UNITED STATES DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION

Hearing

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

Monday,
July 6, 2026

700 Army Navy Drive
Arlington, Virginia

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.
DAVID C. MALEY, ESQ.
KAYLA L. KREINHEDER, ESQ
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[redacted]

On Behalf of the National Drug and Alcohol Screening Association:

DAVID G. EVANS, ESQ.
[redacted]

On Behalf of Smart Approaches to Marijuana:

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

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

JOHN M. MCNICHOLS, ESQ.
T. ZACHARY HORTON, ESQ.
Torridon Law PLLC
[redacted]

On Behalf of DUID Victim Voices:

DAVID G. EVANS, ESQ.

[redacted]

On Behalf of Kenneth Finn, M.D.:

DAVID G. EVANS, ESQ.

[redacted]

ALSO PRESENT:

GRAYSON E. PHILLIPS, ESQ., Law Clerk
LUKE NIFORATOS, Executive Vice President of Smart Approaches to Marijuana (SAM)
DECLAN HURLEY, Torridon Law summer associate

C-O-N-T-E-N-T-S

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

9:02 a.m.

JUDGE JULIUS: We are on the record. Today is July 6, 2026. This is day 5 in the matter of Schedules of Controlled Substances, Proposed Rescheduling of Marijuana. DEA docket No. 1362, hearing docket 26-96. I hope everyone had a happy and safe Independence Day holiday. We are back in this case.

First things first, I will do procedural matters, statement of representation of who is in the courtroom today. Government Counsel, will you please state your appearances for today's hearing?

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

JUDGE JULIUS: Welcome, Counsel. And for Smart Approaches to Marijuana?

MR. McNICHOLS: Morning, Your Honor. John McNichols, Chase Harrington, and Luke Niforatos on behalf of Smart Approaches to Marijuana, accompanied by Declan Hurley of my law firm.

JUDGE JULIUS: Welcome, Counsel. And

on behalf of the Opposed States?

MR. McNICHOLS: John McNichols, Chase Harrington, and Zach Horton on behalf of the Opposed States.

JUDGE JULIUS: Thank you very much, Mr. McNichols. Do we have anybody here on behalf of Dr. Kenneth Finn, MD? No. DUID Victim Voices or National Drug and Alcohol Screening Association? I don't see Mr. Evans or Mr. Keneally present currently. So as of now, Dr. Kenneth Finn, MD, DUID Victim Voices, and National Drug and Alcohol Screening Association, although they indicated that they would be present today, are not currently present. We also have Dr. Phillip Drum who I believe has only noticed his intention to appear on his day of case in chief.

So, as far as parties that are represented today, we have the government, Smart Approaches to Marijuana, and the Opposed States. We are running ahead of schedule. We are set to start with opening statements from Smart Approaches to Marijuana. I don't know, I believe one of your witnesses required a subpoena. If we get to that witness, I don't

know, because that, I think, was scheduled to happen tomorrow, if you're prepared to do that today.

MR. McNICHOLS: Yeah, the other witness, Dr. Akinfiresoye, is scheduled to appear tomorrow. I think it's probably better to take her tomorrow than today simply because that's her day of appearance, and I suspect we'll take up most of the day with Dr. Madras anyway, Your Honor.

JUDGE JULIUS: Okay. Sounds good. Just trying to get a foreshadowing of what we'll get to today just for expectation management. Any other preliminary matters before we start with SAM's case in chief?

MR. McNICHOLS: There is one, Your Honor. In order to help with our opening statement, we'd ask to move into evidence SAM Exhibits 6, 8, 9, and 10. I've asked the government whether they have any objection to that, and Mr. Lonich has courteously informed me that they do not.

(Whereupon, the documents referred to were marked as SAM’s Exhibit Nos. 6, 8, 9, and 10 for identification.)

JUDGE JULIUS: Can you just confirm that for the record?

MR. LONICH: Yep, that's correct, Your Honor.

JUDGE JULIUS: Excellent. We will go ahead and admit it. Was that 6, 8, 9, and 10?

MR. McNICHOLS: That's correct.

JUDGE JULIUS: Okay.

MR. McNICHOLS: SAM Exhibit 6, 8, 9, and 10.

JUDGE JULIUS: SAM Exhibit 6, 8, 9, and 10 will be admitted without objection.

(Whereupon, the above-referred to documents marked as SAM’s Exhibit Nos. 6, 8, 9, and 10 were received into evidence.)

JUDGE JULIUS: Mr. McNichols, any other preliminary matters?

MR. McNICHOLS: No, Your Honor.

JUDGE JULIUS: Okay. Opening statement whenever you're ready, sir.

MR. McNICHOLS: Thank you. We have a PowerPoint that will accompany this, if we could pull up to the first page, please. And is this on display for Judge Julius, and could we get it for the courtroom as well?

MR. PHILLIPS Do you want it on your screen or --

JUDGE JULIUS: That's fine on the main screen.

(PowerPoint presentation displayed on main screen.)

MR. McNICHOLS: Thank you. All right. Your Honor, we've seen this movie before. This is the fourth time since 2000 that DEA has considered whether to move marijuana out of Schedule I into some latter category under the Controlled Substances Act. And every time, up until now, HHS and the FDA and DEA have all said that it should not move out of Schedule I because it has no currently accepted medical use and because it carries a high risk of abuse.

The only thing we submit to Your Honor that should justify a different outcome this time is if there were new and different data. In other words, clinical data showing that marijuana actually works for the indications for which it's offered and that its effects on society are not as bad as we previously had thought. We do not have that data and on the clinical evidence, there clearly is more data

than there was 11 years ago when HHS last considered this, but the data looks exactly the same as it did before. To grasp that, all we have to do is look at what HHS put into the memorandum that's been submitted to Your Honor now as ALJ Exhibit 1. Page 27, as to the pain indication, University of Florida concluded, and this is a quote, "That the results of marijuana as a treatment for that indication were inconclusive or mixed." As to the anorexia indication, this is a quote, page 27, "FDA review of systematic reviews showed mixed results." As to the nausea indication, "FDA review of systematic reviews showed mixed results."

That's how the data looked in 2015 too, and as Dr. Chiapperino testified, those data and the results of those studies would not have justified a finding of a currently accepted medical use under the test that FDA and HHS and DEA used in 2015, which is the only test that those entities had ever used up until this case. If you don't have stronger data, then how do you get to a different result? Well, we know. You change the test.

They used a new test that didn't exist when they started the process of scientific and medical review, and which they'd never used before. Under that test, to justify a currently accepted medical use, you only need some, that's a quote, “some credible scientific evidence to support it.” Now, what does that mean in practice? Well, now we know, and this was just an astonishing admission during Dr. Chiapperino's testimony, page 376 of the transcript or page 33 of day 2, lines 12 to 15. In describing his methodology to my colleague, Mr. Keneally, on cross-examination, what he said was, There might only be a couple of studies. If one was positive and one was not, we would still consider the results of the first study. That's the quote we have on the slide here. Now, that might be a lot of things, but that is not science.

Science is about considering all the evidence and not about considering only the results that point in a particular direction. Yet by their admission, that's what they did in applying this test. It's not science, but that's what they did, by their own account.

Now, on the question of marijuana's potential for abuse, is the data on that issue now more favorable than it was in 2015 when we were here the last time? The answer to that again is no.

As we pointed out in cross-examination of Dr. Chiapperino, the number of Americans who are using marijuana recreationally, which is to say to get high, has gone up. The number of Americans who go to the emergency room because of marijuana has gone up, and the number of Americans who are hospitalized because of marijuana disorder has gone up. So, how do they get to a different outcome here? Well, they brought in a whole new set of comparator substances, which they say show that by comparison, marijuana is not that bad. Of course, I'm talking about heroin, cocaine, oxycodone, and fentanyl, all of which were used as comparators to marijuana in the HHS memorandum. And this is what they say at page 64 of ALJ Exhibit 1, that in terms of the ranking order of severe harms, such as overdose, death, poison center calls, things like that, marijuana has a lower, “propensity for serious outcomes.” Now, we've seen this movie before,

too. Back in 2015, the petitioners in that proceeding had the same idea. They said, look at how marijuana compares to the Schedule II substances, like cocaine and oxycodone, in terms of its effects. And HHS rejected that idea in that proceeding, and this is the quote from the HHS analysis in 2015, which has previously been admitted as SAM Exhibit 11, page 8. "The mechanism of actions of the above Schedule II substances, that's cocaine and oxycodone, are wholly different from one and other, and they're different from THC and marijuana as well. And then the conclusion of that paragraph, these differing mechanisms of action result in vastly different behavioral and adverse effect profiles, making comparisons across the range of pharmacologically diverse Schedule II substances inappropriate.

Now, if there is any reason why that same principle doesn't apply here and now, the government has not provided it. There is simply no justification for picking a grab bag of pharmacologically dissimilar substances, which happen to be the deadliest ones, and then put them up against marijuana and say, grade it on a

curve. Marijuana's not so bad. When they otherwise have no pharmacological or physiological similarities in the way they affect the body.

The other thing they did to get to a different outcome this time from the one they had last time is to disregard all of the non-fatal health effects that they focused on in the 2015 recommendation, things like psychosis; I know Your Honor has heard a lot about that so far. This was a huge component of HHS analysis in 2015. Here is -- and obviously -- I don't expect Your Honor to read these pages here. I put it up here merely to illustrate the fact that they went on for two pages to discuss the association of marijuana use with psychosis. That was a key part of their analysis of the adverse effects and of the public health effects of this drug. There is no such section, no analogous section in the HHS recommendation that gives rise to this proceeding here. They simply omitted it, and that's the case even though, as of today, the link between marijuana use and mental health effects is stronger than it was in 2015. Can we take a look at the next slide,

please?

This is from the 2026 National Drug Control Strategy document, which we've just admitted, SAM Exhibit 10, page 52. It says that one study found over 30 percent of patients with a substance-induced psychosis later developed bipolar or schizophrenia spectrum disorders, and nearly half of those with cannabis-induced psychosis developed bipolar disorder or schizophrenia. Additionally, convergent evidence from multiple sources suggests that cannabis exposure increases the risk of psychosis and that prevention of marijuana use could serve to reduce the prevalence of psychosis in addition to reducing cannabis use disorder and other consequences.

Now, how does marijuana compare to other substances in terms of its mental health effects? Again, don't take my word for it. We have another quote here from SAM Exhibit 10, which is the 2026 National Drug Control Strategy document. On this point here, it's the second quote that I think is really critical there, where it says, “while all drugs carry some level of risk, marijuana has the highest conversion

rate from psychosis to schizophrenia and bipolar disorder." It's the worst, in other words and yet, HHS didn't focus on that, didn't mention it in its recommendation, simply bypassed it.

Now, in order to help us understand what the HHS analysis should have looked like, we've got two witnesses today -- or one today and one tomorrow. They're both women, they're both scientists, they're both PhDs, and then the real critical issue, they've both been experts for the DEA on the very subject that's at issue here, which is to say marijuana and its appropriate scheduling.

The first one is Dr. Bertha Madras, who we're going to hear from in a few minutes. She's a professor of psychobiology at Harvard and an expert in addiction. She's been on the staff of the president twice, first under President Bush II and then under President Trump. She was the expert for the Drug Enforcement Administration in 2014 in a criminal case where the defendant challenged marijuana scheduling in Schedule I. She was the government's only expert in that case, and in that case, the United States won.

The second expert, who will appear tomorrow, is Dr. Luli Akinfiresoye. She's a current employee of the DEA. She works in the Drug and Chemical Evaluation Section. She was the expert for DEA in hearing 2444 just 18 months ago, since canceled, but was their expert in this same marijuana rescheduling proceeding, where she submitted an eight-factor analysis that we'll discuss with her tomorrow, which is virtually the mirror image of the one that HHS did. In the studies that she cites in her eight-factor analysis, it says there is no medical use for this drug, that it does not reduce pain, that it does not help you get off opioids, and that it is linked to psychosis and schizophrenia. The studies that she cites in her report, again, were studies done after the last time. They're very recent. They're done after the last time the DEA considered the same question. So, everything in her report cuts against what the DEA is trying to do now as the proponent of this rescheduling rule, which is why they didn't call her as a witness and why we thought that we should because her testimony and her opinions, I think, will help, Your Honor,

with the appropriate outcome in this case. Thank you.

MR. LONICH: Just for the record, Your Honor, that last comment was verging into argument, and it's not highlighting the case.

JUDGE JULIUS: Understood. It was an opening statement, and I think argument is okay in that one. It's not evidence, but --

MR. McNICHOLS: Right.

