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,
June 29, 2026

700 Army Navy Drive
Arlington, Virginia 22202

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

BEFORE:

THE HONORABLE DEREK C. JULIUS,
Chief Administrative Law Judge

APPEARANCES:

On Behalf of the Government:

JAMES J. SCHWARTZ, ESQ.
STACY M. RACE, ESQ.
LISA K. MAN, ESQ.
Office of Chief Counsel
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, Virginia 22152
[redacted]

On Behalf of the National Drug and Alcohol Screening Association:

DAVID G. EVANS, ESQ.
[redacted]

PATRICK D. KENNEALLY, ESQ.
Burke Law Group, PLLC
[redacted]

On Behalf of the Tennessee Bureau of Investigation:

REED N. SMITH, ESQ.
Assistant Attorney General
Office of the Tennessee Attorney General
[redacted]

APPEARANCES: (continued)

On Behalf of Smart Approaches to Marijuana:

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

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

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

On Behalf of DUID Victim Voices:

PATRICK D. KENNEALLY, ESQ.
Burke Law Group, PLLC
[redacted]

DAVID G. EVANS, ESQ.
[redacted]

APPEARANCES: (continued)

On Behalf of Kenneth Finn, M.D.:

PATRICK D. KENNEALLY, ESQ.
Burke Law Group, PLLC
[redacted]

DAVID G. EVANS, ESQ.
[redacted]

ALSO PRESENT:

GRAYSON E. PHILLIPS, ESQ., Law Clerk
LUKE NIFORATOS, Executive Vice President of Smart Approaches to Marijuana (SAM)
VERONICA S. JAE, ESQ., Associate Chief Counsel, U.S. Food & Drug Administration

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

(9:01 a.m.)

JUDGE JULIUS: Good morning. We are on the record in the matter of Schedules of Controlled Substances: Proposed Rescheduling of Marijuana, Hearing Docket Number 2026 96, DEA Docket 1362.

Today is June 29, 2026. I am Derek C. Julius, Chief Administrative Law Judge at the Drug Enforcement Administration, or DEA.

The DEA Administrator designated me to preside over this hearing. This is a formal administrative hearing conducted under the Administrative Procedure Act, Controlled Substances Act, or CSA, and implementing regulations.

This hearing is being conducted at the DEA hearing facility in Arlington, Virginia, with the Government and its witnesses participating in person, counsel for interested persons and pro se interested persons appearing in person, and some witnesses for the interested persons appearing in person and others appearing remotely via VTC.

This hearing follows a May 21, 2024,

Notice of Proposed Rulemaking in which the U.S. Department of Justice proposed transferring marijuana from Schedule I of the CSA to Schedule III, consistent with the view of the Department of Health and Human Services, or HHS, that marijuana has a currently accepted medical use, as well as HHS's view about marijuana's abuse potential and level of physical or psychological dependence.

The proposed rule specified the changes to Title 21 of the Code of Federal Regulations; namely, amending 21 CFR Section 1308.11 regarding Schedule I controlled substances by removing paragraphs (d)(23) and (58), and redesignating paragraphs (d)(24) through (57) and (59) through (104) as paragraphs (d)(23) through (102), respectively; and revising newly redesignated paragraph (d)(30).

Further, the proposed rule would amend 21 CFR Section 1308.13 regarding Schedule III controlled substances by adding paragraphs (h) through (j). The specific language of those regulatory changes is found in the Federal Register Notice for the proposed rulemaking and is incorporated by reference.

Under the proposed rule, if the transfer of marijuana to Schedule III is finalized, the regulatory controls applicable to Schedule III controlled substances would apply, as appropriate, along with existing marijuana specific requirements and any additional controls that might be implemented, including those that might be implemented to meet U.S. Treaty obligations.

If marijuana were transferred into Schedule III, the manufacture, distribution, dispensing, and possession of marijuana would remain subject to the applicable criminal prohibitions of the CSA. Any drugs containing a substance within the CSA's definition of "marijuana" would also remain subject to the applicable prohibitions in the Federal Food, Drug, and Cosmetic Act.

An August 29, 2024, Notice of Hearing on this proposed rulemaking was ultimately withdrawn and those proceedings terminated.

On April 22, 2026, Acting Attorney General Todd Blanche issued a final rule that, in relevant part, placed drug products containing marijuana that had been approved by

the Food and Drug Administration, or FDA, and marijuana subject to state licenses -- strike that, subject to state issued licenses, into Schedule III of the CSA.

That same day, Acting Attorney General Blanche issued a new Notice of Hearing on this proposed rulemaking. That notice instructed that all potential, quote, "interested persons," end quote, as defined in 21 CFR Section 1300.~~00~~01(b), on the process of filing written notices of intention to participate in the hearing.

On June 18, 2026, after reviewing the written notices of intention to participate, the DEA Administrator granted seven interested parties' participation requests. Those seven interested persons, and the Government collectively, constitute the designated parties who will participate in this hearing.

The issue in this hearing is to determine whether marijuana, as statutorily defined in the CSA at 21 U.S.C. Section 802A , other than the products already scheduled in Schedule III, should be moved to Schedule III of the CSA.

Counsel for the Government and numerous interested persons are present in the courtroom. We were advised that pro se interested party Phillip A. Drum, PharmD, would not be present today, which is consistent with the preliminary order stating that counsel and parties need not be present for days on which they were not presenting their case in chief. Parties are advised that non appearance on a day of this hearing is deemed a waiver of the right to cross examine a witness or raise objections to testimony for that day.

I will now ask that counsel present today state their appearances as I identify each designated party. Will Counsel for the Government please state their appearance?

MR. SCHWARTZ: Good morning, Your Honor. We have James J. Schwartz for the Government, and at counsel table with me I have Stacy Race and Lisa Man.

JUDGE JULIUS: Very good. Thank you, Mr. Schwartz.

Will Counsel for National Drug and Alcohol Screening Association please enter your appearance?

MR. EVANS: Good morning, Your Honor. My name is David Evans, and I represent NDASA.

JUDGE JULIUS: Very good, sir.

MR. KENNEALLY: Good morning, Your Honor. Patrick Kenneally, and I also represent NDASA.

JUDGE JULIUS: Excellent.

Will Counsel for Tennessee Bureau of Investigation please note your appearance?

MR. SMITH: Good morning, Your Honor. Reed Neal Smith on behalf of the Tennessee Bureau of Investigation.

JUDGE JULIUS: Good morning, sir.

Will Counsel for Smart Approaches to Marijuana please state your appearance?

MR. McNICHOLS: Good morning, Your Honor. John McNichols from Torridon Law. We're here with Patrick Philbin, Chase Harrington, and Luke Niforatos on behalf of Smart Approaches to Marijuana.

JUDGE JULIUS: Good morning to you all.

Will Counsel for the Opposing States, Nebraska, Idaho, and Indiana, please enter or state your appearance?

MR. McNICHOLS: That's also me, Your

Honor, on behalf of Torridon Law. I'm accompanied by Chase Harrington and Zach Horton, also of my law firm.

JUDGE JULIUS: Thank you very much. I will note that Louisiana, previously an interested person in this case, withdrew, so the Opposing States are still Nebraska, Idaho, and Indiana.

Will Counsel for DUID Victim Voices please state your appearance.

MR. KENNEALLY: Good morning, Your Honor. Patrick Kenneally on behalf of DUID Victim Voices.

MR. EVANS: Again, Your Honor, David Evans on behalf of DUID Victim Voices.

JUDGE JULIUS: Thank you, gentlemen.

And will Counsel for Kenneth Finn, M.D. please enter your appearance.

MR. KENNEALLY: Your Honor, Patrick Kenneally on behalf of Ken Finn, along with David Evans.

JUDGE JULIUS: Thank you both again.

For the clarity of the record, we will take a similar roll call of appearance at the beginning of each day just to note who is

present.

I issued a preliminary order and other standing orders regarding the conduct of this hearing in accordance with 21 CFR Section 1316.59(f). I'm including those in the record, along with Administrative Law Judge, or ALJ, Exhibits 1 through 59.

(Whereupon, the above-referred to documents were marked as ALJ Exhibits Nos. 1 through 59 for identification.)

JUDGE JULIUS: In addition, I am in receipt of the National Drug and Alcohol Screening Association's prehearing statement, which was not originally included as an ALJ exhibit, but I will hereby incorporate that as ALJ Exhibit 60, and that will be reflected in an updated table of contents following this hearing.

(Whereupon, the above-referred to document was marked as ALJ Exhibit No. 60 for identification and was received into evidence.)

JUDGE JULIUS: I'm also currently in receipt of virtual copies of Government Proposed Exhibits 1 through 6 for identification.

(Whereupon, the above-referred to

documents were marked as Government Exhibits Nos. 1 through 6 for identification.)

JUDGE JULIUS: I note that Government Proposed Exhibits 1 and 3 were already included as ALJ exhibits, and Government Proposed Exhibits 2, inclusive of Tabs A through D and 4 were subject to a granted unopposed motion to take administrative or judicial notice. So those are already part of the record.

I'm also in possession or receipt of virtual copies of National Drug and Alcohol Screening Association Proposed Exhibits 1 through 15 for identification; Tennessee Bureau of Investigation Proposed Exhibits 1 through 32 for identification; Smart Approaches to Marijuana Proposed Exhibits 1 through 44 for identification; the Opposing States Proposed Exhibits 1 through 19 for identification; DUID Victim Voices Proposed Exhibits 1 through 84 for identification; Kenneth Finn, M.D., Proposed Exhibits 1 through 110 for identification; along with affidavits marked as Stack Proposed Exhibits 1 through 84 for identification.

(Whereupon, the above-referred to documents were marked as NDASA Exhibits Nos. 1

through 15 for identification.)

(Whereupon, the above-referred to documents were marked as TBI Exhibits Nos. 1 through 32 for identification.)

