to marijuana's medical utility.

JUDGE JULIUS: Anything further, Mr. Lonich?

MR. LONICH: I don't believe that that's the witness's testimony. I believe that's a little bit of counsel's position. Also, we've

already established that this is one of the most studied substances, so I don't believe that this is relevant to anything that Your Honor has to consider.

JUDGE JULIUS: I will overrule the objection only to the extent that the testimony is about his looking at gaps and what he views as the shortcomings of the research.

MR. HARRINGTON: Dr. D'Souza, a moment ago you said that there are limitations, I believe that was your word, in current research --

THE WITNESS: Yes.

BY MR. HARRINGTON:

Q On marijuana and pain. Could you describe what those limitations are?

A Sure. At the time that we conceived the design of the study that's ongoing, we reviewed the literature very carefully and we concluded that there were a number of limitations to the existing literature, including: Number one, the sample sizes of most of the studies were quite small, usually 20 to 50 subjects, which is really not adequate. The second was many of the studies did not adequately blind -- were not adequately blinded, both the subjects and the study staff.

Third, that the studies relied exclusively on subjective outcomes and not more objective outcomes. Fourth, the studies did not take into account the previous exposure to cannabis in the participants of that study.

Q In your --

A The --

Q Oh, I'm sorry. Please finish your answer.

A No. Those are some of the limitations.

Q In your expert opinion, is there currently available today enough clinical evidence about marijuana's effects with respect to pain to demonstrate whether it has an accepted medical use?

MR. LONICH: Objection, Your Honor.

THE WITNESS: I don't believe so, but --

JUDGE JULIUS: Hold on, Dr. D'Souza, we have an objection. What's the objection?

MR. LONICH: I was going to renew the objection that this witness is not an expert in pain management. And I also believe it's close to the ultimate question, the ultimate issue here that Your Honor has to consider. So they can present whatever studies they want, but to ask

that question, that's inappropriate.

JUDGE JULIUS: I understood the second part of the objection. I mean, ultimately, whether there's enough is what the Court has to determine, but he has -- what is your response? Sorry for thinking out loud. Mr. Harrington, what's your response to the first part of the objection that it's not part of his expertise?

MR. HARRINGTON: He was tendered as a expert, I think you made him a provisional expert on marijuana's effects on the brain and body, and this would be part of the brain and body. And if I could answer with respect to the second part of the objection, I believe the limitation about testifying to the ultimate issue pertains only to, like, mental state in criminal proceedings. It certainly, I don't believe, would apply in civil proceedings or administrative proceedings. He would only be testifying in his capacity as an expert.

JUDGE JULIUS: Understood. I'll go ahead and overrule the objection. He can testify as to what his opinion is. Ultimately, it's not binding on the Court who has to make the ultimate decision, but I will hear what he has to say. And then we

did provisionally accept him as an expert on marijuana's effect on the brain and body, so with that provisional expertise I will go ahead and overrule the objection.

MR. HARRINGTON: Thank you. Dr. D'Souza?

THE WITNESS: Sorry, I --

BY MR. HARRINGTON:

Q Would you like me to -- allow me to repeat the question. Is there currently available today enough clinical evidence examining marijuana's effects with respect to pain to determine whether it has an accepted medical use?

A I'll restrict my comments to psychiatric conditions and pain. I think my review paper in JAMA from a few months ago concluded, and it was consistent with the similar paper in The Lancet Psychiatry that at least for psychiatric indications, right now we don't have enough evidence to support the efficacy of cannabis or cannabis products in the treatment of psychiatric disorders, and that's offset by well-known risks associated with the use of cannabis.

In terms of pain, the International Association for the Study of Pain, which I believe really has the necessary experts in pain research,

their consensus statement was that they did not recommend cannabis or cannabinoids for the treatment of pain. I don't know if there's a revised consensus statement, but the last one that I read, that was their conclusion. The reason we are doing this study right now is to really address many of those limitations.