JUDGE JULIUS: Understood.

MR. McNICHOLS: Unless the Court has questions, we can call our first witness.

JUDGE JULIUS: Yeah, feel free to call Dr. Madras.

MR. McNICHOLS: Thanks. Smart Approaches to Marijuana calls Dr. Bertha Madras as a witness.

JUDGE JULIUS: Good morning, ma'am.

THE WITNESS: Good morning.

Dr. BERTHA K. MADRAS, having been first duly sworn, testified as follows:

JUDGE JULIUS: Yes, up here at the witness stand and before you're seated, if I could swear you in.

THE WITNESS: Yes.

(The witness is sworn.)

JUDGE JULIUS: Please raise your right hand if you're able. Do you swear or affirm that everything you say in these proceedings will be the truth, the whole truth, and nothing but the truth?

THE WITNESS: Yes, I do.

JUDGE JULIUS: Thank you. You may be seated.

THE WITNESS: Thank you.

JUDGE JULIUS: Before Mr. McNichols begins his direct examination, I just want to give you some quick instructions about the process of testifying for clarity of the record.

THE WITNESS: Thank you.

JUDGE JULIUS: Please wait until the entire question is asked before you begin your answer. Before beginning your answer, pause for a moment to see if the question draws an objection. If you hear the word objection, just sit tight. I'll address the objection, and then I'll tell you if you can answer the question or not. If at that point you need to ask for repetition of the question, you may do so. If at any time you receive a question that you

don't understand, please say that you don't understand the question before you try to answer it. If you answer a question, we will assume that you understood the question. Okay?

THE WITNESS: Thank you.

JUDGE JULIUS: Thank –

THE WITNESS: Very clear.

JUDGE JULIUS: Thank you very much. Mr. McNichols, your witness whenever you're ready.

DIRECT EXAMINATION

MR. McNICHOLS: Thank you. Ma'am, could you please state your full name for the record?

THE WITNESS: My name is Bertha Madras.

BY MR. McNICHOLS:

Q What do you do for a living, Dr. Madras?

A I am currently a professor of psychobiology in the Department of Psychiatry at Harvard Medical School. My office is at McLean Hospital with a cross-appointment at the Massachusetts General Hospital.

Q How long have you been at Harvard Medical School, ma'am?

A 40 years.

Q As a professor and academic at Harvard Medical School, what is your main area of focus in your research?

A My main area of focus is studying the effects of drugs on the brain, primarily addictive drugs and also therapeutic drugs.

Q Can you give us some examples of the kinds of addictive and therapeutic drugs that you have researched in your career, ma'am?

A I have researched cocaine, methamphetamine, MDMA or ecstasy, opioids, the psychoactive component of marijuana, THC, cannabidiol, and other cannabinoids. I've also investigated the targets of antipsychotic and antidepressant and antihyperactivity drugs in the brain.

Q Where were you educated, Dr. Madras?

A I was educated at McGill University, both my bachelor's and my PhD.

Q And when did you obtain your PhD?

A In 1967 -- I'm 100 years old.

(Laughter.)

Q You're under oath, ma'am. I have to remind you. After you obtained your PhD from

McGill in 1967, did you later go on and do additional academic study or fellowships?

A I did postdoctoral research at Tufts University, and then my mentor became the chair of the Department of Biochemistry at Cornell Medical College. He asked me to follow him there. Thereafter, I did postdoctoral research at MIT and then was a research associate at MIT.

Q Now, in addition to your work at Harvard as an academic, have you also held positions in government?

A Yes. I have been appointed twice by two presidents. The first was President George Bush, who appointed me as Deputy Director for Demand Reduction in the White House Office of National Drug Control Policy. It was a Senate-confirmed position. My second presidential appointment was President Trump appointed me to one of six commissioners on the Opioid Commission, or its full title is Combating Drug Addiction and the Opioid Crisis.

Q When did you hold the latter position, Dr. Madras?

A In 2017.

Q And in the course of your career, have

you designed medications?

A I have designed and co-designed with a medicinal chemist collaborator over 600 medications.

Q Can you give us an example of one of the medications that you have designed or co-designed?

A Well, one of them was an improvement over cocaine. The goal was to try to identify medications to treat psychostimulant abuse, especially cocaine. In that case, we discovered that it also may be a very effective imaging agent for the brain, and we converted it into an imaging agent, which became widely used for that purpose.

Q Radioactive cocaine?

A Radioactive analog of cocaine. Much more potent, much more selective than cocaine.

Q And do you have scientific publications as well, Dr. Madras?

A I have over 200 scientific publications. The majority are peer-reviewed. Some are essays, some are editorials, some are commentaries. I have book chapters, and if I include abstracts for scientific meetings, it

would number over 400.

Q And to go back to your phrase, Dr. Madras, what does peer-reviewed mean in the context of your publications here?

A Peer-reviewed means when you write a rigorous scientific manuscript, it is reviewed by people who are experts in the field who decide whether or not it's worthy of publication.

Q Could you please turn to tab 5 of the binder of exhibits we've put in front of you there, ma'am? And let me know when you're there.

A I am there, sir.

Q Okay. And do you recognize the document at tab 5?

A Yes.

Q What is it, ma'am?

A It's my curriculum vitae.

MR. McNICHOLS: All right. At this point, Your Honor, we'd move into evidence SAM Exhibit 5, which is the curriculum vitae of Dr. Bertha Madras.

(Whereupon, the document referred to was marked as SAM’s Exhibit No. 5, for

identification.)

JUDGE JULIUS: Any objection?

MR. LONICH: No objection, Your Honor.

JUDGE JULIUS: SAM Exhibit 5 will be admitted.

(Whereupon, the above-referred to document marked as SAM's Exhibit No. 5 was received into evidence.)

MR. McNICHOLS: Thank you. Now, have you previously given expert testimony on marijuana and its effects?

THE WITNESS: I have given expert testimony in a number of venues. Probably the most significant one was in the Schwettder v. the Department of Justice case in the Eastern District of California, a federal court. The case was based on the desire of the defendants to reschedule marijuana from Schedule I to Schedule III. I was the sole expert witness for the Department of Justice in that case.

BY MR. McNICHOLS:

Q Can you turn to tab 1 in that binder, which I think is marked as SAM Exhibit 1, please?

A I am there.

Q And do you recognize the document at tab 1 or SAM Exhibit 1?

A Yes. That was the declaration I wrote.

Q For which case, ma'am?

A For Schwe~~tt~~der v. the United States of America, yes.

Q The same case you're talking about?

A Yes, except on the opposite side.

MR. McNICHOLS: All right. At this point, Your Honor, we move into evidence SAM Exhibit 1, which is Dr. Madras' declaration in the Schwetter matter.

(Whereupon, the document referred to was marked as SAM's Exhibit No. 1, for identification.)

JUDGE JULIUS: Any objection?

MR. MALEY ~~LONICH~~: Yes, Your Honor. The Government will object to this exhibit on several bases, the first of which is relevance. This is testimony from an entirely different proceeding and in an entirely different context. This case that they are referencing is not an administrative hearing such as the one today. This is also a 2014 declaration, which predates HHS's recommendation by nearly a decade. The

declaration also ostensibly includes legal conclusions, which would be improper testimony for this tribunal. I would reference paragraph 35 of the declaration, which states, Marijuana continues to meet the criteria for Schedule I under the Controlled Substances Act.

A bit of a prospective objection, the Government would contend that this doesn't speak to the offered expertise which was laid out by Smart Approaches to Marijuana in their pre-hearing statement or in counsel's opening statement that Dr. Madras is an expert on addiction.

JUDGE JULIUS: Thank you, Counsel.

MR. MALEY ~~LONICH~~: That would be it, Your Honor.

JUDGE JULIUS: Any response to the objections, Mr. McNichols?

MR. McNICHOLS: Yeah. We haven't yet tendered Dr. Madras as an expert to the court. We don't expect to put the statements in this in front of Your Honor for their factual content. We're simply providing it as background to help establish that, in fact, she is an expert on marijuana, if for no other reason than she's

been designated an expert as such, in previous proceedings.

MR. MALEY ~~LONICH~~: And if I could be heard once more on that issue.

JUDGE JULIUS: Sure.

MR. MALEY ~~LONICH~~: The pre-hearing statement submitted by Smart Approaches to Marijuana specified explicitly that she is an expert in the science of addiction and the effects of addictive substances on the brain. Nowhere in that pre-hearing statement does it state that she is an expert on marijuana.

JUDGE JULIUS: Understood. I'm going to admit SAM Exhibit 1. Certainly, the weight with regard to context can be made --

MR. MALEY ~~LONICH~~: Understood.

JUDGE JULIUS: By the government. It's being offered simply to show that she has given expert testimony on behalf of the government in the past. I'll go ahead and admit it, but it goes to weight.

(Whereupon, the above-referred to document marked as SAM's Exhibit No. 1 was received into evidence.)

MR. MALEY ~~LONICH~~: Understood. Thank you.

JUDGE JULIUS: Continue, Mr. McNichols.

MR. McNICHOLS: Dr. Madras, have you also lectured on the medical uses of marijuana as well?

THE WITNESS: Yes. As a preface to that response, I was commissioned by the World Health Organization to write a monograph on the update on cannabis and its medical uses, in which I summarized all the current literature on marijuana with regard to its medical uses and also gave testimony at the expert witness conference in Geneva, Switzerland on it.

I have also lectured in numerous venues in the United States. I've given testimony at the state level in a number of states, including New York, Vermont, New Hampshire, Maryland, Florida, Alabama, and others.

BY MR. McNICHOLS:

Q And were those lectures on the medical uses of marijuana?

A Yes.

Q Okay. Could you please turn in the binder you have to SAM Exhibit 4, please? Tab 4.

A It is here.

Q Okay. And is that the monograph you were speaking about a moment ago?

A Yes, precisely.

Q Okay. And what's the title of it, ma'am?

A Update of Cannabis and Its Medical Use.

MR. McNICHOLS: Okay, we move the admission of SAM Exhibit 4, Your Honor.

(Whereupon, the document referred to was marked as SAM's Exhibit No. 4, for identification.)

JUDGE JULIUS: Any objection?

MR. MALEY ~~LONICH~~: No objection, Your Honor.

JUDGE JULIUS: SAM Exhibit 4 will be admitted.

(Whereupon, the above-referred to document marked as SAM's Exhibit No. 4 was received into evidence.)

MR. McNICHOLS: Thank you. And did you prepare a report on cannabis and its medical uses for the U.S. Senate Committee on the Judiciary?

THE WITNESS: Yes.

BY MR. McNICHOLS:

Q You did. Can you please turn to tab 2

in the binder that you have, ma'am?

MR. MALEY ~~LONICH~~: Your Honor, if the government could just be heard on a procedural question, it appears that the binder has been placed in front of the doctor and is not being passed exhibit by exhibit from the clerk. Is there any reason for us not to adhere to that methodology?

JUDGE JULIUS: I think it's just for administrative convenience.

THE WITNESS: It's convenient.

JUDGE JULIUS: Ma'am, just don't look at any document until instructed to do so. I understand that the full binder of exhibits is there, I think it was just for procedural convenience.

MR. MALEY ~~LONICH~~: Understood.

JUDGE JULIUS: Thank you, Counsel. Just to make the record clear.

MR. McNICHOLS: Thank you.

JUDGE JULIUS: Please continue, Mr. McNichols.

MR. McNICHOLS: Of course. Do you recognize the document at exhibit -- excuse me, at tab 2 of the binder?

THE WITNESS: Yes, I do, sir.

BY MR. McNICHOLS:

Q And what is that document, ma'am?

A It is a document titled Cannabis and Medicinal Properties. It was included on the record of hearing before the Crime and Terrorism Subcommittee of the U.S. Senate Committee on the Judiciary, and it was filed for July 13, 2016.

Q And who prepared it, ma'am?

A I prepared it.

MR. McNICHOLS: All right. We move the admission of SAM Exhibit 2, Your Honor.

(Whereupon, the document referred to was marked as SAM's Exhibit No. 2, for identification.)

JUDGE JULIUS: Any objection?

MR. MALEY ~~LONICH~~: No objection.

JUDGE JULIUS: SAM Exhibit 2 will be admitted.

(Whereupon, the above-referred to document marked as SAM's Exhibit No. 2 was received into evidence.)

MR. McNICHOLS: Thank you. And in the course of your career at Harvard, have you developed courses on addiction, Dr. Madras?