(Whereupon, the above-referred to documents were marked as SAM Exhibits Nos. 1 through 44 for identification.)

(Whereupon, the above-referred to documents were marked as States Exhibits Nos. 1 through 19 for identification.)

(Whereupon, the above-referred to documents were marked as DUID Exhibits Nos. 1 through 84 for identification.)

(Whereupon, the above-referred to documents were marked as Kenneth Finn Exhibits Nos. 1 through 110 for identification.)

(Whereupon, the above-referred to documents were marked as Stack Exhibits Nos. 1 through 84 for identification.)

JUDGE JULIUS: And, finally, Phillip A. Drum, PharmD, Proposed Exhibits 1 through 67 for identification.

(Whereupon, the above-referred to documents were marked as Phillip A. Drum Exhibits Nos. 1 through 67 for identification.)

JUDGE JULIUS: If any party seeks to introduce an exhibit that has not yet been provided, that party will need to seek permission and demonstrate good cause for the late filing. Parties are also reminded, if they have not already done so, that they are required to provide hard copies of their exhibits consistent with the preliminary order by no later than the morning of their assigned day to present.

These proceedings are being conducted with some use of VTC. A unique VTC link will be provided by my law clerk to the parties that provided notice that one or more witnesses would be testifying via VTC. That link will be provided no later than the day before the party will be required to appear.

I remind everyone, including parties and attendees in the gallery, that the only recording permitted is the recording generated by the contract reporting company, and permission is expressly withheld from anyone else to do so.

If anyone is observed on a cell phone or using any other recording capable device,

including, but not limited to, any device that can produce a picture, video, or audio capture or recording, such as a Smartwatch, or if their cell phone is heard during the hearing, they will be removed by DEA security.

We have arranged to provide expedited electronic copies of transcripts to the parties. Transcripts of each day's proceedings in PDF format will be provided to the parties by this tribunal within two business days of that day's proceedings.

At the conclusion of this hearing, each party will have the opportunity to propose corrections to the transcript as required by agency regulations. I will provide more instructions on this following the hearing. The full, final, corrected transcript of these proceedings will be posted to the DEA website.

This hearing is scheduled to begin today, June 29, 2026, and conclude on July 15, 2026, recessing only on July 3, 2026, for the federal Independence Day holiday.

Each day, we will commence the proceedings promptly at 9 a.m. Eastern Time and finish no later than 5 p.m. Eastern Time.

There will be a 60 minute lunch break each day at noon and short 15 minute comfort breaks in the morning and afternoon sessions.

If anyone needs to leave the courtroom or gallery during the hearing, please use the two courtroom doors in the back. If you are not a DEA employee, you will need to be escorted outside of this courtroom. Please do not use the emergency exits to the side of the courtroom unless there is a true emergency. An alarm will sound.

Those with visitors badges must wear them in a visible area at all times while inside the DEA building and courtroom. If you lose your visitor's badge, you will not be granted reentry.

I remind everyone that there will be no colloquy between counsel, and apart from opening statements or when directed by me, there will be no argument presented during the proceedings. Because of the numerous parties and counsel, I anticipate that objections may require coordination to address in an orderly fashion for clarity of the record, especially if multiple parties object to the same matter.

Each designated party should internally identify a single person to raise objections to the tribunal on behalf of that party. If there is an objection, counsel or the pro se party will please stand, say the word "objection," and wait to be recognized by me, at which time that counsel or pro se interested party will identify themselves by name, state which designated party or parties they represent, and then concisely state the rule and raise -- reason for the objection.

I will allow the opposing party to briefly respond. I will then rule on the objection, and the hearing will continue without further discussion.

Pro se and counsel for interested parties, if they are able, should stand when making objections, examining a witness, or addressing the Court.

Examinations will be conducted at the podium. My law clerk will keep the official time for each party's opening statements and examinations. A five minute warning will be provided when the party has five minutes remaining in each particular session. The

official time for examinations will begin when the first question is asked. Questions I ask of the witnesses, if any, will count against the party's total time. Time spent discussing objections to any question during examination will not count against the time limit for the party conducting the examination.

Are there any issues to address before I turn the case over to the Government for their case in chief? Yes, Mr. Evans.

MR. EVANS: Yes, Your Honor. David Evans, representing NDASA and Dr. Finn and Edward Wood. Your Honor, I would like you to look at DEA Exhibit 4, which I believe you have, page 3. Exhibit 4, page 3.

JUDGE JULIUS: Okay.

MR. EVANS: If the Court and the DEA counsel will look at the footnote on page 3, and I'll read it for the record. "Footnote 1. This opinion memorializes advice we provided you on February 16th, 2024. To aid our analysis, we solicited and received written views from HHS and DEA on all -- on all three questions, and from the State Department on the third question.

"See Memorandum for the Office of Legal

Counsel from DEA, January 30th, 2024, DEA response. Memorandum for Gillian E. Metzger, Deputy Assistant Attorney General, Office of Legal Counsel, from Samuel Bagenstos, General Counsel, HHS, re OLC's request for reviews on issues related to the scheduling of marijuana under the Controlled Substances Act, January 29th, 2024, HHS response.

"Single convention requirements for cannabis and scheduling under the Controlled Substances Act, February 12th, 2024, state response."

Your Honor, I'm bringing this up because it has come to my attention that at the time that this was written and -- and this references the beginning of 2024 -- you served as the head of the Foreign Division of the DEA's Office of Legal Counsel.

It appears from this footnote that there were some issues that were raised regarding the State Department, regarding the single conventions. If you, in any way, had anything to do with any of those opinions, your choice is to recuse yourself as the judge. I'm not making a motion at this point because I

don't have enough information. I'm merely asking that the counsel and Your Honor look into this to see if there's any reason for concern.

I'm bringing this up because in law school, and when I got admitted to the bar, I took an oath to zealously represent my client. And I mean no offense to the Court, but I would be remiss if I didn't address this issue. We're just seeking clarity at this point.

Thank you, Your Honor.

JUDGE JULIUS: Thank you very much, Mr. Evans.

Would anyone else like to be heard on this issue?

MR. McNICHOLS: No, Your Honor.

MR. SMITH: No, Your Honor.

JUDGE JULIUS: Government?

MR. SCHWARTZ: Nothing, Your Honor.

JUDGE JULIUS: I can -- I can state that I had nothing to do with anything that went over to HHS on this. Anything that would have come from the State Department would have come from the State Department, not from my section. The foreign section that I was the head of advised our then 92 foreign offices on

operational matters. I -- I had nothing to do with

MR. EVANS: Well, we're primarily concerned about the Memorandum for Office of Legal Counsel from the DEA.

JUDGE JULIUS: Well --

MR. EVANS: And there -- there seemed to have been an opinion also from the -- that office. So I think the Court has cleared it up. If the Court has a memory of this, we will certainly

JUDGE JULIUS: I had nothing to do with that. I know there was an Office of Legal Counsel Memorandum, and that would be from main Justice. I don't know anything about this memo that came from DEA counsel's office, if there were one.

MR. EVANS: I appreciate you clearing that up, Your Honor. Thank you.

JUDGE JULIUS: Absolutely. Thank you for bringing that up. I understand, and I took no offense to your -- to your raising the issue. I'm very interested in making sure that we have a full, fair hearing as well, so I very much appreciate you raising the issue, so that we can

clarify that.

MR. EVANS: Well, my experience with DEA administrative judges has been very positive, and so

JUDGE JULIUS: Very good. I hope to

MR. EVANS: -- I'm happy to hear your response.

JUDGE JULIUS: I very much hope to keep that trend going.

MR. EVANS: Okay.

JUDGE JULIUS: Thank you, sir.

Any other matters before I hand the case over to the Government for their case in chief? Yes, sir.

MR. SMITH: Your Honor, on behalf of TBI, I just have one question of clarification. So TBI has only designated one witness in this case, but the schedule for presentation day addresses == schedules us as if we have two witnesses. I just wanted to seek some clarification on that issue.

JUDGE JULIUS: That may be a clerical error. You would have four hours for your single witness as opposed to two hours for two. So to the extent the schedule inadvertently

reflects two hours for one witness, two hours for a second, the second witness should just be viewed as the -- the second two hours for your single witness.

MR. SMITH: Okay. Thank you, Your Honor.

JUDGE JULIUS: Thank you very much for clarifying.

Anything else?

MR. McNICHOLS: Not from us, Your Honor.

JUDGE JULIUS: Okay. Thank you, everyone.

Mr. Schwartz?

MR. SCHWARTZ: Thank you, Your Honor.

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

MR. SCHWARTZ: Good morning, Your Honor. The Government is here today as the proponent of the proposed rule signed by a previous attorney general recommending the movement of marijuana from a Schedule I to a Schedule III controlled substance.

As proponents of the rule, the Government will be presenting witnesses and

documents supporting that recommendation. At the outset, however, it is important to note two things that this hearing is not about.

First, it is not about recreational use of marijuana. It is about regulation, not legalization. By definition, all controlled substances in Schedule II through V must have a currently accepted medical use and must be issued to an ultimate user by a practitioner who has made a determination that there is a legitimate medical use for the substance.

Second, regarding currently accepted medical use, the hearing cannot be about whether the two part test used by HHS in determining currently accepted medical use is legally permissible. That decision has already been made. The United States Department of Justice's Office of Legal Counsel issued its opinion in 2024 that satisfying HHS's two part inquiry is sufficient to establish that a drug has CAMU, currently accepted medical use, even if the drug has not been approved by the FDA. That decision is binding on the Department of Justice, including the DEA and this Tribunal.

In support of the proposed rule, the

Government is providing two -- two witnesses to assist the Tribunal, a scientist and a practitioner. This will provide the Tribunal with a wide range of facts and opinions to assist it in its determination.