I failed to mention that I did a similar laboratory study looking at the effects of THC on pain, double-blind, randomized, placebo-controlled study where we invited healthy individuals. And yes, we inflicted five different kinds of pain. Chemical pain using something called capsaicin, which is the principal active constituent of chili peppers that's well known to induce pain. Mechanical pain, cold pain, thermal pain. And we found that there was really no effect of THC on any of those acute pain outcomes in healthy individuals. So the VER study, while promising, is one study. I think generally we need a body of evidence, and I don't think we've met that threshold as yet.

Q Earlier, Doctor, you mentioned that psychiatric conditions can offset potential therapeutic benefits. Have I restated that?

A I said that there's very limited evidence to support the efficacy of cannabinoids for psychiatric indications, and in the balance, there is a growing body of evidence of psychiatric harms associated with cannabis.

Q And you --

A And so the risk-benefit is not favorable for psychiatric conditions.

Q So in determining whether there's a medical use, is it appropriate to look at risk and benefit?

A Yes.

Q And so when evaluating the benefits of a potential substance, would it be appropriate to take into account psychiatric risks?

A Absolutely.

Q Is the evidence for psychiatric risks with marijuana less strong, equivalently strong, or stronger than the evidence for benefits of marijuana?

A I think it's stronger at the present time.

Q What does it mean for a substance to have an accepted use as a medicine to you?

A As a physician, for me it would be that

there are clear benefits, and those benefits outweigh the risks.

Q And at this time, do you think the benefits of marijuana outweigh the risks?

A No.

Q Dr. D'Souza, would you please turn with me to tab 18, Exhibit 18?

A Yes.

Q And this, I believe, is Cannabis in Psychiatric Disorders: Cart Before the Horse?

A Correct.

Q Could you please turn to page 2 of this exhibit? The very top column starts with the word sixth.

A Yes.

Q Could you either read the first two sentences of that paragraph or summarize the point you're making in your own words?

A Sure. Sixth, since cannabinoids have been proposed for use in psychiatric conditions, many of which are chronic, this will necessitate long-term dosing. The cannabinoid system is highly adaptive. Chronic exposure to cannabinoids leads to the development of tolerance and dependence, as evidenced by downregulation of

brain cannabinoid receptors, as well as withdrawal upon discontinuation. These factors will need to be accounted for when considering these compounds as long-term treatments for chronic psychiatric disorders.

Q Dr. D'Souza, should those factors also be accounted for in considering cannabinoids or cannabis as a long-term treatment for other chronic conditions?

A Yes, I suppose you can extrapolate from this.

Q So, if someone were to seek marijuana as a therapeutic drug for a chronic condition, in the cost-benefit analysis, they would also have to weigh the chronic risks from a psychiatric perspective as well?

A Correct.

Q I see. Doctor, are you familiar with state medical marijuana programs?

A Yes.

Q And are state medical marijuana programs designed to answer questions about efficacy or safety?

A No.

Q Does the fact that many patients receive

marijuana through state programs establish that marijuana is medically effective?

A No.

Q How many states authorize marijuana for numerous and unrelated medical conditions?

A I can't speak about other states, but I've served on the Physicians Advisory Board for the State of Connecticut's Medical Marijuana Program since its inception in 2013. And I think right now there are about 60 conditions for which marijuana is approved by the State of Connecticut's Medical Marijuana Program.

Q How do those --

A And that --

Q I'm sorry. Forgive me.

A And that may be growing.

Q How do the different approved indications relate to each other in terms of mechanism of action?

A So for me as a clinician scientist, that seems to be one of the biggest challenges to get my head around because to me, there's nothing -- there's no obvious common pathophysiology to conditions as diverse as sickle cell disease, psoriasis, ulcerative colitis, PTSD and so on and

so forth. There's no common pathophysiology that would explain why one product should be beneficial for all these 60 conditions.

Q Dr. D'Souza, is dosing an important consideration in the assessment of whether a drug has an accepted medical use?

A Absolutely.

Q Is there a standard dose for marijuana?

A No, and that's one of the challenges I think that I would face as a physician and as a clinician. For most drugs that I prescribe, when the drug is released, there's clear guidance based on the research on the clinical trials about what an appropriate dose is, how frequently it should be administered, and for how long. I don't think we have that kind of information as yet for any of the conditions for which medical marijuana has been approved.