THE WITNESS: Yes. I was charged by the Dean of Harvard Medical School to develop the first course on addiction and addiction biology for fourth-year Harvard Medical School students that was ever offered. It was an elective course, and the number of students grew rapidly because they said it was a dreadful void in their education. I've also developed a Cold Spring Harbor course on addiction biology in 2000, which runs to this day, although I no longer direct the course.

BY MR. McNICHOLS:

Q Okay. And in the modules of the course or the units of the course, what are the substances that you cover?

A In every course that I've given on addiction, we cover marijuana, opioids, psychostimulants such as cocaine and the amphetamine family. We cover hallucinogens, and we cover benzodiazepines, anxiolytic drugs, every type of drug that targets the brain that produces behaviors consistent with compulsive use.

Q And did you prepare a report on marijuana in connection with this rescheduling

proceeding?

A I did prepare a report consistent with the schedule, yes.

Q Yes. Can you please turn to Exhibit 3 or tab 3 in the binder that you have, ma'am?

A I have it, thank you.

Q All right. And do you recognize that document?

A Yes. I prepared this in 2024.

Q And what's the title on the document, ma'am?

A Rescheduling Marijuana from Schedule I to Schedule III.

Q Okay and you prepared it in connection with this rescheduling?

A Precisely.

MR. McNICHOLS: All right. Your Honor, we move the admission of SAM Exhibit 3.

(Whereupon, the document referred to was marked as SAM's Exhibit No. 3, for identification.)

JUDGE JULIUS: Any objection?

MR. MALEY ~~LONICH~~: No objection, Your Honor.

JUDGE JULIUS: SAM Exhibit 3 will be admitted.

(Whereupon, the above-referred to document marked as SAM's Exhibit No. 3 was received into evidence.)

MR. McNICHOLS: Thank you. Dr. Madras, have you received any payment from Smart Approaches to Marijuana in connection with your appearance here today or with your preparation of the report?

THE WITNESS: Zero.

MR. McNICHOLS: Okay. Your Honor, we tender Dr. Madras as an expert in addiction biology, the uses of marijuana for medical purposes, and the effects of marijuana on the human brain and body.

JUDGE JULIUS: Yes, Counsel?

MR. MALEY ~~LONICH~~: Your Honor, the government would reiterate the statement I made earlier. As it's laid out in Smart Approaches to Marijuana's pre-hearing statement, we were on notice that Dr. Madras is an expert in the science of addiction and the effects of addictive substances on the brain specifically. That statement is followed by effectively two non sequiturs discussing her roles in government service, and that she was called as an expert

witness without any explanation as to what her expert qualification in that particular case was and seems to insinuate that it is related to the scheduling of controlled substances, which is ultimately the question of this tribunal's proceedings today.

Given that and the opening statement that counsel made that she is to be tendered as an expert on addiction, the scope that has been offered seems to be changing. I understand that it is the tribunal's preference that these arguments be made in post-hearing statements. We would just like to establish on the record that the government contests the scope of her expert testimony.

JUDGE JULIUS: Understood, Counsel. Any response, Mr. McNichols?

MR. McNICHOLS: I think the government has been on notice certainly since 2024 when Dr. Madras submitted her report in this case that she was going to cover a range of effects concerning the use of marijuana in state programs and a variety of its adverse effects in addition to the purported medicinal uses that are currently on offer in these states. I don't

think there's really an element of surprise, and certainly the other writings that she's testified to so far in this proceeding would establish the basis for her expertise in all of these categories.

JUDGE JULIUS: Understood, Counsel. Consistent with the Court's preliminary order, we will provisionally accept her expertise qualifications. I do note, although in the introductory paragraph of the preliminary statement, it does say Dr. Madras is an expert in the science of addiction and the effects of addictive substances on the brain. The content of the summary of her testimony does specifically relate to marijuana, just looking at the bolded topic lines of the outline. It is applied specifically to marijuana. So, provisionally with the consistency with the preliminary ruling, we will consider her an expert for now.

MR. McNICHOLS: Thank you, Your Honor.

JUDGE JULIUS: Thank you.

MR. McNICHOLS: Dr. Madras, in connection with your testimony here today, have you prepared slides to accompany your discussion

of the issues in this case?

THE WITNESS: I have prepared slides, but I would say the vast majority of them, over 90 percent, are slides that I have presented previously in literally hundreds of presentations to lawyers, to judges, to families, to prevention experts, to addiction experts on marijuana.

MR. McNICHOLS: We have a collection of slides, Your Honor, that we've tendered to the government yesterday as SAM Exhibit 47. Formally speaking, these are demonstratives, but I'd like to make them part of the formal record by moving their admission prior to introducing them through her testimony.

(Whereupon, the document referred to was marked as SAM's Exhibit No. 47, for identification.)

JUDGE JULIUS: Any objection?

MR. MALEY ~~LONICH~~: No, Your Honor.

JUDGE JULIUS: You said that was SAM Exhibit 47?

MR. McNICHOLS: Yes, Your Honor.

JUDGE JULIUS: SAM Exhibit 47 will be admitted.

(Whereupon, the above-referred to document marked as SAM's Exhibit No. 47 was received into evidence.)

MR. McNICHOLS: Thank you. Can we pull that up please to the cover page?

MR. LONICH: I would put it on my screen.

JUDGE JULIUS: Okay. Just one minute. We're having some technical issues.

MR. McNICHOLS: Yes, of course, Your Honor.

JUDGE JULIUS: I will also note, while we're in pause just for clarity of the record, Mr. Evans, who is counsel for Dr. Finn, DUID Voices, and the --

MR. EVANS: Also.

JUDGE JULIUS: National Drug and Alcohol Screening Association is now in the courtroom.

MR. EVANS: Dr. Finn. Did you say Dr. Finn?

JUDGE JULIUS: Yes.

MR. EVANS: Again, thank you for allowing my presence.

JUDGE JULIUS: Absolutely. We just want to make sure the record is clear as to who

is in the courtroom and represented today. So thank you, Mr. Evans. Nice to have you with us again.

MR. EVANS: Would you mind writing that down?

JUDGE JULIUS: I will. Just putting that down at the time. Okay and we can go off record.

(Whereupon, the above-entitled matter went off the record at 9:40 a.m. and resumed at 9:42 a.m.)

JUDGE JULIUS: We'll go back on the record. Go ahead, Mr. McNichols. Thank you.

MR. McNICHOLS: All right. Thank you. We'll start with the basics, Dr. Madras. In the first case, what is marijuana?

THE WITNESS: Marijuana is a plant. There are three different species. There's cannabis sativa, cannabis indica, and cannabis ruderalis, which is a very minor species of cannabis. It is a plant that contains at least 120 cannabinoids and many other constituents, including terpenoids, flavonoids. Its two main constituents are THC, delta-9-THC, and cannabidiol, which is CBD.

For those of you who don't know what delta-9 means and delta-8, if you look at the ring which has an OH above it, there are three double bonds, three parallel lines, and the position of those determines whether or not it's designated 9 or 10 or 8 and so on.

BY MR. McNICHOLS:

Q You can include me in those who didn't know that, Dr. Madras.

A Delta just refers to a double bond.

Q Of course.

A And nine is the position on the ring.

Q Let's talk about the two chemicals up on the slide here known as THC and CBD. In terms of their addictive or intoxicating potential, how do they compare to each other?

A One is intoxicating. So, we can go through all of these.

Q Yeah.

A THC is the substance that has the addictive potential. CBD does not. THC is the intoxicant. CBD is not. THC impairs cognition. CBD does not. THC can promote anxiety. CBD has been investigated as an anxiolytic, which means to calm down anxiety. THC is

psychotomimetic. What that means is that it can produce symptoms of psychosis. CBD does not, but it also has been investigated as a potential antipsychotic. THC can promote or diminish seizures. CBD has anticonvulsant activity in it.

The targets of THC and CBD differ. The THC clearly binds to the cannabinoid one, the cannabinoid two receptors in the brain, which I can explain subsequently. It is a partial agonist, which means it has not a full-blown effect like the brain's own signaling messages. CBD is a modulator of the cannabinoid one receptor and the cannabinoid two, but it also binds to fatty acid amide hydrolase. It binds to trace receptor potential vanilloid one and two, which are potentially involved in pain reception. It also binds to the serotonin 5 HT1A subtype and a few other receptors.

CBD is, in fact, what I would consider a very dirty drug or else, another polite way of saying it is it's promiscuous.

Q Understood.

A THC, there is some minor data that it may be neuroprotective, but there's plenty of

data that it is not. There is some data that cannabidiol could be neuroprotective.

Q In broad strokes, Dr. Madras, how does marijuana and its constituent components -- how do they affect the brain -- human brain?

A If I may just venture into a deep dive for a moment.

Q Yes, ma'am.

A The brain is the master communicator and controller of communication in our body. Without our brain, we don't function. The brain is composed of over 80 billion nerve cells that control every function in our body: breathing, appetite, thirst, speech, cognitive function, judgment, love, you name it. It is the controller. How does the brain do these various functions? It has chemical signals that message one nerve cell to the other, and these chemical signals are called neurotransmitters. There are over 100 different types of them.

We produce endocannabinoid signaling. We have endocannabinoids in our brain that actually signal one nerve cell towards another. They send messages, and the interpreter of these signals are called receptors, and there

are two main interpreters, cannabinoid one and cannabinoid two. The two main chemical messages that are cannabinoids in the brain are 2-arachidonoyglycerol and anandamide. 2-AG is the main one in the brain. Anandamide does exist in the brain but also in the periphery. They modulate communication in brain regions. They modulate many functions in eight key brain regions, including motivated behavior, including learning, memory, appetite, motion, pleasure, mood, pain, planning, judgment, sleep, hormone production, and so on. And most importantly, they're important for brain development in the fetus and in the adolescent. THC --

Q And how does -- I'm sorry, Doctor. Please go on.

A THC resembles the chemical messages that our brain produces, but the resemblance is that of an imposter, it is not identical with 2-AG. We know from biology that a change of one atom from a hydrogen to a fluorine to a chlorine can make a huge difference in the pharmacology of drugs. So THC looks like, but is not identical with 2-AG. It targets the same targets that our own chemical messages of the cannabinoid class

target, and it produces different effects than our own chemical signals do.

Q In terms of the pharmacology of drugs, Dr. Madras, is the idea of using marijuana as medicine -- is that a new idea?

A It is an old idea. In the United States, when marijuana finally crossed the Atlantic Ocean and arrived on our shores, it was included in the Pharmacopeia, in the U.S. Pharmacopeia in 1854. For those who are unaware of what the Pharmacopeia is, it's an independent organization that classifies the purity, the dosage, the different forms. It contains photographs of different pills and different formulations for every single drug that is used in the United States. The British have one as well. It was included in the Pharmacopeia of the United States, and it was considered at that time a drug that has profound psychoactive effects. It exhilarates, it intoxicates, it promotes delirium, hallucinations. Then it can promote drowsiness and stupor. It has other effects, it
was listed as an aphrodisiac and increases appetite. It can promote catalepsy, which means

abnormal, stable postures that are unusual and sleep. It was recommended for a whole host of indications: neuralgia, gout, tetanus, hydrophobia, cholera, convulsions, chorea, hysteria, mental depression, insanity, uterine hemorrhage, spasm, nervous inquietude, pain, and uterine contractions.

In fact, in 400 CE, a 14-year-old girl was buried in the Negev Desert in what is now Israel. She died in childbirth. She had a fetus in the breech position. Her pelvis was too small to deliver the child, and there were ashes of metabolites of marijuana beside her nose, allegedly used to try to promote uterine contractions at the time. But the cautions in the Pharmacopeia included a number of them. They included alarming side effects with large doses, and also the cautions were that there were massive variations in potency that could not be regulated.

Q How did marijuana fall out of favor as a medicine in the United States?

A It fell out of favor and was withdrawn by 1942 from the Pharmacopeia. It was withdrawn first in the British Pharmacopoeia about two

decades earlier. Marijuana never enjoyed great popularity. American physicians hardly used it during the Civil War because it had unpredictable potency, and opioids were far more effective. By the end of the 19th century, pharmaceutical companies tried to make forms of marijuana, but they failed to develop dependable, pure compounds. So it was removed from the U.S. Pharmacopeia, and a decade earlier, it was removed from the British Pharmacopoeia. There was no opposition to its removal because it was hardly used. There was minimal clinical use. The alternatives were much more effective, and there was abuse potential concerns. And those abuse potentials go back to the 12th century.

Q On the subject of medicine, Dr. Madras, in general terms, how do we convert a whole plant like marijuana, into a drug for medical use?