The first witness is Dominic Chiapperino. Dr. Chiapperino is a scientist who has been employed at the Food and Drug Administration since 2002. Dr. Chiapperino will testify FDA performed a rigorous 10 month categorical analysis of marijuana as legally defined by the Controlled Substances Act to determine whether FDA could recommend a rescheduling of marijuana.

This analysis utilized a team of highly trained professionals performing the review, including physicians, pharmacologists, and epidemiologists. The 10 month analysis ultimately led to a recommendation that marijuana is best placed in Schedule III.

Dr. Chiapperino will testify about the important takeaways from FDA's analysis and recommendation. A significant part of the work performed by FDA was a determination that marijuana has a currently accepted medical use

for drug scheduling purposes. Dr. Chiapperino will discuss that determination and the test that was applied by FDA to make that decision.

He will testify that ultimately FDA determined marijuana has a currently accepted medical use for three conditions: anorexia associated with a medical condition, nausea and vomiting associated with chemotherapy treatment, and for the treatment of pain. Importantly, Dr. Chiapperino will also discuss FDA's analysis of the CFR -- of the CSA 812(b) factors as to the proper schedule for placement of marijuana after the determination that it has a currently accepted medical use.

He will testify that FDA recommended the best placement for marijuana, pursuant to 812(b), is in Schedule III. This was based on an analysis of comparator controlled substances in Schedules I through IV, looking at things like abuse potential, physical dependence, including withdrawal symptoms, and psychological dependence.

He will also testify as to why, based on the FDA analysis, marijuana no longer fits the statutory definition for Schedule I

controlled substance.

The Government's second witness is Dr. Cory Burchman. Dr. Burchman has been a physician for over 30 years and practiced as a board certified anesthesiologist and pain management physician until 2019. Dr. Burchman is an important witness for Your Honor because, while FDA's work on recommending that marijuana should be moved to Schedule III is comprehensive, the testimony from a physician who can describe the real world impacts of treatment of pain with marijuana versus other controlled substances, like opioids, will be of great assistance to the Tribunal.

Dr. Burchman has an extensive career treating pain, which includes the use of both opioids and marijuana for that treatment, and he can discuss in a practical setting the impacts it has on patients.

Dr. Burchman will testify to his observations and experience comparing opioids and marijuana for the treatment of pain based on such things as effectiveness, habituation, withdrawal, and safety concerns. He will also discuss how he has personally successfully

transitioned patients from opioid to marijuana for treatment of their pain.

He will be able to -- to describe, based on his tenure as a physician and his education, the risks of opioid dependence on his pain patients and his experience with outcomes for patients who now use marijuana to treat pain. As part of the comparison between opioids and marijuana, Dr. Burchman will discuss the significant differences in opioid versus marijuana withdrawal.

He will also discuss the vastly different dangers posed by marijuana overdose versus an opioid overdose. Based on his many years as a practitioner, he will describe personal interventions he has performed in opioid overdose cases and that he has seen hundreds of tragic opioid overdose deaths.

This is in stark contrast to his experience with marijuana overdose. Dr. Burchman will testify he has not seen a single overdose death that resulted exclusively from a marijuana overdose.

Lastly, Dr. Burchman will testify basically regarding the nuts and bolts of

prescribing marijuana to actual patients. He will describe the process by which he prescribes marijuana for pain, the guidance he gives to his pain patients who choose marijuana. This includes guidance on product concentration and dosing, and he will also describe how he ensures compliance with his recommendations for use of marijuana for his patients.

Finally, Dr. Burchman will testify about safety measures within the New Hampshire marijuana industry -- he's a New Hampshire practitioner -- the safety measures within the New Hampshire marijuana industry that ensure patients receive marijuana that is safe for consumption.

As Your Honor reviews the proposed rule, the supporting documents from HHS, and listens to testimony from the Government witnesses, it is important to note you will not read in the documents -- what you will not read in the documents nor hear from any of the Government witnesses.

The Government is not putting forth any evidence to suggest that marijuana is not dangerous. All controlled substances by

definition are dangerous. That is why they are scheduled in the first place. However, controlled substances must be evaluated by the risks they pose balanced with the medical use they provide.

The proposed rule, the supporting documents, and the Government witnesses will establish that marijuana has a currently accepted medical use. With that determination, marijuana can no longer remain in Schedule I. Thus, the evidence will show in totality, when analyzed with the 812(b) factors, marijuana as a controlled substance best fits within the definition of a Schedule III controlled substance.

Thank you, Your Honor.

JUDGE JULIUS: Thank you, Mr. Schwartz.

MR. SCHWARTZ: My co-counsel, Ms. Man, will take it from here.

JUDGE JULIUS: Okay.

MS. MAN: Good morning, Your Honor.

JUDGE JULIUS: Good morning, Ms. Man.

MS. MAN: The Government would call Dr. Dominic Chiapperino to the stand.

JUDGE JULIUS: Okay.

MR. PHILLIPS: We have to get him.
MR. SCHWARTZ: Yeah, he's in the
JUDGE JULIUS: Feel free to send someone to go get him --
MR. SCHWARTZ: Okay.
JUDGE JULIUS: -- wherever he is.
MS. MAN: I hope it's where we left him.
And, Your Honor, just so -- for ease, I know there are some ALJ exhibits. How would you like me to present them to Dr. Chiapperino? I know the Government's hard copies are there, but I'd like to show him ALJ exhibit -- an ALJ exhibit. How do I do that? Is there a binder?
MR. PHILLIPS: I can pull it up on his monitor.
MS. MAN: He may -- he may need it in paper. He forgot his
MR. PHILLIPS: I can also hand him the paper copies.
MS. MAN: That would be fantastic. He forgot his glasses.
JUDGE JULIUS: Sounds like we've reached a solution?
MS. MAN: Yep.

JUDGE JULIUS: Excellent.

MS. MAN: I just don't want to spring anything on somebody at the last minute.

JUDGE JULIUS: Understood.

And before you're seated, once you get up there, if you can just raise your right hand.

WHEREUPON,

DOMINIC CHIAPPERINO

was called for examination by Counsel for the Government, and having been first duly sworn,

was examined and testified as follows:

THE WITNESS: Yes, I do.

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

And before we begin questions, I just want to give you a few brief instructions just to help for clarity of the record. Please wait until the entire question is asked before you begin with your answer. Please pause shortly after the question is asked just in case there's an objection to the question.

THE WITNESS: Mm hmm.

JUDGE JULIUS: If you hear the word "objection," please don't start your answer. Wait for me to rule on any objection, and then

I'll instruct you on whether you may answer the question or not. And if you need repetition of the question, just say that you need repetition.

THE WITNESS: Thank you.

JUDGE JULIUS: If at any time you do not understand a question that you've been asked, please say that you do not understand the question before you try to answer it. We'll get it rephrased in -- into a question that you do understand. If you answer a question without telling us that you don't understand it, we will assume that you understood the question. Okay?

THE WITNESS: Understood. Thank you.

JUDGE JULIUS: Very good.

Ms. Man, whenever you're ready.

MS. MAN: Thank you.

DIRECT EXAMINATION

BY MS. MAN:

Q Good morning, sir.

A Good morning.

Q I'm going to ask that today, as you address the Court, that you keep your voice up. There's a microphone in front of you.

A Mm hmm.

Q If somehow you don't end up speaking

into the microphone and we can't hear you, I'll let you know you've got to speak up. Does that work?

A Yes. Thank you.

Q Thank you. Good morning. Could you please state and spell your name for the record?

A Sure. Dominic Chiapperino, D O M I N I C C H I A double P E R I N O.

Q And, sir, is there an honorific that you prefer I use today?

A Dr. Chiapperino is fine. Thank you.

Q Dr. Chiapperino, tell us about the education where you earned the honorific of "doctor."

A I was a graduate student at University of Maryland. I got my Ph.D. in Organic Chemistry in 2000.

Q And prior to your Ph.D. studies, did you earn other degrees?

A Yes, I did. I --

Q And what were they?

A I graduated from the University of Pennsylvania Wharton School in 1985 with a Bachelor's of Science in Economics.

Q Where are you currently employed?

A I work for the FDA.

Q And what is your role within the FDA currently?

A I work within the Center for Drug Evaluation and Research, which I'll often call CDER. I work in the Controlled Substance Staff. I am the Director of that staff, which is located in the Office of the Center Director.

Q And, Dr. Chiapperino, how long have you been the Director of the Controlled Substance Staff, otherwise known as CSS?

A I received that position in April of 2018.

Q And prior to your appointment as Director of the CSS, did you have a role within CSS?

A Yes, I did.

Q What was that role?

A In 2015, I joined CSS. I was their regulatory and liaison team lead.

Q Prior to your work at CSS, did you work as a chemistry reviewer for the FDA?

A Yes, I did.

Q What were some of your responsibilities as a chemistry reviewer?

A Yes. The main responsibilities of a chemistry reviewer within CDER is to review chemistry, manufacturing, and controls data related to drug quality. I did this for investigational drugs under investigational new drug applications and also for drugs submitted under a marketing application -- a new drug application. This is to assure the quality, potency, and purity of drugs that humans would use.

Q I'd like to show you what's been marked as Government's Exhibit 5. Mr. Grayson -- Mr. Phillips, I believe, is going to show you Government's Exhibit 5.

THE WITNESS: Thank you.

BY MS. MAN:

Q If you wouldn't mind taking a look at Government's Exhibit 5, Dr. Chiapperino. Let me know when you've had a chance to review it. Look up when you're done.

A This is my CV.

Q And is it a fair and accurate representation of your resume?

A Yes, it is.

MS. MAN: Your Honor, at this juncture,

the Government would move Government's Exhibit 5 into evidence.

JUDGE JULIUS: Any objection?

MR. McNICHOLS: No objection.

MR. EVANS: No objection.

MR. KENNEALLY: No objection, Your Honor.