Q Are you familiar with any practice of dispensing a controlled substance to a patient in which the healthcare provider allows the patient to determine their own dose?

A I suppose there are some instances, but I would say that in those instances, there would be widely available data to guide dosing that a

clinician could rely on. Or, it could be the case that someone has been taking that drug for a significant period of time where the clinician and the patient have established what's safe and what's effective. But I don't think that's the case as yet with cannabis.

Q With respect, though, to a dangerous and controlled drug, are you familiar with any instance in which dosing is ultimately determined by the patient?

A I would say when it involves drugs that have abuse liability, physicians would be much more conservative in what freedom they would give patients to arrive at a dose.

Q For drugs that have that abuse potential, have you ever advised a patient to self-titrate such a medication?

A No.

Q When patients receive a recommendation for marijuana, let's limit this just to the State of Connecticut, which I think you have probably more familiarity. How much marijuana are they allowed to obtain on the basis of one recommendation?

A I believe it's a substantial amount. I

don't know the exact amount, but it's substantial.

Q How would it compare to, say, opioids?

A I think opioids are generally much more controlled.

Q With respect to marijuana, if I'm approved in Connecticut to use marijuana, do you know how many days, weeks, or months of supply that I can obtain at once?

MR. LONICH: Objection, Your Honor.

THE WITNESS: I think I lost you for a few --

JUDGE JULIUS: Yeah.

THE WITNESS: For a -- July 15, 2026

MR. HARRINGTON: It worked out because there's an objection anyway, so.

JUDGE JULIUS: Yes. Hold on, sir. Mr. Lonich.

MR. LONICH: I believe this has already been asked and answered, and also the witness doesn't -- he hasn't testified that he's ever recommended marijuana. He's never worked in a dispensary. I don't think he has the foundation to answer that question. And also, he's already established that he's not sure how it works. I mean, his answer was a substantial amount. We're

asking the same question again, so.

JUDGE JULIUS: To the extent that it's based on asking the same question, I would allow it to be asked. If he changes his answer that becomes a different problem. But do you have a response to the lack of foundation?

MR. HARRINGTON: Well, I just think that --

JUDGE JULIUS: Objection?

MR. HARRINGTON: If the witness doesn't know the answer to this question, then he can explain that to me, but I just wanted to see if I could narrow or clarify what he meant by a substantial amount and put more detail to that.

JUDGE JULIUS: I'll allow that question.

MR. HARRINGTON: All right. Dr. D'Souza, before the feed broke, the question I'd asked you was, do you know how much of a supply of marijuana a patient could obtain on the basis of a recommendation, whether in days, weeks, or months?

THE WITNESS: So I don't know the precise amount.

BY MR. HARRINGTON:

Q I see. All right.

A But it's a substantial amount, yeah.

MR. HARRINGTON: Okay. All right. I think I have no further questions, Your Honor.

JUDGE JULIUS: Okay. Thank you very much, Mr. Harrington. Dr. D'Souza, thank you very much. We're a little bit past our normal 5:00 ending time. I don't want to press the government. I assume you will have some cross that you want to do tomorrow, or no?

MR. LONICH: We will, Your Honor. I'm prepared to go now if we want to push through, but if not, we can wait until tomorrow.

JUDGE JULIUS: No, I'm not keeping us here past --

MR. LONICH: That's fine.

JUDGE JULIUS: When I promised people I would let them go. So, Dr. D'Souza, thank you so much for your testimony this afternoon. We'll start with you first thing tomorrow morning at 9:00. Please don't discuss your testimony with anyone overnight or review any additional documents or anything. We just want to get the testimony from you, and we will see you tomorrow morning at 9:00.

DR. D'SOUZA: Thank you.

JUDGE JULIUS: Thank you. Any other

procedural matters before we adjourn today?

MR. LONICH: Nothing on the government's honor.

MR. HARRINGTON: Nothing from SAM or the States, Your Honor.

JUDGE JULIUS: Thank you, all. We will be in recess until tomorrow at 9:00 a.m., our last day on the schedule. Thank you, everyone. We'll be in recess.

(Whereupon, the above-entitled matter went off the record at 5:02 p.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