A So there are many plants that yield medicinal chemicals. In fact, about 35 percent of our pharmaceuticals that are sold as medicines in this country are originally -- the design came from nature's own design. With

regard to psychoactive drugs, the coca plant gives rise to cocaine. The papaver somniferum, the opium plant, gives rise to morphine and thebaine. The marijuana plant gives rise to delta-9-THC. Ergot, which is a fungal contaminant on rye, gives rise to ergot, which can be converted to LSD. St. Vitus dance, which is a terrible side effect of eating rye contaminated, was well-recognized even hundreds of years ago. So these pure products, these compounds were isolated from these plants and shown to be the critical, critical component that had medicinal properties. And then they were converted into medicines and formulated according to purity, according to known fixed doses, all of these and many others from plants.

Then they started as medicines. They were converted to street drugs. Now, there is a reexamination of whether or not some of them, certainly with regard to marijuana and hallucinogens, should go back into the medical category.

Q In terms of developing drugs, Dr. Madras, what does it mean to isolate a particular compound from a plant?

A Isolation is critical in order to develop a compound that is pure, a compound that you know precisely the dose. So let's take a look at four products that came from plants. Long before the FDA, long before we developed modern forms of medicine, digitalis was known to help failing hearts and foxglove was used. The problem with foxglove is that it can be toxic because the doses were not reproducible. The doses were not fixed. The plant produced different doses. It also produces other compounds like di~~goxin~~itonin, which is used in labs to dissolve cells and can be a poison as well.

We also had atropine from the belladonna plant. It was known for over 2,000 years. But when it was isolated, it could be administered in surgical suites at a fixed dose, at a safe dose, and in absolute pristine form. Aspirin was known -- the bark of the willow tree was known to reduce pain and also to reduce fever. It was isolated from the bark of the willow tree and then converted into acetylsalicylic acid, which is now aspirin.

The bark produces salicylic acid.

Quinine was found in the cinchona bark

in South America, and it was used to treat malaria until it was isolated and it was generated as a pure drug. So what are the advantages of purifying drugs? They are highly purified. You know you're not getting contaminants in them. They treat specific illnesses. You can study the mechanism of action. You can control with exquisite, exquisite quality the dose. It's regulated. It's consistent. You can produce batch after batch, thousands and hundreds of thousands of batches, at precisely the same fixed dose. An overdose is not possible unless someone consumes them in a manner which is different from a prescription. Also, by isolating them, there's a tremendous advantage in that you can produce variants that are better than what the plant produced originally, more effective, more potent, more selective.

Q Are these criteria that you have on the slide right here, Dr. Madras? Are these now incorporated into FDA's criteria for drug evaluations?

A Yes.

Q Let's --

A Because currently that is the case.
Q Let's -- let's talk about FDA's criteria.
A Yeah.
Q Go ahead. If you can, in very general terms, Dr. Madras --
A Yes.
Q Explain what the FDA looks for.
A So the FDA looks for in -- the vast majority of drugs that the FDA approves, it wants purity. Is it a pure compound? Does it have predictable chemistry? In other words, when you start with a certain protocol of chemicals to make the drug, are you always getting exactly the same compound as you presume to get and as happened in the past? Is the production consistent? Are the production methods validated? Every time you synthesize it, will it come out with exactly the same product? Are toxic effects in animals and in humans known? How much gets into the bloodstream? How much gets into its target? That falls under the umbrella of pharmacokinetics. How much gets into the bloodstream? How much is metabolized? How much

gets to its target is known as pharmacodynamics. What happens when a drug hits brain receptors or receptors in the rest of your body? Is it contaminated? Is it impure -- with microbes, with chemicals, with heavy metals, pesticides, insecticides, and so on? Is it a safe dose range? Is it effective and safe for a specific illness? What is the therapeutic versus the side effect window? Is it narrow? Is it broad? The narrower ones are more dangerous because if a person takes twice the dose, it may kill them. Are the side effects acceptable? What about follow-up case reports, safety updates? Post-approval surveillance is part of the criteria that the FDA uses on all these drugs.

Q And by these standards, Dr. Madras, how does marijuana stack up?

A If marijuana is considered a generic term for anything goes in dispensaries, which includes gummy bears and chocolate bars and beverages and suppositories and creams and vapes, it doesn't meet any of the standards for purity, for potency, products for each medical indication. It doesn't fit the standards of a fixed dose range, a dosing regimen, which means

how often do you take this drug? How often should you use it? Do you use it during the night? Is it four times a day? That's what a doctor's prescription looks like. The route of administration.

Every single FDA-approved drug is approved for a specific way that you take it. It's not, well, you can smoke it, you can vape it, you can drink it, you can do -- marijuana simply doesn't fit these rigorous criteria that have taken our nation over 90 years to develop and to improve on in order to make sure that our drug supply is safe.

Q In terms of the criteria for effectiveness and safety, what is the role of clinical trials in evaluating those characteristics of a drug?

A The role of clinical trials is daunting. It is essential. It is rigorous, but it is the most important measure we have to ensure safety and effectiveness of a drug. So most clinical trials now are randomized, which means half the people get the drug, half the people that are perfectly matched get placebo, get a neutral non-pharmacological agent usually,

but there are many exceptions to that and they are double-blinded. The patient doesn't know what they're getting, and the doctor administering it doesn't know what they're getting. And that guarantees, absolutely guarantees, that the studies should come out fairly.

Let me just deviate, may I, for one quick anecdote. For thousands and thousands of years, bloodletting was the norm for treating almost every disease. The ancient Egyptians used it, the Greeks, the Romans, the ancient Hebrews, the Middle Ages. Our President, George Washington, was subject to bloodletting of almost half his blood volume on his deathbed because everyone assumed by so-called common sense, because blood contained poisons and ~~t~~humors, that if you just get rid of blood, the person could be treated and cured. A French physician said, I've got a whole group of patients in this hospital with terrible lung problems, lung infections, flu, and pneumonia. He said, everybody's treating them with bloodletting, but I'm going to take a whole cohort of patients, divide them into two groups

that have the same symptoms. One I'm going to drain their blood; the other I'm not. And he found it made no difference, and that was the end of bloodletting in medicine for most common purposes.

Q Can you also describe the effect of clinical trials on the use of Laetrile as a treatment?

A Yes. So here is an excellent example of how clinical trials are essential to prove that a drug has safety as well as efficacy. I have tried to find the number of states that passed Laetrile as an anti-cancer medication in the 1970s. It is somewhere between 17 and 27. I've seen both those numbers. It was on ballot initiatives. The public was convinced that Laetrile is a great anti-cancer agent because there was some common sense involved. It had hydrogen cyanide. It was a toxin, and there was a feeling that these extracts of apricot pits could actually hone in on the cancer cells and deliver poison to those cells. It was widespread. It was passed. It was approved.

Then, our excellent National Institutes of~~n~~ Health and the FDA stepped in and said, what

is the real story with Laetrile? Is it effective or not? And what they did was the NIH, National Institutes of Health, sponsored a double-blinded clinical trial of Laetrile in cancer patients, and they found no effect. Zero. But worse, two problems. They found that these people delayed legitimate evidence-based chemotherapy, some in the public, that it could delay legitimate chemotherapy, and that Laetrile was actually toxic to people. It was not effective. It was, in fact, detrimental. And it passed the country -- it circumvented the country because it was considered an anti-cancer drug, a chemotherapy. That's why marketing of drugs by political processes are so dangerous.

Q Let's talk for a moment about state medical marijuana programs and what they entail. I know there's some variability by state, Dr. Madras, but as a general matter, how long have those programs been around in the United States?

A The first state to pass so-called medical marijuana was California. It was the Compassionate Care Act, Proposition 215. It went into effect in 1996. What is so interesting about this state is that the

governor of California decided to see after the fact whether or not marijuana has any medicinal uses. And so he put aside -- the total is over 8,000,000 dollars eventually for the Center for Medicinal Cannabis Research in California to see if marijuana has, in fact, medicinal properties after Prop 215 was passed.

Since that time, it has been a moving and expanding target of applications. The original was -- called the Compassionate Care Act. The original was to try to treat AIDS wasting, cachexia, and also chemotherapy-induced nausea in cancer patients. Those were the way it was sold to the public. Eventually, those indications grew and grew, and we can see from this slide what the indications are.

In Arizona, we have cancer, glaucoma, HIV, AIDS, hepatitis, amyotrophic lateral sclerosis, Crohn's disease, Alzheimer's disease, cachexia, severe and chronic pain, nausea, seizures, epilepsy, and so on and so forth.

Q Across the United States, is there some variability in the types of conditions that are treated with marijuana?

A Yes. There are some states that have

only six indications. The poster child is Illinois.

Q And how many are there, doc?

A This is 40. This is an old slide. As I said I cobbled together slides from my presentations. It has over 46 now. And I can say with a measure of certainty that the science behind these indications is, in most indications, close to absolute zero.

Q Are clinical trials required before marijuana can be authorized for particular conditions?

A No.

Q Let's talk about the types of evidence that is available on marijuana as a treatment for these conditions. Just to give us some example, I mean, what is? And again, in general terms, what are we looking for and what do we have?

A We're looking for randomized, double-blinded, placebo-controlled trials. Sometimes trials do comparators, they compare one drug with another. But most of the time, the drugs are compared to a placebo to determine if the pharmaceutical, isolated and pure, has an

effect. They look for large sample sizes and large sample sizes ~~large~~ means in phase 1, it's under 100. That means they just give it to people who are not ill to see if the doses that they think will be valid are, in fact, safe.

In phase 2 trials, the sample sizes are bumped up to hundreds, in some cases nearly 1,000 or more. In phase 3 trials, they're multi-center. That is to see whether or not other, many other sites across the country with different physicians, different levels of care, are getting the same data in thousands -- usually thousands, it could be hundreds -- of people.

They use standard dosing formulations and good manufacturing practice. There's replication across studies that are essential. The results are published in peer-reviewed publications, and the results are also gleaned in systematic reviews and meta-analysis to make sure that there is a huge database of these therapeutic indications stemming from clinical trials.

Q Based on your review of this evidence, Dr. Madras, is there evidence that cannabinoids

show any promise for specific medical conditions?

A The closest promise for specific medical conditions that I would say was popularized in the early 2000s, and this came from the CMCR, the Center for Medicinal Cannabis Research, in California. They sponsored the trials, and that was in neuropathic pain, which I can get into in a moment, and there are tremendous weaknesses in those trials. The quality evidence is that whole plant cannabis or marijuana is not FDA approved. Some cannabinoids show promise for specific medical conditions. The ones that have been FDA approved have been approved for cachexia, as well as chemotherapy-induced nausea and vomiting.

The evidence for botanical cannabis is weak. It's inconsistent. The quality of the studies are low. There's a high level of bias, and in some cases, the evidence is null.

Q Dr. Madras, you're familiar with HHS's recommendation and its conclusions concerning the indications for which cannabis, in its view, could have a currently accepted medical use?

A I am.

Q As to those indications and the ones that HHS evaluated, how do the clinical trials stack up in terms of evaluating its efficacy?

A HHS leaned very heavily on the National Academy of Science, Engineering, and Medicine report in order to promote the view that cannabis is useful for chronic pain. The NASEM report I have read in depth, and it is deeply flawed, and I can get into that if there is --

Q This is as good a time as any, Dr. Madras.

A Yes. Thank you. The NASEM report leaned on meta-analysis of a number of studies that were done with isolated cannabinoids, with nabiximols, as well as the very few smoked forms of cannabis, the very few clinical trials and their report was substantial evidence for chronic pain. It makes no sense for them to have drawn that conclusion for a number of reasons. One is that the neuropathic pain studies that the report leaned on, several that were done, as I said, by the CMCR. The first and most important flaw in that is that those trials were very small numbers of patients, 25,

30, and so on. The second flaw with those neuropathic trial studies was that the studies were extremely short duration, a couple of days to a few weeks. The third problem with those trials is that the types of marijuana that were used in them, in this case, they were NIDA's provided THC-laden cigarettes with fixed concentrations. These are the studies, thank you.

They don't resemble what's in dispensaries at all currently. The trials went from about 3.5 percent THC the maximum was 10 percent, and several of them said 10 percent or even 8 percent was too high, we have the same results with 3.5. But THC is now 15 to 20 percent in dispensary marijuana. In vapes and concentrates, it can be as high as 90 percent THC. The doses that are delivered -- and the NASEM also conflated the FDA-approved Marinol, which is dronabinol and Syndros and nabilone, with smoked marijuana. They simply did not draw the distinction. So, there are at least actually 10 flaws in the NASEM report, which I won't bore people with. But if you look at the specific -- just the specific Abrams et al., he

insisted that all his subjects be experienced marijuana smokers. The reason he insisted on it was because he thought that, if they weren't, they may get frightened by the experience, the psychoactive experience, and the potential of psychosis and so he wanted experienced marijuana smokers. Another study as well did precisely the same thing. They used experienced users.