JUDGE JULIUS: I'll admit it. Thank you.

(Whereupon, the above-referred to document was received into evidence as Government Exhibit No. 5.)

MS. MAN: Thank you very much.

BY MS. MAN:

Q Dr. Chiapperino, as the Director of CSS, did you oversee the scheduling and rescheduling of controlled substances?

A Yes.

Q Since your time as the Director in April 2018, how many scheduling and reschedulings did you oversee?

A Our reviews covered about 120 to 130 substances. Sometimes the documents we produced covered multiple substances, so there were probably 40 or so drug evaluations for those

substances.

Q And did one of those schedulings and reschedulings include the rescheduling of marijuana?

A Yes, it did.

Q I'd like to direct your attention to the process of scheduling and rescheduling.

A Mm hmm.

Q What does it mean to "schedule a controlled substance"?

A To schedule a controlled substance is to place a substance in one of the five schedules under the Federal Controlled Substances Act: Schedules I, II, III, IV, or V.

Q And how does the process start?

A It can start in a number of ways. One way is if a manufacturer or a drug applicant submits a new drug application to the FDA, and that drug has abuse potential and may require scheduling, we would initiate a drug evaluation and provide that to DEA.

If there's an emergent drug of concern in the community, DEA will usually be the agency that does that surveillance and will request an eight factor analysis or scientific and medical

evaluation from the Department of Health and Human Services, HHS.

Q So that request can come from a number of different places.

A Yes. Oh, and also petitions. Any petitioner can request a change in control status for a substance, and if that petition is submitted to DEA and found adequate, they would refer it to FDA for a review of the petition and a drug evaluation.

Q So once the request comes in and is accepted for review by the FDA, what happens next?

A The request will be routed to the Controlled Substance Staff. Within our staff, we'll make decisions about which staff will be involved on that assignment, and we'll determine if any other parts of the drug center would need to be involved or any other, you know, agencies that may have data that we would want.

Q So once the request for rescheduling marijuana came across your desk, who -- who, if anyone, did you select to work on the rescheduling effort?

A Sure. So the request came in end of

October or early November. Once the official request came from the Department to start the drug evaluation, within our staff we selected a pharmacologist who would work with their team leader. We selected a medical officer who would work with the medical officer team leader. This is all within CSS.

We also began discussions with other offices across the center. For example, the Office of Surveillance and Epidemiology has a number of professionals with -- PhD epidemiologists, PharmDs, medical doctors within OSE, Office of Surveillance and Epidemiology.

There ended up being a team formed of about 14 professionals that would begin looking at the epidemiological databases as part of this effort.

Q Outside of the individuals that came from the CSS, were there any other government agencies that assisted in this process?

A Yes. We worked with some folks in the Office of the Assistant Secretary for Health. We worked toward the end of the process with our colleagues at the National Institute on Drug Abuse.

And I did forget to mention that within the drug center we also consulted with a chemist and botanist, and we also worked with the Office of -- in the Office of the Commissioner. The Intergovernmental Affairs team helped us form some discussions with states to obtain some data at some point in the process.

Q And once you've assembled this team, how -- how do they review the data? What is that process?

A Well, we -- as a team, we discussed data sources that would be relevant. Once we made determinations about the data and formed some working groups to concentrate in certain topic areas, people understood their assignment, what their responsibilities were, and what their specific -- what specific data they would be responsible for reviewing.

Q And would it be accurate for me to say that these working groups met on a regular basis?

A Yes. In the beginning, we met more frequently to begin the process and get it organized. We formed three working groups. One focused on laboratory studies, chemistry,

animal, human studies in the literature that would comprise some of the eight factor analysis.

We formed a group that involved many OSE representatives who would be studying databases to establish the prevalence of marijuana use in relation to comparator substances. And we formed a third working group also with many folks in OSE who would analyze the epidemiological databases and literature for harms associated with marijuana use and comparators being used.

Q All in all, how long did this entire process last?

A We completed the review in 10 months, and I did leave out one part -- that we also had a group who were focused on the currently accepted medical use reviews. That was sort of a fourth working group.

Q After these four working groups convened and their regular meetings, how long did the whole process take? You mentioned that you got the request in October.

A Yeah.

Q But you didn't mention the year.

A We were finalizing documents, and the evaluation was complete and signed and transmitted to DEA in August of 2023.

Q And so the October that you started the -- when you started your review of all of these materials, that was October 2022?

A Yes.

Q Okay. Just wanted to make sure I was clear. Would it be fair to say that this was a priority for the Controlled Substance Staff?

A Yes, it was.

Q I'm going to show you what's already been moved into evidence as ALJ Exhibit 1, if Mr. Phillips wouldn't mind.

A Okay. Thank you.

Q Dr. Chiapperino, if you wouldn't mind taking a look at ALJ Exhibit 1. Take your time, and when you're finished reviewing it, look up at me.

A Yes. I recognize this as our evaluation in two parts.

Q And is that document in front of you, ALJ Exhibit 1, the summary of the 10 months of work you and your exhaustive team put in?

A Yes, it is.

Q Okay. Dr. Chiapperino, what is marijuana?

A Marijuana is the plant cannabis sativa, and most relevant to these proceedings, I'll discuss it in terms of its legal definition. So in the Controlled Substances Act at 21 U.S.C. 802(16), marijuana is defined as the plant cannabis sativa, and here I'll paraphrase, but it is also in the documents on page 2; the plant, all of its compounds, products, and derivatives.

And there is an exclusion from that category, an exclusion for hemp. Hemp was established in 2018 by the Agriculture Improvement Act. It defined "hemp" as cannabis sativa, all plants, products, derivatives, preparations with not more than 0.3 percent Delta 9 tetrahydrocannabinol by dry weight.

So Delta 9 tetrahydrocannabinol, hereafter I'll just say THC, is the primary constituent in the cannabis plant. It is the plant with the effects for which marijuana is used non medically, and hemp that is low in THC is now excluded from the definition of "marijuana" in the CSA.

Q So for the purposes of rescheduling, you and your team's evaluation of marijuana, it was as it is legally defined by the CSA, correct?

A Yes.

Q And is there an analysis that determines whether a substance should even be scheduled?

A I'm sorry. Can you repeat the question?

Q Sure. Is there an analysis which determines whether a substance should even be scheduled?

A Well, yes, the same eight factor analysis that

Q Did your team conduct

A Yeah.

Q this eight factor analysis on the marijuana as it's legally defined by the CSA?

A Yes.

Q Based on that analysis, did you and your team reach a determination about whether marijuana should be scheduled?

A We did.

Q And what was that determination?

A We believed it should be placed in Schedule III, which would involve a transfer from Schedule I to Schedule III.

Q But that it should be scheduled all together.

A Excuse me?

Q It should be scheduled all together. I don't think anybody here is going to argue that it's not going to be scheduled, correct?

A Correct.

Q Okay. So do the substance -- controlled substances in Schedule I have a currently accepted medical use?

A No, they don't.

Q So if a controlled substance were found to have a currently accepted medical use, it could no longer remain in Schedule I, correct?

A It would be considered for one of the other four schedules, yes.

Q So if your team determined that marijuana had a currently accepted medical use, it could not by definition of the statute stay in Schedule I.

MR. McNICHOLS: It's a little leading, Your Honor.

BY MS. MAN:

Q If your team determined that

JUDGE JULIUS: Well, I -- I agree. Do you have any response to the objection?

MS. MAN: It's a preliminary matter. I'm establishing groundwork, but I can rephrase the question.

JUDGE JULIUS: Go ahead. Thank you, Ms. Man.

BY MS. MAN:

Q So if your team determined that marijuana had a currently medical -- accepted medical use, where would -- would it -- what would you -- you determine about whether or not it could stay in Schedule I?

MR. McNICHOLS: Same objection.

THE WITNESS: We -- no. I --

JUDGE JULIUS: I'll allow it.

MR. McNICHOLS: Thank you.

THE WITNESS: Sorry. Sorry.

JUDGE JULIUS: Go ahead.

BY MS. MAN:

Q Could it stay in Schedule I?

A It should not stay in Schedule I. It would be more appropriate in meeting the

criteria of another schedule in the CSA.

Q How many medical conditions would you need to find that marijuana has a currently accepted medical use for before moving it out of Schedule I?

A Just one medical use.

Q And how many did your team ultimately find?

A We found three that met the criteria for a currently accepted medical use.

Q What were the three conditions that your team found where marijuana had a currently accepted medical use?

A Marijuana used for pain, for anorexia associated with a medical condition, and nausea and vomiting, usually in the context of chemotherapy.

Q So after your team determines that there is a therapeutic condition where marijuana has a currently scheduled medical use, the next question -- would the next question be what schedule it goes into?

A Correct.

Q I'd like to talk about your recommendation of rescheduling. Before you

began your process, where was marijuana scheduled?

A Schedule I.

Q After you completed your process, did the FDA make a recommendation as to whether marijuana should remain in Schedule I?

A We did.

Q What was that recommendation?

A That it should not. That it should be placed in Schedule III.

Q It's my understanding that there are three findings that your team needs to make --

A Mm hmm.

Q -- to determine the scheduling recommendations. What are those three recommendations?

A Yes. So after considering all of the data under the eight factors, we have to distill that information to make three findings. The first is the substance's degree of abuse potential. The second is whether the substance has a currently accepted medical use. That's a yes or no. And the third is the degree of dependence liability if we are considering it for one of the schedules associated with medical

use.

If we were considering it for Schedule I, the third finding would be whether the substance has a lack of safety for use under medical supervision.

Q I'd like to direct your attention to the analysis your team did to determine whether or not marijuana has a currently accepted medical use. Just so I'm clear, when you're discussing currently accepted medical use today in front of this Tribunal, this means currently accepted medical use for the purposes of drug rescheduling.

A Correct.