Now, it's pretty rare for the FDA to approve a drug and say that the only way they'll accept a clinical trial is if the person is experienced in using this drug before they actually even start the clinical trial. What this means is that they shaped the trial in order to accommodate the particular and unique properties of marijuana, which is psychoactivity, psychotomimetic effects.

The other thing is that in several of the studies, I wish I'd made a table of all of these comparisons, because I have done it, but I didn't bring the slide, is that they were not blinded. The patients knew. They were experienced marijuana users. They knew they were getting marijuana. If they were using marijuana, they had to withdraw from it before

the trial so that they would be THC negative before the trial and the only THC in their system would come from the smoked cigarettes that they were given. That made no sense because if a person is used to marijuana and then starts to smoke again after withdrawal, it could bump up their positive sensations.

So, there were many flaws with these studies. Short term, very low doses compared to what is currently being sold in dispensaries, very small ~~ends~~ n's, non-blinding, experienced users, and so on. But if you now look at the largest meta-analysis that has ever been performed on neuropathic pain by the International Association for the Study of Pain, IASP, it was published in 2025. What it says is that of 313 clinical trials, 313, which embraced 48,000 patients specifically for neuropathic pain, they list every possible drug in these clinical trials, and they omit cannabinoids. The reason they omit them is they decided 10 years before, in 2015, that the cannabinoids were the -- the trials were flawed, there was insufficient evidence, and there was nothing more recent updated, and they recommended

against using them in 2015. They didn't even include them in this massive comprehensive study on neuropathic pain.

Q Are there clinical trials comparing marijuana to opioids in terms of their analgesic capabilities or effects?

A There are very few. There are very, very few. Side-by-side comparisons, there may be one or two studies, and I don't think we can lean heavily on those results because they're not large. They're not comprehensive. But if you look at pain comparing marijuana with opioids for acute pain, there's very strong evidence. In fact, one of the CMCR studies tried to use marijuana by inducing pain in skin. I can't -- I think they either pinched or needled, presented some sharp object, and they found that it was ineffective in reducing that acute pain. That’s been published. That was a reasonable trial, and it was ineffective.

Post-operative pain, opioids are standard of care. That's modifying these days; there may be other alternatives for that, but there's insufficient evidence for marijuana in post-operative pain. In fact, marijuana is

contraindicated in surgical cases because you need a lot more anesthesia to get a person to sleep if they've been heavy marijuana users, and the recovery is more difficult. So I don't think that's an indication.

For cancer pain, there's extremely strong evidence that opioids are effective in alleviating cancer pain. GW Pharmaceuticals did two phase 3 studies in this country testing nabiximols, which is THC and CBD, for cancer pain, and they failed in two phase 3 trials, and they just abandoned it. For chronic non-cancer pain, there's moderate efficacy but substantial, substantial risks for opioids, and they should never be first line of use for chronic pain. The marijuana, the benefits are small, and they're often below clinically meaningful thresholds.

Neuropathic pain, we've already dealt with. There's moderate efficacy. Opioids are not first line of attack for neuropathic pain.

Q And then on the last one, the opioid-sparing effect, Dr. Madras, there's been some testimony about that thus far.

A Yeah.

Q In the case, what does the science show about the opioid-sparing effect?

A Well, there are three. There are three major issues that I think are worth mentioning here. One is that people who are in treatment for opioid use disorder and who also use marijuana, there's one study that showed they're more likely to drop out of treatment for opioid use disorder and continue the OUD. There's a study showing that youth who use marijuana before the age of 18 -- the highest risk for developing opioid use disorder is use of marijuana before the age of 18. The studies that said that as states that had accepted, adopted medical marijuana, their overdoses declined. Buchbauer study, which was reversed by Shover a few years later showing that, in fact, the states that had adopted medical marijuana, opioid overdoses increased. These are ecological studies that have so many fallacies. You know, the concept of causation versus correlation is a very, very critical one, and in this case, they just lumped -- I mean, some of the states that adopted marijuana may have also adopted widespread distribution of

naloxone so that they rescued people and much more effectively than in states that didn't distribute naloxone, and the fact that they adopted medical marijuana may have been a coincidence.

Q I want to come back and talk to you about causation versus correlation and coincidence because that's come up in this trial so far. But before we do that, and before we get to our comfort break, I have just a few more questions on the way medicine is being practiced at the state level. In terms of what's going on at dispensaries at the state level, I mean does it require, for example, a physical exam of the patient who wants to get marijuana?

A No.

Q Okay. What is the process?

A Some states have tighter regulations, but in the majority of cases, there is no necessity for physical exam. There is no necessity for an ongoing relationship with the patient so that the patient is seen periodically. It's a state-by-state regulation. There are no broadly universal standards for how to address this. They allow cannabis, 12

states at least, allow the recommendation of cannabis for any medical condition that the doctor may deem will be worthwhile. Any medical condition essentially means it's completely and totally arbitrary without science behind it, without data behind it. They don't --

Q Dr. Madras, hold on. They're making an objection.

A Oh, I'm sorry.

JUDGE JULIUS: Objection?

MR. MALEY ~~LONICH~~: Yes, Your Honor. The Government would like to object to any testimony as it relates to the medical requirements, given that Dr. Madras has not been qualified as a medical doctor. Anything about the ongoing treatment of patients seems outside the scope of her expertise.

JUDGE JULIUS: Mr. McNichols?

MR. McNICHOLS: Yeah. She has written -- it is true that Dr. Madras is not a physician, but she has written extensively on the use of marijuana as a medical treatment. She also teaches at a medical school. So, while she's not a clinician and does not treat patients herself, certainly she's made an

academic study of the subjects about which she's testifying.

THE WITNESS: Yes. And I have –

JUDGE JULIUS: Hold, hold on, ma'am.

THE WITNESS: I'm so sorry.

JUDGE JULIUS: You're okay. Anything further?

MR. MALEY ~~LONICH~~: No, Your Honor.

JUDGE JULIUS: I understand the objection. I will allow the question and testimony. It goes to weight.

MR. MALEY ~~LONICH~~: Understood.

JUDGE JULIUS: Thank you. Please proceed, Mr. McNichols.

MR. McNICHOLS: Thanks. And just on that subject, one of the words you have on the slide here in red is budtenders, which is a word that's come up in this trial so far. What does that mean in terms of who's actually making recommendations for cannabis in the state programs?

THE WITNESS: These are people who are untrained, unlicensed, who man the desks at dispensaries. That is their designation. There is no physician or pharmacist present in almost

all the dispensaries, and I believe it's less than 20 percent have a physician oversight.

The budtenders, there have been several studies where people walk into various dispensaries and try to figure out what budtenders are recommending for which condition and they've documented them. There are at least two to three studies that I'm quite familiar with. They recommend things based on their own impressions, their own views on marijuana. They recommend indica for some indications or sativa or 20 percent. They simply do not have standards for training like a pharmacist does. A pharmacist takes massive amounts of their own funding to go to pharmacy school and develop the expertise needed to stand behind a counter in a pharmacy and give advice to a patient who comes in with a prescription.

In this case, the budtender's advice for cancer, this was one of these views. Let's push high potency THC. CBD's only for the naive. We want them to progress from cannabidiol, which is neutral in many ways, to high THC. If they don't use it to intoxicate, it could turn them off. You could lose a

customer if they're not. People already using cannabis want to be more intoxicated. These are quotes directly from these people in these dispensaries that were asked what kind of advice do they give. They also give what I consider mal-advice to pregnant women. There are 400 dispensaries in Colorado that were surveyed in terms of first trimester cannabis use. Everyone in this room knows the first trimester is critical for brain development. The brain begins with one cell, and it develops into 80 billion. In the first trimester, billions are already formed to begin the heart to beat, to begin the legs to move, to begin the digestive system, to just begin that control. So, the brain is one of the most rapidly -- that is why children are born with such large heads disproportionate to their bodies because the brain is so critical.

In the first trimester, there are vast changes in the brain. Sixty-nine percent recommended cannabis for morning sickness in the first trimester. Sixty-five based the recommendation on personal views. And what we're seeing is an increase. This is a little

bit of old data. There's still current data, more current, but we've seen an increase in pregnant women using marijuana because they go to a dispensary, and they're advised that this is good for them. The question is: Is it good for them, and what are the downsides?

BY MR. McNICHOLS:

Q Just a couple more questions before we take our morning break, Dr. Madras. To what extent are non-patients, other people, getting marijuana from these state dispensary programs?

A Well, there's clear diversion from medical cannabis cardholders. My biggest concern in Colorado: 48.8 percent of adolescents in a treatment program obtain marijuana from someone with a medical marijuana program. Teens using diverted medical marijuana, the higher they use, the more substance related problems. Non-patients commonly get dispensary cannabis from friends and family. There are a number of studies that that are documenting this. Sir.

MR. McNICHOLS: Do we have an objection?

THE WITNESS: Oh.

MR. MALEY ~~LONICH~~: Yes, Your Honor. The government would raise a similar objection that the topic of diversion seems outside of the doctor's expertise as she's been offered today.

JUDGE JULIUS: Mr. McNichols?

MR. McNICHOLS: No, I think if we look back at her writings, as an element of abuse, which is how it factored into the HHS memorandum, Dr. Madras has made some study of this, both in the academic papers she's written and also in the papers she's written for governmental authorities including the U.S. Senate. So, this is within the area where she's actually made some academic study.

JUDGE JULIUS: Anything further?

MR. McNICHOLS: No.

JUDGE JULIUS: Objection noted. I also will note the slide deck was not objected to as an exhibit, and all of this is on there. So I'll allow the testimony, and it can go to weight.

MR. MALEY ~~LONICH~~: Understood. Thank you, Your Honor.

JUDGE JULIUS: Thank you.

MR. McNICHOLS: I was moving on to a

different section if this is an appropriate time for the break.

JUDGE JULIUS: Let's go ahead and do that if that works for you, Mr. McNichols.

MR. McNICHOLS: Yes.

JUDGE JULIUS: Okay. We'll take a 15-minute break. Dr. Madras, please don't discuss your testimony with anyone during the break. But you're free to, you know, get up, stretch your legs, use the facilities should you need.

THE WITNESS: Thank you.

JUDGE JULIUS: We will reconvene at 10:50 a.m. We'll take 15 minutes. We'll be in recess until then. Thank you, everyone.

(Whereupon, the above-entitled matter went off the record at 10:35 a.m. and resumed at 10:50 a.m.)

JUDGE JULIUS: We are back on the record, still on direct examination with Smart ~~Alternatives~~ Approaches to Marijuana. I think you have a little under an hour. My guess is, for scheduling purposes, we'll probably finish up direct, then take our lunch break and then begin with cross after lunch. Does that work for everyone?

MR. McNICHOLS: Yes, Your Honor.

JUDGE JULIUS: Okay. Thank you, Mr. McNichols. Please resume whenever you're ready.

MR. McNICHOLS: Certainly. Welcome back, Dr. Madras.

THE WITNESS: Thank you.

BY MR. McNICHOLS:

Q I'd like to shift gears for a moment from talking about marijuana as a medicine to the other component that goes into the rescheduling analysis concerning abuse and public health. Now, before we start flashing that up, as a very general matter, ma'am, to sort of preview the risks to public health that we're going to talk about here, can you give us an overview of them?

A Well, there are a number of risks to public health, both in terms of brain, body, and behavior—those -- three categories—and also unintended victims. First of all, cannabis use disorder the prevalence is high. It is really high. James Anthony in 1994 said that the prevalence among users was about 9.4 percent. It is now skyrocketing to between 24 to 30 percent. And in medical cannabis users, the

prevalence is higher than it is in some studies -- not all, but some studies -- than recreational users. In veterans, for example, the prevalence of cannabis use disorder among veterans using it medically is over 35 percent. So, there's also excellent comparative studies which we'll get into. The prevalence is high and getting higher, and the reason is that it's being driven by more frequent use. It is being driven by more potent use of products. What factors drive marijuana effects? The dose, the percent THC plus the absolute amount. For example, the medicinal THC that has been approved by the FDA in Schedule III is close to pure THC. It's about 99 percent. But the dose is 2.5 milligrams as a starting dose, up to 10 milligrams. When you have cannabis at 20 percent or 90 percent, but the dose that it contains is, in some cases, in some vapes it's 100 milligrams, 200 milligrams. There are people using cannabis for medical purposes that are using almost a gram a day -- 1,000 milligrams. It's very different than the medically approved dose.

The frequency of use, as I said, is

another critical factor. Whether it's used one time daily, weekly, monthly, or yearly will drive the consequences. And the mode of delivery also, in some cases, shapes the consequences. It can be inhaled with smoking and vaping. Smoked, the THC levels peak at 30 minutes, they subside. I mean, the most robust effects will subside within a few hours. The edibles, THC levels can peak within 30 minutes to 2 hours, and they can subside at a much later date because the gut distribution is much slower than smoking or vaping. One example for us to bear in mind is a young African American male, who was a college student in Colorado, and this was told to me by one of the law enforcement officers. He was walking by. He just started college. He was walking by a dispensary, and they offered him free brownies. They said, just take an eighth of a brownie. I don't know any teenager or young adult who will eat an eighth of a brownie. He ate the whole thing, and he felt nothing because it takes a great deal of time to go from the gut to the brain. And he jumped off a balcony. He was psychotic after that. So, each mode of delivery is critical,

and if we don't have that in regulated dispensaries, the mode of delivery, if we don't have FDA oversight or approval, anything goes.

The age of onset is also critical. Whether or not you're exposed prenatally, whether or not you're exposed as a teenager, whether or not you're exposed as an adult, you do get different, vastly different, effects. We just published a paper this past year on differing effects of THC on the brains of adolescents compared to adults, and the adolescents had an inflammatory response in a key, key brain area, the amygdala, which drives depression, mood, sleep, anxiety, fear, all these emotions that can either catalyze excellence or derail a person. That inflammatory response, we found only in the adolescent and not in the adult brain.

Q You used a term a moment ago, Dr. Madras, called cannabis use disorder.

A Yes.

Q And in general terms, ma'am, what is cannabis use disorder?

A Yes. Like other use disorders for other drugs, cannabis use disorder is a series

of behavioral and psychological symptoms. There's no biometric test. When a person has an infection, you can pick up the bacteria. When a person has cancer, you can identify the cancer either by biopsy or MRI or X-rays. In substance use disorders, there's no really evidence-based biometric test. So, you have to define the disorder of the brain, a diagnosable medical disorder, by what the person is telling you and by their behavior.

There are three categories of what are called the Diagnostic and Statistical Manual Version 5 for cannabis use disorder. One is uncontrollability. You take more than you expect to. You cannot stop, you crave. The second category is behavioral consequences. You do not meet expectations in terms of schools and jobs. You spend a great deal of time using. You give up activities that you've enjoyed. You use in hazardous situations. The third category is a bit of a physiological one, which is tolerance. You need more and more of the drug to produce the same effect, and the second of those biological ones is withdrawal symptoms. All of those.

There are 11 categories that essentially boil down to uncontrollable use despite adverse consequences. That's really the operational definition. Depending on those 11 categories, the more severe, the more you fulfill all 11, the closer you do, it's considered severe. Moderate is between two to five categories are cannabis use disorder. Five to eight could be moderate, and all 11 is quite severe. So, this is just a sampling of people that were diagnosed with cannabis use disorder, and this is the frequency. Continued use despite problems, almost all of them. Repeated efforts to quit down almost all of them. Use larger amounts for longer periods, 80 percent, and so on and so forth.

Q In terms of the prevalence of use disorder, how does marijuana compare to other controlled substances and alcohol?

A Well, the prevalence of marijuana use now is soaring. Even though the prevalence in teenagers had declined during the COVID period and has not recovered, in adults 18 to 25 and in older adults, it has just increased dramatically. If you compare the prevalence to

alcohol use, cannabis use is about a third as much. Excuse me, alcohol is about three times higher. But if you compare the prevalence of cannabis use disorder, it's disproportionately higher. Just look, you don't have to look at numbers, all you have to do is look at the length of the arrows.

There is much more cannabis use disorder proportionate to how many people use the drug than alcohol, and it's rapidly catching up with alcohol use disorder. Currently, there are more daily marijuana users than alcohol daily users. It began to soar in 2010, and now the prevalence of daily use or near daily use is the highest it's ever been in our history, and now it's higher than even alcohol use disorder. Why is that a problem? Because the addiction potential increases dramatically with daily use. It's estimated that people who use daily, 30 to 50 percent will develop a cannabis use disorder.

Q And in terms of geography or region, how do the rates of cannabis use disorder compare in states that have medical marijuana programs to those that don't?

A Well, if you look at the non-medical

marijuana states in that ugly orange color, which I just don't like orange, but anyhow you can see that if we set the prevalence at sort of a low bar for states that don't have medical marijuana, and then look at medical marijuana states, you can see that cannabis use disorder is considerably higher amongst males, amongst females, amongst 18- to 34-year-olds, 35- to 44-year-olds, the differential is the greatest. With 45- to 54-year-olds and 55- to 64-year-olds, the differential is not as high. But amongst the young people, the people of the future, it's the highest.

Q Thank you.

A And so there is a huge increase in in cannabis use disorder in medical marijuana states and a huge increase in poisonings as well, and the increase in childhood poisonings has gone up much more dramatically than adults.

Q And how has the potency or THC content of marijuana affected the rates of cannabis use disorder?

A Well, the potency has definitely influenced the progression, the rate at which you progress to cannabis use disorder, so that

the higher potency of THC is associated with a higher risk for psychosis, for anxiety, lower age of schizophrenia. It's associated with a higher risk for impaired memory, brain function, driving, emergency care, uncontrolled vomiting or cannabis hyperemesis syndrome. It's associated with a higher risk of using other drugs, having social problems, but it's associated with more use, a higher risk for progression to addiction.

Q And in recent decades, what has the data shown as to the potency of marijuana?

A The potency's gone from about three percent -- imagine the study that was done by Don Abrams in which he used 3.5 percent for neuropathic pain and found that to be an adequate dose with far fewer side effects than the 8 percent. And it went up gradually and then dramatically over the past decades, and it was not driven by prohibition. It was driven by commercialization, by medicalization, and by normalization. What do people who produce these products know? The more potent, the greater high, the more tolerance, the more addiction, the more users, the more profit. That is true

for almost every drug that I can think of. The potency of crack cocaine versus insufflated cocaine, the potency of methamphetamine ice versus a different salt form of methamphetamine. The more rapidly a drug gets into the brain, the more receptors it hits, the greater the effect and the greater the addictive potential.

Q In discussing the effects of marijuana use thus far in the trial, we've used a couple of terms, in particular psychosis and schizophrenia. Before we get into how marijuana relates to that, in general terms, Doctor, can you explain what we mean by psychosis?

A Yes. Psychosis is a number of manifestations of the brain being dysfunctional. It can occur with a single or multiple exposures of cannabis. It is accompanied by paranoia, by bizarre thoughts which are considered delusional, by fragmented thoughts, disordered thoughts. I see the exit sign, and it's floating across the room now because the green is so beautiful on a clover leaf. Fragmented thoughts. Hallucinations, especially auditory, you hear voices. Sometimes you can see -- hallucinate. You can feel sensations

that don't exist. In all these cases, the person perceives the world and themselves differently than an observer on the outside.

Q And how does that relate, ma'am, to the term schizophrenia as a medical condition?

A Psychosis can occur under a number of conditions. It can be drug induced. Methamphetamine can produce it, high doses of amphetamine. THC administered to otherwise normal people can develop symptoms of psychosis. But schizophrenia is a chronic disease that occurs when these symptoms persist, and some in the field and some in different countries say they have to persist for at least six months. Others claim that it has to be a year with a repeated diagnosis of these symptoms.

Q And have there been studies over time of the relationship between marijuana use and psychiatric conditions like psychosis and schizophrenia?

A Yes. Well, this is one of the most interesting studies that was done much more than a century ago. It was done in the Bengal Insane Asylum, and it was a 19th century study of Indian hemp and insanity by colonial British

India. They asked the people -- and this is politically incorrect to call it an insane asylum now, but that was the terminology at the time -- whether or not they use cannabis. The admissions to this insane asylum, the most frequently mentioned drug was cannabis over time. Alcohol and opioids were minor players compared to cannabis use because India used people living in India used cannabis for well being purposes for centuries.

Q Have there been more recent studies since this one from 1873 to 1893 of the same phenomenon as well?

A Yes, so this came out long before marijuana became a political issue, but the prevalence of schizophrenia in Ontario, this was reported just last year by Dan Myran at University of Ottawa. What he showed is that the attributable risk fraction over time of cannabis use disorder associated with schizophrenia has increased very significantly for 19- to 24-year-olds, not as much for the younger generation, the younger kids of 14 to 18, most likely because there hasn't been time for them to progress. But what they found is

that, pre-legalization of cannabis, there was 3.7 percent of schizophrenia attributable to cannabis use disorder. Post-legalization, it was 10.3 percent. New cases associated with the use disorder in 2006, 1.6 percent; in 2022, 9.6 percent. Now, bear in mind that people who are using this drug for medicinal purposes have very high rates of cannabis use disorder.

Q And how does dose and frequency of use relate to the risk of psychosis from cannabis?

A So this was a tale of three cities here, London, Amsterdam, and Paris, but it's actually a tale of 11 different sites, including one in South America, by Marta ~~Defort~~Di Forti, one of the world's experts on schizophrenia and cannabis-related schizophrenia. What she found was that if people never used or used THC at less than 10 percent, they had among the lowest rates of schizophrenia. As you increased the dose and as you increased the frequency of use, the risk factor, the odds ratio for developing schizophrenia increased dramatically, and the highest risk were people who were using cannabis daily at greater than 10 percent dose.

Now, these studies have been critiqued.

They've been dissected. They've been thrown around for many, many years now. This was a 2019 study, but the basic fundamental premise has not been refuted because 11 sites is really a powerful indication.

Q And --

A So please.

Q Go ahead, ma'am. I'm sorry.

A Okay.

Q Yeah. How did the results in the study in Denmark compare with the ones in the other cities that you've described?

A Denmark has seen a twofold increase in the incidence rate of cannabis-induced psychosis from 2.8 per 100,000 person years in 2006. Ten years later, it was double the rate, 47.7 percent of people with cannabis-induced psychosis converted, converted to either schizophrenia or bipolar disorder after follow-up. Now, conversion to schizophrenia is a very grave issue because schizophrenia is a chronic lifelong disease that generally captures people at the prime of their lives and can derail their potential forever. Some are highly functional, but many are not.

Q There's been some testimony in the case thus far about the concepts of causation versus correlation when it comes to the side effects of marijuana use. Can you explain in general, ma'am, what are the differences between causation and correlation?

A Well, I will insult your intelligence by giving an example that I use in general for general populations, general presentations. The example I give for correlation is that in the winter, there's snow, there's ice, and as the seasons change, we get warmer weather, more sunshine, the roads are favorable, travel is easy, and almost all wars begin in the summertime or the early fall, World War I, World War II, you can go through all of these wars, because conditions are favorable for war.

Now, in that sinusoidal wave, we can also correlate it with watermelon use, ice cream use, outdoor sports and if someone was naive or truly uninformed, they would say, well, what if eating ice cream catalyzes wars? Because they correlate perfectly. They go up in tandem; they decline in tandem. That's the ultimate fallacy of correlation.

A bigger problem, a more nuanced is heart attacks increase dramatically in the summer months. That's because the weather warms up. It's not that the warm weather causes the heart attack; it is the fact that people are much more active in the summer and they're doing sports that exert their hearts beyond their capacity.

Q What are the Bradford Hill criteria, Dr. Madras?

A Over the years, people struggled with how do we prove that something is cause and effect, not just coincidental, which is what correlation is. Austin Bradford Hill, Sir now, he proposed that we have to look at a few criteria. He proposed six, and then it expanded to nine. How strong is the association between one thing and another? How strong is the association between smoking and lung cancer? How consistent is it across countries? If people smoke in Iceland or they smoke in Brazil, do they all have a much higher incidence of lung cancer if they smoke, or is it just restricted to one small community? What about the timing? Does the lung cancer begin before they start

smoking, or does it begin after they start smoking? What about the dose response? If a person smokes one cigarette a day, will they still get as much lung cancer as a person who smokes 20 cigarettes a day? What about biological plausibility? Does smoking cause damage to the lungs, and is the damage consistent with cancer or cardiovascular disease? What about specificity? Do people get lung cancer if they've never smoked? Do people who smoke never get lung cancer even if they smoke 20 cigarettes a day? That's specificity. Can you induce lung cancer by giving an animal cigarette smoke every day? And coherence, does the whole picture fit? Is there a genetic component, a pharmacological component, and all that?