Q So rather than me saying currently accepted medical use for the purposes of drug scheduling or rescheduling, which is kind of a mouthful, would you be comfortable if I just refer to it as currently accepted medical use, or CAMU?

A Yes.

Q So it's my understanding that after your process led to a finding that there is a CAMU for marijuana, that it does not belong in Schedule I, is that -- am I correct?

A Yes. The process involves reviewing all -- all things in parallel. So we were conducting the assessment of currently accepted medical use as we were evaluating other data for the other findings.

Q And how many avenues are there by which FDA can reach their finding about whether or not there's a currently accepted medical use for marijuana?

A There are three.

Q What's the first one?

A The first is the most straightforward. If FDA approves a new drug application allowing for the marketing of that new drug, the active ingredient in that drug, if it needs to be controlled, would be said to have a currently accepted medical use by virtue of the FDA approval.

Q What's the second one?

A The second I'll refer to as the five point test. This comes from the DEA's 1992 Federal Register Notice after a long legal process that led to establishing a method that had consensus to consider five elements. Those five elements represent a standard of evidence

for medical use that are very similar to a new drug approval in that it relies on data from clinical trials mostly.

Q What -- what was the third avenue?

A The third avenue is the two part test that was established in 2023.

Q Which team did -- which avenue did you and your team employ?

A We were directed to use the two part test.

Q And has that two part test been used since it was implemented by HHS?

A Yes. We have considered -- every time we review a substance, we consider all three methods, including the two part test. Depending on the circumstances of the drug, it may be a rather brief assessment, if there is no widespread therapeutic use of the substance, but we do apply that test to all substances even if it is short.

Q So utilizing the two part test, were there considerations that you consider under the two part test that would not have been in your calculus under the five part test?

A Yes.

Q What were those calculations?

A So under the two part test, part 2 of that test is to look for credible scientific support, which does involve looking at clinical trial data and data from observational studies. That part resembles the five point test, which relies a lot on publicly available clinical trial data.

However, the part 1 of the test is predicated on the idea that there is widespread medical use of a substance under the supervision of healthcare practitioners operating in a regulatory program for medical use. And all the

Q Is that consideration under -- taken into account during the five part test?

A No, it would not be.

Q And what else does the two part test weigh that the five part test does not?

A It's a totality of the -- of the data kind of evaluation. So we looked at a number of different data sources in part 2, but we did look at clinical studies. We looked at some data from surveys about medical use patterns. We considered the FDA approval of two drugs.

Marinol in 1985 contains Delta 9

tetrahydrocannabinol, the minus trans isomer in particular, which has the alternate name dronabinol. Marinol, as dronabinol, is approved for nausea and vomiting and for anorexia associated with AIDS wasting. And the fact that marijuana has its primary constituent in common with Marinol and another medicine, Syndros, which is the same drug substance in an oral solution form, was another consideration in our evaluation.

Q Does the two part test also take into consideration state programs?

A Yes, it does.

Q And that's not something the five part test takes into account.

A Correct.

Q Prior to conducting the CAMU test, did you know whether or not marijuana would be found to have a CAMU?

A No, we did not.

Q I'd like to draw your attention to part 1 of the two part test.

A Mm hmm.

Q What is part 1?

A Part 1, conducted by staff in the

Office of the Assistant Secretary for Health, is a landscape analysis of sorts. It looks at all -- it looks at the extent of use across the states, the -- the fact that healthcare practitioners can gain experience in certain therapeutic indications that are common to many of these states. There are 38 states plus D.C. plus territories that have regulatory programs to make marijuana accessible as a medicine.

They considered also the longevity of some of those programs to determine that there was sufficient time for healthcare practitioners to gain experience in using marijuana as a medicine in these therapeutic indications.

Q So did HHS, through OASH, identify any health conditions that were approved for marijuana for use in the state programs that they assessed?

A Yes, they did.

Q How many therapeutic health conditions did HHS identify?

A In their part 1 evaluation, they appended a table that had, I think, 15 or so therapeutic indications that all met the criteria of having widespread use across the

states.

Q Out of those 15 health conditions, how many did FDA examine?

A We ended up selecting seven indications. Six of them were on that list, and a seventh was selected only because our own landscape analysis identified such -- a lot of use for that indication, anxiety.

Q Why did you limit your review to seven when -- when HHS identified 15 possible therapeutic conditions?

A It's a resource issue. As we talked about earlier, we only need to identify one therapeutic use of medicine -- of marijuana as medicine to make a finding of CAMU. We chose seven because we did not know what the data would be like for any of those therapeutic indications.

We looked for the most widely used indications or the indications where marijuana was most widely used, where there was maybe the largest number of clinical studies available, and from survey data, the most commonly used as people reported.

Q So after deciding to examine seven

medical conditions, I'd like to direct your attention to part 2 --

A Mm hmm.

Q of the CAMU test. What does part 2 of the CAMU test assess?

A Whether there's credible scientific support for any of the therapeutic indications identified in part 1.

Q Did you and your team find credible scientific support to demonstrate a currently accepted medical use of marijuana to treat certain conditions?

A Yes, in three

Q What were those three conditions?

A Pain, anorexia associated with a medical condition, and nausea and vomiting.

Q I'd like to direct your attention to the five buckets of information that

A Mm hmm.

Q FDA utilized to determine that there was --

A Mm hmm.

Q -- CAMU for those three conditions.

A Yes.

Q Could you tell me what the five buckets

of information are?

A Yes. I won't go -- deep dive in any of them until I've listed them all. The first was a set of surveys. The second was a systematic literature review conducted by the University of Florida epidemiology team looking at the literature available for all seven indications. The third was our own medical officer team doing that same literature review. The fourth were some state surveys available from -- one was from Minnesota, one was from Maryland. They both provided useful data. And the fifth was consideration of the FDA approved use of Marinol and Syndros.

Q I'd like to talk about the University of Florida literature review first. Why did the FDA contract with the University of Florida to do a literature review?

A Again, a resource issue. Our goal was to do the review expeditiously. We had a lot of staff already working on various parts of it. The medical use part of the review was going to be probably a very large component of that review. And we were -- we had the availability of a contract to make use of, so we decided to

outsource that part and gave them directives about what we wanted them to do.

Q What were your team's takeaways about whether or not there was credible scientific support for whether marijuana has a CAMU in treating anorexia as a medical condition?

A For anorexia, both the UF team and our own medical officer found credible scientific support for that medical use. It was based on, I think, three clinical trials, and in one of those clinical trials, there was evidence of benefit, and the study was rated to have a moderate quality of evidence. "Moderate quality of evidence" in these systematic reviews means that the true effect of marijuana is probably similar to the observed result or reported effect.

Q And what were your team's takeaways regarding whether or not marijuana has a currently accepted medical use when treating nausea and vomiting in conjunction with chemotherapy?

A We made a finding that it did meet the threshold for credible scientific support. Similar, there was a handful of studies

available, and in some of those studies benefit was identified with a moderate quality of evidence.

Q And what about your team's takeaways when it came to whether or not there was a CAMU for treating pain?

A Pain was the indication for which there were the most available studies. There were 39 randomized clinical trials. There were eight observational studies. Most of the observational studies were excluded on the basis of bias as evaluated under the systematic review process for determining bias. For the remaining studies included, there -- they did -- they considered whether some of those studies were of similar design to be pooled. There was a meta analysis as part of it.

Overall, when the pooled data were considered, there was a small margin of benefit. There were also some adverse events reported. However, in a more narrow category of neuropathic pain, the studies were more supportive of a therapeutic benefit for patients with neuropathic pain. I think there was at least one study with moderate quality of

evidence showing benefit.

Q I'd like to direct your attention to the in house -- the literature review that was conducted by your in house team.

A Mm hmm.

Q So not the University of Florida team, your

A Yeah.

Q FDA team. What were your team's takeaways about whether there was credible scientific support for whether marijuana has a CAMU when treating anorexia as a medical condition?

A I think we shared the views of the U of F, yeah.

Q And what about your team's takeaways regarding pain, whether or not marijuana had a CAMU for treating pain?

A We thought that it did. We also brought in results from AHRQ's living survey of -- or living study, systematic review of people using pain. That study has, I believe, evidence of some benefit to patients, and our own medical officer looked at the literature and had similar findings with U of F.

Q And what were your team's takeaways when it came to whether or not marijuana had a credible -- had credible scientific support for whether or not marijuana had a CAMU for treating nausea and vomiting in conjunction with chemotherapy?

A We agreed with UF and found similar results in our literature review.

Q I'd like to draw your attention to the surveys that you just spoke -- told us about.

A Yeah.

Q Your team examined -- how many surveys did your team examine?

A There were four surveys. These surveys were also used in other parts of the eight factor, but since the information was informative for how people are using marijuana medically, we also summarized some data from those surveys in the CAMU, part 2.

Q And are these surveys national surveys?

A Yes. They are all national surveys. Would you like me to begin describing some of them or?

Q No, I would

A Yeah.

Q I think it would be best use of our time if we

A Yeah.

Q highlighted what was important for you --

A Okay.

Q -- and your team through the --

A Sure.

Q -- surveys.

A Sure. So from -- so the four surveys were the International Cannabis Policy Survey; Monitoring the Future, which is eighth, tenth, and twelfth graders surveyed; the Behavioral Risk Factor Surveillance System survey of 18 years and older subjects across the nation; and then the NSDUH survey, National Survey on Drug Use and Health.

We focused on the proportion of people using marijuana medically. It tends to be roughly half of the people using marijuana in general. The age of people using marijuana medically definitely skews towards the older members of the population as -- which makes sense for some of the conditions that people use marijuana for.

We looked at patterns of purchasing marijuana, and it was clear that state dispensaries were the largest source of people using marijuana, both medically and non medically. Second in that list was from a friend or relative. We considered the -- the pattern of asking for healthcare practitioner advice before seeking marijuana to use as a medicine, and --

Q I'd like to ask you a question about that.