So, these are some of -- in terms of the correlation and the causation debate with psychosis and schizophrenia, the strength of the association is extremely strong. People who start young, people who use frequently, people who use high potency, the odds ratio of developing schizophrenia go from two to four to six. Consistency, Sweden, Denmark, Israel, New

Zealand, the United States have all shown -- there's seven countries, I haven't mentioned all -- that early onset of marijuana use, and especially cannabis use disorder, is consistently a risk factor for developing schizophrenia across all these countries. The timing. Does schizophrenia begin before you start using marijuana, or does it begin after? Invariably, it begins after. The dose response. If you smoke more marijuana at higher potencies, is the risk increased? Yes, clearly. Biological plausibility. It's a problem. It's strong, but I would temper it a bit because we don't even know the origins of schizophrenia. We do know a few important data points. Almost every person who's treated for schizophrenia gets drugs that block dopamine D2 receptors. That is a given. All the antipsychotics that are effective, except one new category that just came on board a few years ago, they all have that in common. They block dopamine receptors. Marijuana increases dopamine in the brain. It regulates glutamate. It regulates GABA. So, we see dysregulation of dopamine, glutamate, and GABA in schizophrenia. Probably the strongest

point about biological plausibility is that marijuana-induced psychosis can be dampened by the same drugs that dampen schizophrenia.

What is used to alleviate the symptoms of marijuana-induced psychosis? The same drugs as schizophrenia. The specificity is weak. Schizophrenia has many, many origins. Infections in mother, preterm deliveries, trauma during childbirth, trauma of the child, genetics, and so, so many, many, many causes. Early extreme childhood stress. So obviously, cannabis doesn't cause schizophrenia in everybody, and obviously, there are many people who've developed schizophrenia who've never touched the drug, so the specificity is weak.

Moderate to strong, the experimental. Cyril D’Souza, DL, and a number of others. There are almost 19 studies now in which they've administered THC to otherwise normal people, and they develop psychosis symptoms at high doses. So the coherence, people who have a genetic predisposition for schizophrenia also have a predisposition for cannabis use disorder. There is some coherence in terms of the genetic susceptibility to it. There's some coherence in

terms of some of the brain changes. But the coherence could be deemed moderate or strong depending on how you want to interpret the data. But I would say six are pretty reasonable out of these and right now, the majority of psychiatrists, that I am familiar with and that have published, say that cannabis is a component cause of schizophrenia, not just an association.

Q In terms of the side effects, is there any difference between adult users of marijuana and minors or adolescents who use marijuana?

A Adolescents are much more vulnerable to the effects of schizophrenia, to all the consequences.

Q Can we go to the next -- can we explain why, if Dr. Madras?

A Yes, because so they're much more vulnerable to brain changes. The adolescent brain is vulnerable because it is undergoing tremendous changes, so different from the young latent periods of a child between 4 and 10, different than the early toddler phase, different than the fetal phase.

The frontal cortex of the adolescent brain is the last to mature. What is the

frontal cortex? It's the one that tells you cost-benefit equations. It's the one that predicts consequences if you're going to do something foolish. The amygdala, which is deep in the brain, is the emotional part of the brain, and the frontal cortex, as the brain develops, begins to dampen the emotional part of the brain. It reduces impulse control. It increases your ability to foresee the future and foretell the consequences of actions. Adolescents do not have that strong connection yet. They have many other changes that are ongoing, which we don't have time to do, but they're much more vulnerable to risk-seeking, and they feel the effects of drugs more profoundly than adults do. Adults also temper their responses because they know their responsibilities.

We can continue here and what is unknown by the vast majority of parents and the vast majority of youth is that the endocannabinoids are critical, critical, critical for brain development. They tell neurons, nerve cells, what type to become because the brain has many different types of

nerve cells. They guide them to their connections. They modulate the signals between them. The endocannabinoid system is critical for brain development during the fetal period and during the adolescent period.

Q Can changes in the adolescent brain attributable to marijuana use be seen in things like MRI studies and the like?

A Yes. One of my colleagues, Marisa Silveri, literally reviewed -- this is old, this is 2016. It's 10 -- she reviewed all the brain changes in adolescent marijuana users. This is magnetic resonance imaging, which can give you very different views of the brain. One type of imaging can give you the anatomy. One type of imaging can give you connectivity. One type of imaging can give you function, which part of the brain is functioning. And she found a number of changes -- she found in the literature, she surveyed the literature of all these multiple studies and showed that marijuana changes the brains of adolescents. The changes are very robust in that period, and some of the studies correlated these changes with impaired function, learning, memory, executive function.

Q On the subject of learning, how does marijuana use in adolescents affect academic performance and achievement?

A Yes. This is a very recent study and again, a meta-analysis of 63 studies which involved 438,000 individuals. Adolescent marijuana users are more likely to be absent from school, more likely to drop out from school, more likely to be unemployed. They're less likely to enroll in university, less likely to get post-secondary degrees, less likely to get high grades in school, less likely to complete high school.

Q And have there been studies that would tie IQ or intellectual quotient in--?

A Yes.

Q Adolescents to marijuana use as well?

A The first robust study was a longitudinal study, the Dunedin data from New Zealand, done by Madeline Meyer, who's now at the University of Arizona. In it, she showed that if a person begins using marijuana in adolescence and then persists in using it until they're 35 or older, that they have a drop of eight points in IQ. An eight-point drop is not

trivial. It drops a person from the 50th percentile average to the 29th percentile, which is below average, and IQ predicts access to university education, lifelong total income, access to a good job, performance on a job. The Dunedin studies showed persistent cannabis users had less skilled jobs than their parents, poor memory and attention. It was not explained by analysis of all the covariates: alcohol use, tobacco use, other illicit drug use, or family history of substance use disorders.

Q Now, in --

A This is her slide. She gave it to me.

Q In terms of a, well, a phrase we've used before, which is use disorder, I mean, how does that affect adolescents as compared to adults?

A Adolescents are much more vulnerable to developing a cannabis or marijuana use disorder. If you look at them, this is a study by Beth Hahn, Wilson Compton, Carlos Blanco, and Chris Jones at NIDA. What they showed is that after 12 months cannabis use, about 10 percent of adolescents showed symptoms of cannabis use disorder among the users. Among adults, it was

half. As you went up to year four, 20 percent of the kids showed symptoms of cannabis use disorder. The adults, only half of that.

Q In terms --

A By the way, Beth Hahn is one of the best epidemiologists we've had.

Q And in terms of the prevalence of cannabis use disorder among adolescents, how does that compare to alcohol use disorder in that demographic?

A It is now higher. Cannabis use disorder among adolescents 12 to 17 years old or among 18 to 25 years old is higher than alcohol use disorder. There's an increase in number of people. These are NSDUH, or National Survey on Drug Use and Health data, I gleaned these from the most recent report.

Q And have there been studies of the relationship in adolescence between cannabis use disorder and self-harm?

A There's an increased prevalence of suicidality, suicidal thoughts, suicide risk. If children with attention-deficit hyperactivity disorder use cannabis, their risks of suicide are higher than those who don't. Their risks of

conduct disorder are higher than if they don't. The risks of trying an attempt at suicide is higher than compared with if they don't use.

Q And is there any relationship between the use of marijuana among adolescents and the use of other drugs or other substances?

A Yes. There is definitively, definitely risk. The results are definitive. This was a study that was done with Beth Hahn, Bob DuPont, myself and Shea. And what we found is that adolescents, if they use marijuana, are almost 10 times more likely to smoke cigarettes, to binge on alcohol, to have heavy alcohol use, and to use illicit drugs.

Q Is there even a relationship between adolescent marijuana use and the use of opioids?

A Yes. The opioid -- this was a study done by Adway Wadeker. It was a very interesting study, and since then there's been a follow-up that's more powerful than this one, but he excavated the National Survey on Drug Use and Health and showed that the highest risk for opioid use disorder, higher than mental illness, an encounter with a drug seller, with age, with health, with easy access, with income, with

education, employment, alcohol use before 18, race, obesity, disability, gender, risk of trying heroin, probation. Every single confound, the risk is lower than if they begin marijuana use before the age of 18 -- the risk of developing an opioid use disorder.

Q What does the phrase multi-generational drug use mean, Dr. Madras?

A There is very solid evidence that parents who use drugs are very likely to have children who use drugs, and this extends to grandparents as well. Multi-generational. What we're seeing now is that 8 percent of parents living with children use marijuana most days, 5 percent use daily, 6.7 percent of parents have cannabis use disorder. Four times as many parents use it daily now than they did 12 years ago. This is from 24, which is where the data rise. More than 5.9 million children are living with parents who use marijuana most days and what is the consequence?

Q That was my next question. What is the consequence of this?

A This is a study. Again, this I did with Beth Hahn, Wilson Compton, Chris Jones, and

Eleanor McCance-Katzss, who was the head of SAMHSA at the time. We excavated again the NSDUH data and found that children living in the same home with either a mother or a father or both, who are 12 to 17 years old, if the parents never use, the child's use is between 5 and 10 percent. If the parents have a lifetime use of marijuana, but not the past year, which means they have a tolerance to it probably and think it's a rite of passage, but they're not currently using, the use rates of 12- to 17-year-olds go up to about 15 percent. If parents use in the past year less than 52 days or more than 52 days, the probability of a child using marijuana just escalates.

What is most interesting is that 18-to-30-year-old offspring who are living in the same household have the same risks. They too will mirror their parents use in terms of the risks of using.

Q Has the rise of medical marijuana and its availability in states attended to changes in youth attitudes about the use of marijuana?

A It certainly has. Youth now have the lowest perception of risk of marijuana since we

ever began to record these data. This is Monitoring the Future. This is 2022 data. I don't know why I don't have their most recent, but again, this is a slide I presented probably about three years ago. Their perception of risk of marijuana is only 27.6 percent of youth believe that marijuana has a risk, and that's an all-time low. It plummeted from 2007, where more than half of youth felt that way. But if you look at heroin, it's way up there. They think it's dangerous. Cocaine, they perceive as dangerous. Alcohol, more than five drinks a day, they think is dangerous. Tobacco, one pack a day, most think it's dangerous. LSD plummeting because of the hype in the media, but it is still over 50 percent. Only marijuana is the outlier. Their perception is that it's safe, it's non-addictive, it's a medicine.

Q And is there any relationship between the number of dispensaries in an area and the rate of use among adolescents?

A There is a correlation between the number of dispensaries. We also have to recognize that in an unregulated industry, a lot of the marijuana is being sold with packaging

that appeals to young people. But there is a correlation between the density of dispensaries, proximity to schools, and youth use.

Q Another question that's come up in the subject of abuse is the extent to which one person's using marijuana can have an effect on other people. And I mean, will use of marijuana in pregnancy have an effect on the mother?

A Yes. This is very recent. It just came out last year and it involved 356,000 pregnancies, so that's a very high number. What was shown, which actually surprised a lot of people, is daily marijuana use in the pre-pregnancy period gives rise to more nausea and vomiting during pregnancy. So, the risk of mild and severe nausea and vomiting in the first trimester increases if you use pre-pregnancy. The highest risk is daily use before and during pregnancy, the most severe forms of nausea and vomiting.

Q And in -- sorry, go ahead.

A So bud tenders who say, oh, it's going to relieve you, are just misinforming women.

Q In terms of maternal use of marijuana, what kind of effect does that have on the

developing fetus?

A There have been studies that are really compelling, and some are, I would say, strong, but we need more data. As I said, THC in marijuana interferes with the developing fetal brain because the role of THC in the developing brain is to tell nerve cells what shape and what function they should become. It is to guide them in terms of where they're supposed to touch other nerves and communicate with them. It organizes the brain. The brain has myriad circuits, circuits that involve motor function, circuits that involve sensory function, circuits that involve perception of self, circuits that involve perception of reality. Multiple circuits. And marijuana interferes with these developing, critical, developing processes. It changes signaling systems. It creates mistakes in the migration of nerves, because nerves actually move through the brain and set themselves into locations, not from locations where they're destined to go and these migratory patterns can change.

This was a study that was done about 12 years ago showing that, as I said, the

endocannabinoids promote birth of new neurons, tell them what type to become, guide them to the targets and form connections. But this was a study that was done with THC, and they found that the THC reorganizes the connections between nerve cells. It affects the circuits in the cortex. It disrupts development and maintenance of connections that are critical for executive and cognitive function. There are other studies like that, this is just an example.