A Yeah.

Q What did that

A Yeah.

Q -- survey data tell you and your team about -- what information did they give your team about the involvement of healthcare professionals and the use of marijuana?

A It was fairly high overall. They -- they looked at -- they -- in -- in one table, we have the reported results based on whether the state has -- where marijuana is completely illegal in the state, whether the state offers medical marijuana only, or whether the state offers both medical and recreational adult use

of marijuana.

In states where it is illegal to have marijuana, there was still a 47 percent rate of people seeking advice of a healthcare practitioner before using marijuana medically. Presumably, they were getting it from an illicit source in that state. In --

Q What about for states where

A Yeah.

Q it was legal? What did

A Yeah.

Q that data show you about how individuals would seek out healthcare practitioners in states where marijuana was legal?

A In states that it was legal for medical use, the percentage was higher. It was, I think, 60, 61 percent. In states that had both medical and recreational, it was still almost 60 percent. It was, I think, 59 percent.

Q So what did that tell you and your team?

A Well, if marijuana is accessible in a recreational program, many people could just get that, and if that was their intent, to use it

non medically. The fact that many people are still seeking healthcare practitioners' advice in states where they have access to marijuana with or without that advice shows that medical use is genuine, and people are very interested in using marijuana as a medicine.

Q I'd like to direct your attention to the state programs that your -- you and your team examined. You testified earlier that you -- you and your team examined Maryland and Minnesota's state programs.

A Yes.

Q What, if anything, did the Maryland study tell you, or the Maryland State program tell you and your team?

A Well, the Maryland State program was a survey of people who were using marijuana from Maryland dispensaries. At the time of the survey, marijuana was medical only. They did not bring recreational use online until 2023. Most people in that survey responded with information about the uses, that they were using Maryland -- that they were using marijuana for, which was consistent with the selected indications in the CAMU review.

I think there were some data about buying patterns and things like that, but -- and there was also reports of adverse events or, rather, there was an opportunity to report on whether they experienced adverse events. And safety data -- there were not many significant adverse events.

Q I'd like to -- I'd like to ask you a few questions about what you just told us and the Tribunal.

A Yeah.

Q What, if anything, did the Maryland State program tell you about significant safety issues in the use of medical -- marijuana in the medical -- medical field?

A For people using marijuana for these indications, there were very low incidence of safety concerns.

Q Low incidence of safety concerns?

A Low incidence of reported adverse events, serious adverse events.

Q And regarding the Minnesota State program, what were your team's takeaways from the Minnesota State program?

A The Minnesota survey -- in Minnesota,

if you're going to access medical marijuana, you fill out a patient questionnaire each time you would access marijuana for medical use. On that questionnaire, there are questions about their intended use, their experience with marijuana so far.

One of the things of note was the rate at which people return for a second purchase of marijuana. We noticed, I think, somewhere around 50 percent did come back to continue using marijuana, but 50 percent did not. Presumably, there is experimentation and a decision not to continue using marijuana medically.

Q What, if anything, did your team take away from the Minnesota State program when it came to the safety profile of marijuana?

A Yes. Well, Minnesota did report -- Minnesota respondents indicated which therapeutic uses they were using marijuana for, and they also reported whether they were having any adverse events in that use. And I believe there were no significant adverse events reported.

Q You just

A Or very infrequent.
Q I'm sorry I cut you off.
A Yeah.
Q So how would you characterize the safety profile from the Minnesota State program?
A I think marijuana was used with a reasonable amount of safety in -- in Minnesota.
Q You just told us that in Minnesota, they also took note of which conditions people used marijuana for.
A Mm hmm.
Q What was the most common condition that marijuana was used for in the Minnesota studies?
A I believe it was anxiety, but there were several psychiatric indications of interest for people: anxiety, depression, PTSD, bipolar disorder. I think those were the four main of psychiatric, and then also a number of other indications such as pain, nausea, and vomiting, headache. Yeah.
Q And pain is one of the indications that your team ultimately found a CAMU for.
A Yes.
Q And same with nausea and vomiting.
A Yes.

Q Let's move on to the FDA approved medication, the last bucket of information your

A Sure.

Q -- team examined with the CAMU test. Please tell the Tribunal about what your team gleaned from FDA approved medications.

A Well, the FDA approved medications contained dronabinol, which is the very same most abundant cannabinoid in the cannabis plant. Obviously, these FDA approval actions signify safety and efficacy for use of dronabinol in that patient population.

It lent more validity to a finding of credible scientific support that that same active ingredient is in cannabis as the most abundant compound. And we did our evaluation in many ways where marijuana is essentially a delivery system for delta 9 THC. Based on the legal definition, we treated it that way.

Q So what was your team's takeaways from the FDA approved medication?

A That it lent support for credible scientific support.

Q I'd like to direct your attention to one of the other findings that your team has to

make

A Mm hmm.

Q in order to move this -- that one to your recommendation, which is the relative abuse potential --

A Mm hmm.

Q compared to other drugs.

A Yes.

Q What does it -- what does that mean, the relative abuse potential compared to other drugs?

A So the CSA has five schedules, and in doing an evaluation, we're asked to consider what is the relative degree of abuse potential of a substance. In order to do that, we look at substances already controlled that might be useful as comparators, see what the profile of use patterns is, the tendency for that abuse and non medical use to produce harms, and consider differences among, you know, the test drug -- in this case, marijuana -- versus the comparators.

Q Now, can a single test or assessment provide a complete characterization for relative abuse potential?

A No. No. Sorry.

Q I think it's when you lean down
A Yeah.
Q it's a little harder for me to hear you.
A Yeah.
Q And why is -- why -- why does no single test or assessment provide a complete characterization?
A Well, it's a -- it's a complex assessment. It considers the effects of the drug, the toxicities associated with the drug, the use patterns, and we -- we brought a lot of that data into our evaluation from a number of epidemiological data sources.
Q So what comparators did you and your team use?
A From Schedule I, we included heroin. From Schedule II, we included fentanyl, oxycodone, hydrocodone, and cocaine. From Schedule III, we included ketamine. And from Schedule IV, we included benzodiazepines as a class, and zolpidem, and tramadol.
Q And what, if anything -- did you use a comparator that was also not a controlled substance?

A We did. We included alcohol in this evaluation.

Q Why would you include alcohol if it's not a controlled substance?

A Yes. We rarely, if ever, use an uncontrolled substance as a comparator. Marijuana is somewhat unique in the large amount of access people have legally in adult recreational use programs. It resembles the use of alcohol as a legal substance for adults to use. And considering that its legal status -- the legal status of marijuana contributes to such prevalent use, the numbers of people using marijuana is larger than a lot of the comparators.

It would provide -- it would create a very outsized difference in the data. We looked at alcohol as a -- a good comparator for how people use a -- a substance recreationally and the harms that that widespread use might cause even with a legal substance, alcohol.

Q Let's talk about harms first, since you just brought that up.

A Mm hmm.

Q Regarding harm, what did you determine

about marijuana and the other comparators?

A Well, generally speaking, the absolute numbers, due to high prevalence of use in some categories, was high for marijuana. As a rate, in almost every database, harms associated with marijuana was generally lower than all of the comparators or a good number of the comparators. Certainly, it was lower than heroin, cocaine

Q Okay.

A and often lower than alcohol.

Q Would you consider -- would you characterize that as -- that as a risk ratio?

A Yes.

Q And so I -- I'm sorry. Could you tell me one more time what the risk ratio was for marijuana compared to your other comparators?

A Are you asking for a precise number or are you asking me to explain the concept of the risk ratio evaluation?

Q What was the risk ratio evaluation you made regarding marijuana and Schedule I heroin? What was the result?

A Well, there were many different database -- like, types of harms considered

Q Yeah. Let's go with that.

A like emergency room visits, hospitalizations, poison center calls. In general, in -- when correcting for -- when adjusting for utilization, heroin would be a -- a higher rate of serious adverse harms.

Q I'd like to talk to you about overdose deaths when it

A Mm hmm.

Q comes to medical intervention.

A Mm hmm.

Q Are you telling the Court today that marijuana has fewer overdose deaths than the comparators?

A Yes, that's what we observed.

Q Were those overdose deaths from the use of marijuana alone?

A It's often complex to evaluate an overdose death a single entity or polydrug. Marijuana, when it is a single entity in a case report, events of death are very rare, usually attributed to a secondary event, like an accident or a fall or self harm. Compared to Schedule I and II substances in our evaluation, overdose deaths are far more common; fentanyl, obviously, the source of this nation's

devastation from opioid overdose deaths.

Q So how would you compare -- how do overdose deaths from marijuana compare to overdose deaths from Schedule II opioids?

A Can you repeat that? Sorry.

Q Sure. How do overdose deaths from marijuana compare to overdose deaths from Schedule II opioids?

A Much lower. Actually, as I said, very few cases of overdose death with marijuana. Usually, it's not the overdose; it's the secondary event.

Q How would you -- how do overdose deaths from marijuana compare to overdose deaths from Schedule I substances that you compared?

A It is much lower with marijuana. Can you repeat the question? Sorry.

Q Sure.

A Yeah.

Q How do overdose deaths from marijuana compare to overdose deaths from heroin?

A Much lower.

Q I'd like to draw your attention to the third finding that had to factor into your recommendation: relative safety or ability to

produce physical dependence compared to other drugs.

A Mm hmm.

Q What was the team's determination regarding the physical dependence of marijuana?

A That marijuana -- continuous use of marijuana does lead to physical dependence. Physical dependence is the physiological adaptation to the repeated use of a drug, and it manifests. When you discontinue the drug or vastly reduce the dose of the drug, you would produce a withdrawal syndrome, if that person had become physically dependent.

Q So let's talk about withdrawal. Did you and your team do a comparison of marijuana's withdrawal symptoms with withdrawal symptoms from other substances?