So, what we find is that there are brain changes with prenatal marijuana exposure and these are pre-clinical, the brain changes, because it's very difficult to do this in humans. But they change signaling, cell growth, migration errors. There's lower white and gray matter, and there are changes in the morphology, the shape of the cells. At birth, these are done by obstetricians, gynecologists, and researchers. There's pre-term birth, premature births. The head circumference is smaller. Birth weight is lower. More admissions into the neonatal intensive care unit. Then the last four are studies that were done retrospectively on women who use marijuana in the ABCD study,

which is the Adolescent Brain and Cognitive Development study, which is an ongoing study that, hopefully, will continue for years. What they found is that children who were exposed to marijuana had attention, cognitive, executive function deficits, social problems, proneness to psychosis, and problems with sleep. And all of these changes, again, are retrospective, so it's very difficult to really do a controlled clinical trial. You can't, it's unethical. But these are studies that I temper with the fact that they're retrospective, so you have to ask the mother if they recall using.

Q The last subject that I want to cover with you, Dr. Madras, concerns the testimony we've received so far concerning the difference in overdoses between opioids, cocaine, and other substances on one hand, and marijuana on the other. Can you explain how, for example, opioids affect the brain and how that compares to how marijuana does?

A Well, opioids do serve very primitive functions, including heart rate and breathing. This is a cross-section of a brain. It was done by Miles Herkenham at NIH, and he gave me these

slides many years ago showing the red areas are areas where there are cannabinoid CB1 targets. This is where marijuana works in the brain. And that blue shape is the brain stem. That is the area of the brain that controls breathing. What you can see is that area's almost empty of red. There are no cannabinoid receptors there, so it does not affect breathing. This is the new opioid receptor imaging. Cross-sectional, again, very similar. And what you can see is that -- that is the brain stem, and it's chock-full of opioid receptors, and these receptors regulate breathing. And when you sledgehammer them with opioids, breathing slows down and stops. So, marijuana will not kill you with an overdose. It can kill you in other ways: suicidality, traffic accidents, many other causes, but it's not instant death that opioids can produce.

Q What does the phrase mechanism of action mean in the context of psychoactive drugs?

A It is important to recognize that every psychoactive drug, other than alcohol, which is just a solvent that affects multiple systems in

the brain, every psychoactive drug acts on specific communication systems in the brain. Marijuana acts on the cannabinoid system. Cocaine acts specifically on the dopamine, and so does methamphetamine. LSD acts on the serotonergic system. Heroin acts on the opioid system. Every single drug that we know acts on different signaling systems in the brain. Their consequences depend on the type of signals that they are attacking, and modulating, and affecting, and causing to adapt.

Comparing drugs in terms of, well, this one has more overdoses, death, of course, as an outcome is a terrible thing, but schizophrenia is a terrible thing. Addiction is a terrible thing. There are many, many different consequences of drugs that are dependent on the targets of those drugs in the brain.

Q Dr. Madras, thank you very much.

A You're very welcome.

Q I have no further questions.

JUDGE JULIUS: Thank you. The time is now 11:48. I still think it's good for us to take our lunch break and then begin cross-examination. Let's still plan to come back at

1:00. We'll get a little bit more than an hour for lunch today. I don't anticipate any problems from anyone with that. We will come back at 1:00.

Doctor, please enjoy your lunch, but don't discuss your testimony with anyone during the lunch break.

THE WITNESS: Silence.

JUDGE JULIUS: Excellent, and we'll be in recess until 1:00. Have a good lunch everyone.

(Whereupon, the above-entitled matter went off the record at 11:48 a.m. and resumed at 1:00 p.m.)

JUDGE JULIUS: Before we took our lunch break, I think we were ready for cross-examination. Counsel, whenever you're ready.

CROSS-EXAMINATION

MR. MALEY: Thank you, Your Honor. Good afternoon, Dr. Madras.

THE WITNESS: Good afternoon.

BY MR. MALEY:

Q If you're ready, we'll go ahead and begin.

A Yes, please.

UNKNOWN: Directional mics for the audience.

JUDGE JULIUS: One moment.

MR. MALEY: How about now? Any better?

JUDGE JULIUS: There we go. I can hear it now, too. Thank you.

MR. MALEY: Would you like me to repeat that?

JUDGE JULIUS: Go ahead and I think the record caught it, but just for everyone's –

MR. MALEY: Sure.

JUDGE JULIUS: Awareness.

MR. MALEY: Dr. Madras, if you're ready, we'll go ahead and begin.

THE WITNESS: I'm ready. Thank you.

BY MR. MALEY:

Q Dr. Madras, you'd agree with me that the study of marijuana and its use is a complex subject, correct?

A Yes.

Q You'd agree that there are numerous types of inquiry, methods of evaluation, ethical considerations at play in the study of marijuana and its use?

A Yes.

Q And you'd agree with me that there are several types of professionals with various backgrounds and interests involved in the study of marijuana and its use, correct?

A Yes.

Q That there are scientists and researchers, who hold PhDs and work in academia, such as yourself?

A Yes.

Q And that there are doctors of pharmacy evaluating the pharmacological effect of marijuana, correct?

A Yes.

Q And there are doctors of medicine evaluating the medical utility of marijuana, correct?

A Yes.

Q And to be clear, I think we discussed this a little bit on direct examination, you are not a medical doctor, correct?

A No.

Q And you are not a doctor of pharmacy, correct?

A Correct.

Q But it'd be fair to say that you have

dedicated a significant portion of your professional career to the study of addiction, correct?

A It would be fair to say that I've conducted a significant portion of my career to the study of drug effects on brain, body, and behavior.

Q And that would include --

A Which includes in addiction.

Q Thank you. And that would include addictive substances like opioids, correct?

A Yes.

Q And that would include marijuana?

A Yes.

Q And you'd agree with me that in your role, both at Harvard and McLean Hospital, you stay up to date on the body of literature on the science of addiction and the effects of addictive substances on the brain?

A Yes.

Q And again, that includes with respect to marijuana?

A Yes.

Q And you'd agree that there are a large number of studies that have been conducted

regarding marijuana, correct?

A Yes. There are over 50,000 in science citation.

Q And especially with regard to other controlled substances, correct?

A I'm sorry. Could you clarify the question?

Q You would agree that there are a large number of studies regarding marijuana as compared to other controlled substances, correct?

A In comparative studies, there are some. That's not the majority.

Q And you'd agree with me that all these different professionals that we talked about may reach different conclusions in their studies with marijuana, correct?

A Yes.

Q And you'd agree with me that all of these different types of professionals that we just discussed, scientists, researchers, doctors of pharmacy, medical doctors, and the like, conduct their studies with different perspectives, correct?

A I don't understand what different

perspectives mean. Do you mean different professional training or do you mean different views on drugs?

Q Different views on drugs.

A Yes.

Q And if we could turn briefly to something that you've discussed on your direct examination regarding your positions in or related to government service. You testified earlier today that you have served in two significant roles: one, you described as the deputy director for the Office of Demand Reduction in the White House's Office of National Drug Control Policy.

A Yes.

Q Quite a mouthful. And you served as a member on the President's Commission on Combating Drug Addiction and the Opioid Crisis, correct?

A Yes, that's correct.

Q And it'd be fair to say, while you have served in these roles, you have never been an employee of the Food and Drug Administration, correct?

A I have never been an employee of the

Food and Drug Administration. I have been privy to a submission to the Food and Drug Administration for an approval of an imaging agent, so I'm quite familiar with the process.

Q But you'd agree with me that you've never been an employee of the FDA?

A No.

Q And you've never been an employee of the Department of Health and Human Services, correct?

A Correct.

Q And you would agree with me that any scheduled drug is dangerous?

A Oh, I would agree that any scheduled drug has psychoactive effects, but the level of danger certainly depends on the schedule and the data.

MR. MALEY: Nothing further, Your Honor.

JUDGE JULIUS: Thank you, Counsel. Before we move to redirect, I have a question that might -- just for development of the record and making sure I understand the scope --

THE WITNESS: Yes.

JUDGE JULIUS: Of your opinions and your

testimony today.

THE WITNESS: Yes.

JUDGE JULIUS: When you first started, you mentioned what the definition of marijuana, and I believe I heard you list three different kinds?

THE WITNESS: Strains, yes.

JUDGE JULIUS: Okay. Are you familiar with the Controlled Substance Act definition of marijuana?

THE WITNESS: Yes.

JUDGE JULIUS: Okay. So I'm referring to 21 United States Code Section 802, Section 16A.

THE WITNESS: Yes.

JUDGE JULIUS: Subject to subparagraph B, the terms marijuana and marijuana, spelled variously with a J or an H, mean all parts of the plant Cannabis sativa L., whether growing or not; the seeds thereof; and resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds, or resin. And then subpart B discusses what's not included.

THE WITNESS: Yes.

JUDGE JULIUS: In the definition of marijuana, such as hemp and other items. So I guess my question to you is, to what extent does your opinion regarding marijuana that you've testified today vary, if at all, if limited solely to the Controlled Substance Act definition of marijuana?

THE WITNESS: Well, my definition of marijuana would be every form, every product form of marijuana that is distinct and unique from the isolated cannabinoids that have been approved by the FDA. So, the FDA has approved cannabidiol. It's approved THC, and it's approved nabilone, which is a synthetic analog of THC. Those are uniquely different than products that are botanical whole products, seeds, complex mixtures that are not subsumed by these four substances that have been approved by the FDA. So Marinol, which is dronabinol, and Syndros, both of those are THC, are in Schedule III, and they're relatively pure products. Cannabidiol, which has the trade name Epidiolex, is unscheduled currently. Those are purified forms of fixed doses with an extensive

literature on the pharmacokinetics, all the important information that's needed in terms of prescribing. All the other marijuana that's part of the CSA is unregulated in terms of dose, purity, and composition of matter, and I think that those are the ones I referred to today.

JUDGE JULIUS: Okay. Thank you very much.

THE WITNESS: Yes.

JUDGE JULIUS: Doctor, I should have allowed government, do you have any follow-up questions based on Court's question?

MR. MALEY: No, Your Honor.

JUDGE JULIUS: Okay. I just wanted to be fair. Redirect whenever you're ready, Mr. McNichols.

MR. McNICHOLS: I have no redirect, Your Honor.

JUDGE JULIUS: Oh, okay. There we go. Is there any possibility that you would recall the doctor?

MR. McNICHOLS: No.

JUDGE JULIUS: Okay. So, your testimony is now complete. You are free to leave, and you are free to discuss your

testimony since there's no opportunity to recall.

THE WITNESS: Thank you very much.

JUDGE JULIUS: Thank you very much for your testimony, Doctor.

THE WITNESS: Thank you.

MR. McNICHOLS: One question on that, Your Honor.

JUDGE JULIUS: Yes.

MR. McNICHOLS: I know it's been of some interest to Dr. Madras. Would there be any problem if she were to attend the trial tomorrow to listen to additional testimony by other witnesses?

JUDGE JULIUS: If she's just going to attend as an observer and not testify further, I don't see any issue with her coming in as a member of the public.

MR. McNICHOLS: Thank you.

JUDGE JULIUS: Thank you.

COURT REPORTER: I do have one spelling question for her. Please, can I ask her?

JUDGE JULIUS: Yes, go ahead.

COURT REPORTER: Thank you. When you were asked whether you would agree that there

are a large number of studies that have been conducted regarding marijuana, and you said, yes, there are over 50,000, and then you named something in the database -- there over 50,000 in Science Citation?

A No, 50,000 in PubMed and -- that are accessible to Science Citation Index.

Q Science Citation Index.

A Yes.

Q Okay. Thank you.

A But PubMed is the National Library of Medicine that accumulates all quality journal articles, and there are over 50,000 currently.

JUDGE JULIUS: Excellent. Thank you. Thank you very much, Doctor.

THE WITNESS: Thank you.

JUDGE JULIUS: And so I think the next step would be your second witness, who was not subpoenaed to come until tomorrow. Is that correct?

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

JUDGE JULIUS: Okay. So I think that may be it for us as what we can accomplish today. So thank you, everyone. We will convene tomorrow at 9:00 in the morning. As always,

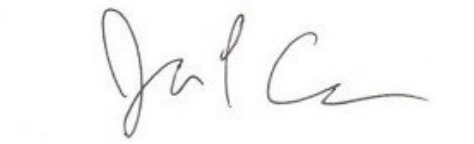
everyone have a good evening, and we will see you tomorrow at 9:00. We'll be in recess until then. Thank you.

THE BAILIFF: All rise.

(Whereupon, the above-entitled matter went off the record at 1:11 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