A Yes.

Q What was your team's finding compared -- comparing marijuana withdrawal symptoms with that of tobacco withdrawal?

A The withdrawal syndrome from marijuana is reported to be similar to -- with tobacco: irritability, sometimes nausea. We have a list of the events if you would like me to refer to

the document. I don't want to misstate or leave out important ones.

Q So your team would compare tobacco withdrawal similar to that of marijuana withdrawal?

A Yes.

Q What about alcohol withdrawal? How does the alcohol withdrawal symptoms compare to that of withdrawal from marijuana?

A Alcohol is a more severe withdrawal syndrome. One of the potential adverse events of withdrawal from heavy use of alcohol could be seizure. There are deaths associated with seizures in a withdrawal context with alcohol.

Q What about benzodiazepines?

A Similar. There's actually similar pharmacology between alcohol and benzodiazepines, and withdrawal from dependence on benzodiazepines can lead to seizure and death.

Q Did you and your team examine psychological dependence?

A We did.

Q What was your team's takeaways from your examination of psychological dependence on

marijuana?

A Psychological dependence is more akin to addiction and substance use disorder. So when we talk about psychic dependence or psychological dependence, we're thinking of substance use disorder in DSM 5 terms, the diagnostic for substance use disorder.

In general, marijuana is associated with cannabis use disorder at a fairly high rate. The -- when you consider mild, moderate, and severe substance use disorder, marijuana skews very heavily toward mild substance use disorder.

Q Mild substance use disorder?

A Yes.

Q As compared to the other comparators that you used for your analysis.

A The comparator substances have a higher proportion of moderate and severe substance use disorder, yes.

Q Based on your recommendations -- based on your three determinations that you just told the Court about, did you and your team make a recommendation for where marijuana should be scheduled?

A We did.

Q What was that recommendation?

A We believe the data supported placement in Schedule III as the schedule most aligned with marijuana's properties.

MS. MAN: Court's brief indulgence, please.

JUDGE JULIUS: Sure. I'll just note we did have, I believe, a scheduled 15 minute break at 10:30. We're about 10 minutes out, so if you want to factor that in.

MS. MAN: Your Honor, could we take that recess now?

JUDGE JULIUS: Yes.

Any objections to the early 15 minute break?

MR. McNICHOLS: Not from us, Your Honor.

MR. KENNEALLY: No, Your Honor.

JUDGE JULIUS: Okay. We'll be in recess for 15 minutes. Let's come back at 10:35. That will give us a 15-minute break.

Thank you, everyone. We'll be in recess until then.

(Whereupon, the above-entitled matter went off the record at 10:21 a.m. and resumed at

10:37 a.m.)

JUDGE JULIUS: And, Ms. Man, whenever you're ready.

BY MS. MAN:

Q Thank you, Your Honor.

Good morning again, Dr. Chiapperino.

A Good morning.

Q Dr. Chiapperino, I'd like to ask you about something you referenced earlier, the risk ratio. Could you explain to us in layman's terms what risk ratio is?

A Yes, we have the absolute numbers of an event. In order to provide context for a comparative assessment, you can consider the overall population and the fact that the frequency of events in that overall population are more of a rate or a probability that the event would -- would happen. Yeah.

Q So, does the risk ratio take into account the prevalence of --

A Yes.

Q -- these substance?

A Yes, in short. It --

Q Okay.

A It is the event divided by the

prevalence of use that could have caused the event, and you establish a rate.

Q So, it's the prevalence of use on one side, correct?

A Yes.

Q And then the number of adverse -- adverse effects on the other side.

A The number of events, yes.

Q And what is the prevalence of use for marijuana?

A It is very high, I believe the surveys estimate it at upwards of 18 percent of the general population. I think that translates to over 40 million people.

Q Oh, so, I -- I can tell you, I'm very poor at math, but I'd like to ask you about that high prevalence. Now, on the other side of the equation, you said the number of adverse events or number of events?

A Yeah.

Q What were the number of events on the other side when it came to marijuana?

A Okay, I'm not sure I'm understanding the question the way you're asking. Can you ask that again?

Q Sure. The number of adverse events for marijuana --

A Mm-hmm.

Q -- was that low or high?

A We'd have to be talking about a particular data source. So, if we want to talk about emergency department visits or a poison center case --

Q Let's talk about emergency room visits.

MR. McNICHOLS: I don't think he finished his answer, Your Honor.

BY MS. MAN:

Q Please finish your answer, then I'll ask.

A Or overdose deaths in, like, the National Vital Statistics mortality database.

I'm finished.

Q Thank you. Let's talk about the ER visits.

A Sure.

Q What was marijuana's risk ratio?

A I think I would want to look at the section that we have on emergency department visits, the NEDS dataset. I don't have values, particular numbers, in my head for some of these

measures.

Q I'd like to direct you to Government's Exhibit Number 5 -- or, excuse -- excuse me, ALJ Exhibit Number 1.

A I believe we'd be on page 43 out of the 252 pages.

Q You got there before me, sir. What, if anything, did your team determine when it came to emergency room visits?

A Yes, I'm going to take a minute and just peruse this, if you don't mind?

Q Sure, absolutely.

A So, in the third paragraph of that section, near the bottom of page 43, we have the utilization-adjusted rate of estimated ED visits, calculated by dividing the estimated annual visits for each substance as reported in NEDS by the number of individuals reporting any past year use.

So, past year use was the value that was used in the assessment to establish the denominator, how many people responding in a survey of past year marijuana use or past year cocaine use, et cetera.

Q When it came to ER visits, what is the

risk ratio of marijuana compared to Schedule II opioids?

A In this particular dataset, the rate was reported as a frequency in a population of 100,000 people, so, it's a per 100,000 people.

For ED visits, marijuana had the second-highest utilization-adjusted rate for ED visits from 2016 to 2020, where the rates for marijuana-related disorder, ranging from 3,472 to 3,940 per 100,000 individuals.

Q How does that compare to Schedule II opioids?

A I don't think that the -- this particular data source captures opioid as a comparator. Sometimes a comparator is not available in a particular data source.

I'm not seeing it in this paragraph. I think we compared to alcohol and cocaine.

Q How did it com -- how was the risk ratio comparing then to alcohol?

A It was higher than for alcohol. Alcohol was reported at 2,225 to 2,327 per 100,000 individuals.

Q And what about the other comparator that you just talked to us about?

A Hmm, I'm sorry, I don't see that in this paragraph. I'll -- I'm sorry, here it is.

For cocaine, the number of ED visits observed for cocaine-related disorder was 11,765 to 14,014 per 100,000 individuals. So, compared to marijuana, that is roughly three times or more the rate.

Q I'd like to draw your attention to overdose deaths. What is the risk ratio when it comes to marijuana for overdose deaths compared to Schedule II opioids?

A We'd have to go probably to one of the other data sources, like National Vital Statistics System the mortality.

Let's see, I'm going to --

Q I'd like to draw your attention to page 53 of the ALJ exhibit that's in front of you.

A Thank you, I'm on that page now. So, these data are over a 10-year period, 2012 to 2021, absolute numbers are reported first.

Fentanyl had the highest total number of overdose deaths, an N of 258,785 over that 10-year period, followed by cocaine at 119,208 deaths, followed by heroin, 118,992 deaths, and benzo -- benzodiazepines at 87,581.

Q You testified earlier before the break that overdose deaths from marijuana alone were extremely rare?

A I did.

Q Does this data that you just read support that?

A Well, I didn't quite get to the numbers on marijuana. Marijuana produced the lowest number of overdose deaths at 5,957. So, yes, in this analysis, marijuana had the lowest absolute numbers of overdose fatalities.

MS. MAN: Your Honor, based on that, the Government --

(Off-microphone comments.)

MS. MAN: Oh, sure.

THE WITNESS: And --

MS. MAN: Your Honor, based on that, the Government has nothing further.

THE WITNESS: Okay.

JUDGE JULIUS: Okay, thank you, Ms. Man.

On our schedule, the next session would be for cross-examination opportunity by National Drug and Alcohol Screening Association.

Mr. Evans, are you ready to proceed

early or --

MR. EVANS: Your Honor, I'm having some copies delivered to my hotel at noon. So, I --

JUDGE JULIUS: Could you go up to the podium?

MR. EVANS: Sorry.

JUDGE JULIUS: We want to make sure that we get your --

MR. EVANS: I -- yeah.

JUDGE JULIUS: -- voice in on the record.

MR. EVANS: I was anticipating starting at 1:00. I'm having some copies of things delivered to the hotel to make it easier for the Court to understand some of the things that I'm talking about, copies of laws and so forth, I -- so, the Court could look at them while I'm cross-examining the doctor.

So, I would appreciate, you know, if a little more time where we start at 1:00 or whatever.

JUDGE JULIUS: I have no issue doing that. It was a little bit of a bump-up in the schedule, so, I have no issue.

I mean, we could -- thank you, Mr.

Phillips.

I have no issue moving you to 1:00 after lunch as originally --

MR. EVANS: Thank you.

JUDGE JULIUS: -- scheduled, Mr. Evans.

MR. EVANS: Appreciate it, Your Honor.

JUDGE JULIUS: Would Tennessee Bureau of Investigation be ready to start early, just so we could swap the spots and -- and just keep moving, or what would your preference be?

MR. SMITH: I think my preference would be to go when we were scheduled, but if it pleases the Court, I think we could move forward if -- if necessary.

JUDGE JULIUS: I think, in interest of fairness, at this point, I'll go ahead and give us an extra-long lunch today.

We can recess for now. We'll reconvene at 1:00, under the original schedule. That'll be with Mr. Evans going first. And then we'll go in order as originally scheduled.

So, that's what we'll do. Thank you, everyone. Enjoy a nice long lunch, and we'll see you back here at 1:00.

(Whereupon, the above-entitled matter

went off the record at 10:49 ~~p~~a.m. and resumed at 1:02 p.m.)

JUDGE JULIUS: Thank you, everyone. Please be seated. I hope everyone had a nice, long lunch. Just some logistical things before we get started.

With regard to objections, I know I said the process would be to stand. I think, for integrity of the record, just make sure, regardless of whether you're standing or sitting, just make sure to make your objection directly into a microphone.

We want to make sure that those comments and those objections get reflected on the record. And, I think, sometimes if people drift too far from a mic, it's not picking it up.

Also, with regard to examination and things that are happening at the podium, just be sure to speak as directly as you can into the microphone. I think again, if you move too far to the right or the left, you may move outside the zone of what's getting picked up.

So, we'll do our best if there's an issue. To the Court Reporter, please let us

know if there's an issue of things getting picked up. We just want to make sure that the record is fully reflective of everything that is said. So, thank you.

Mr. Evans, are you ready to begin your cross examination on behalf of National Drug and Alcohol Screening Association?

MR. EVANS: And, Dr. Finn.

JUDGE JULIUS: And, Dr. Finn.

MR. EVANS: And, Ed Wood.

JUDGE JULIUS: Okay. Are you doing that all in a single session? Or, are you going to --

MR. EVANS: Well, if I can have time, well, I guess I'd be entitled for each client to do the hour. I could spend all day with the doctor.

So, I would appreciate the extra time. I know that Dr. Finn and Edward will have different concerns and different questions, so.

JUDGE JULIUS: Okay. I mean, yes, each interested party is entitled to an opportunity of one hour cross examination.

So, however you want to divide your time between those interested parties.

MR. EVANS: Okay. Oh, you're going to do it now. Oh, okay. Mr. Kenneally is going to do cross for those folks, for Finn and Edward. Okay.

JUDGE JULIUS: Good enough. So, you're just here to do cross examination on behalf of National Drug and Alcohol Screening Association? Is that correct?

MR. EVANS: Yes, sir. Yes, sir.

JUDGE JULIUS: Okay. Thank you very much. If you would please, sir, come back up to the witness booth.

I would just remind you that you remain under oath to tell the truth, the whole truth, and nothing but the truth. I did neglect to admonish you before the break to not discuss your testimony with anyone during the lunch break.

Just to confirm, sir, did you discuss your testimony with anyone during the lunch break?

THE WITNESS: We did not.

JUDGE JULIUS: Thank you very much for confirming that, sir. Any other preliminary matters before, oh, can you clear the Exhibits

that you have from your direct examination?

THE WITNESS: Sure.

JUDGE JULIUS: We'll just start with a clean table in front of you.

THE WITNESS: Okay.

JUDGE JULIUS: And, if Mr. Evans needs you to look at anything, we'll have him pass that to you. Okay?

THE WITNESS: Thank you.

JUDGE JULIUS: Thank you so much, sir.

MR. EVANS: Your Honor, if I have a document to give to the Court, do I ask, can I approach the bench and give it to you, give one to the witness?

Or, will the clerk do that?

JUDGE JULIUS: You need to ask for permission to approach and you can give it to Mr. Phillips sitting in front of me, and then he'll pass it to the witness.

MR. EVANS: Okay.

JUDGE JULIUS: Thank you for clarifying that, sir.

CROSS EXAMINATION

MR. EVANS: Doctor, are you familiar with the case of Alliance for Cannabis

Therapeutics versus DEA?

THE WITNESS: Vaguely. Alliance I think was --

MS. MAN: Objection. Outside the scope of direct.

JUDGE JULIUS: Mr. Evans?

MR. EVANS: Well, this is the case that decided the five-part test, which I think is something that we're dealing with right now. My question is, and has to do with the two-part test.

JUDGE JULIUS: Okay. I'll allow the question based on the purpose of it.

MR. EVANS: Are you aware, I just have a couple questions, are you aware that that case established a five-part test?

THE WITNESS: I am aware of DEA's Federal Registered notice describing the five-part test. I did not follow the legal details of the case.

BY MR. EVANS:

Q Okay. Are you aware if this case was in 1994?

A No. I thought that it was resolved in 1992. I'm not sure which case led to the 1992,

but that was my recollection.

Q Why is HHS and DEA abandoning the five-part test and going to the two-part test?

MS. MAN: Objection.

MR. EVANS: Is the objections --

JUDGE JULIUS: What is the objection basis?

MS. MAN: Your Honor, the two-part test has been established by the OLC opinion, which the Court has taken judicial notice of. That was Government's Exhibit Number 4 that was already accepted.

The OLC opinion has already established that the, the legality of the two-part test. And, we're not here to debate the legality of the two-part test. That's already been accepted and is binding on the Department.

JUDGE JULIUS: And, Mr. Evans, your response?

MR. EVANS: Well, Your Honor, I'm trying to get at the history of what happened. And, what I'm going to be asking the doctor about, is not challenging the two-part test, but asking him questions about how it was administered.

And, one of those things would help, I think, the Court understands why was the five-part test abandoned? Why did they go to the two-part test?

Because, is the two-part test as thorough as the five-part test? And, that would help the Court to understand how the two-part test was implemented, and what are things that were looked at under five-part that they did not look at under the two-part, and also did not look at under the two-part.

And, I'm going to start with the NPRM. So, I'm just trying to set the, you know, the history of what happened. I'll withdraw the question.

I have very limited time, Your Honor.

JUDGE JULIUS: I understand.

MR. EVANS: I'd like to move on. Okay.

JUDGE JULIUS: So, I understand the question's been withdrawn.

MR. EVANS: Yes, sir.

JUDGE JULIUS: Do I understand that correctly?

MR. EVANS: Yes, sir.

JUDGE JULIUS: Okay. Thank you.

MR. EVANS: Doctor, you work for the Food and Drug Administration, is that correct?

THE WITNESS: Yes.

BY MR. EVANS:

Q What is the purpose of the Food and Drug Administration?

A To assure the safety and quality of all the food categories and drug categories, dietary supplements that they regulate.

Q Okay. And, is part of the role of the FDA to protect the public from proposed drugs that might harm people?

A Yes.

Q Is the role of the FDA to disregard political considerations in making decisions like current accepted medical use?

A Yes.

Q Okay. Who told you to review the rescheduling and to start this whole process?

You mentioned that somebody told you to do it.

A I'm not sure of the, it was a decision at the Secretary's level. So, it would be Secretary Becerra.

Q Okay. And, do you know who told him?

A President Joseph Biden.

Q That's correct. He told that to get started. Now, are you familiar with the other order that was issued this year that may have to do with current medical use by the Attorney General?

A I'm familiar with the April order, yes.

Q Okay. And, do you know who told him to do that?

A No, I don't.

Q Okay. And, do you know who donated $750,000 to President Trump's inauguration?

MS. MAN: Objection.

MR. EVANS: I'm getting to --

JUDGE JULIUS: Hold on, sir.

MR. EVANS: Yeah.

JUDGE JULIUS: What's the nature of, what's the basis of the objection?

MS. MAN: This is absolutely outside the basis of Dr. Chiapperino's direct. And, in addition, Dr. Chiapperino is here testifying under a Touhy letter, which does not authorize him to speak about campaign donations.

JUDGE JULIUS: Sustained. Based on the Touhy and the outside the scope as well.

MR. EVANS: Okay, fine. Doctor, I'd like to look at the NPRM, and I have a copy here for you and I've highlighted it.

This is the Government's Exhibit 1. And, I put in some highlights again, to speed things along.

THE WITNESS: Thank you.

MR. EVANS: Now, Doctor, what was your role in creating this NPRM?

THE WITNESS: We provided the drug evaluation to the DEA on August 29, 2023, and the -- (telephone interruption.)

MR. EVANS: Excuse me, I had my phone on for the time to watch. I'll turn it off. Pardon me. Okay.

BY MR. EVANS:

Q All right. And, do you see your work reflected in this NPRM?

A To be fair, it has been two years since that was published. I don't recall all the details of the NPRM, how it may have differed in a few places versus the HHS evaluation.

It is a fair paraphrase or reproduction of the evaluation.

Q Okay. Do you feel that you should have

included something in the last two years?

Have you come to realize that you should have included some things that you left out?

MS. MAN: Objection.

JUDGE JULIUS: Basis?

MS. MAN: This is going to be outside the scope of Dr. Chiapperino's Touhy letter.

MR. EVANS: No. He testified that he had a lot to do with this document, provided the scientific basis.

MS. MAN: Right. But, the Touhy letter --

JUDGE JULIUS: Okay. No colloquy between the attorneys, please.

MR. EVANS: Okay.

JUDGE JULIUS: I will allow the basis of the objection. And then, I will hear, I will acknowledge you.

But, I do not want you speaking back and forth to each other. Understood?

MR. EVANS: Yes, Your Honor.

JUDGE JULIUS: Thank you. So, it's outside the scope of Touhy and what? Anything else?

MS. MAN: Because the question is, since in the last two years, since your recommendation, have you, do you wish that something else was included?

He is allowed to testify about the 2023 recommendation and not anything past that. So, my objection still stands that's outside the basis of the Touhy Letter.

JUDGE JULIUS: Okay. Any response to the objection?

MR. EVANS: My response to that, Your Honor, is that he went into great detail about how he looks at studies, and reports, and clinical studies, and surveys, and so forth in trying to make this evaluation.

So, if he stopped doing that and that there has been things that have developed since, which there have been, that may affect this NPRM, I just wanted to know if he, did he just wash his hands of it at that time, walk away from it?

Or, did he continue doing the evaluations? It's been two years.

JUDGE JULIUS: I understand the objection, or the question and the objection.

But, if it's outside what he's allowed to talk about under Touhy, I can't get information out of him that is beyond what he was allowed to share under the law.

So, sustained.

MR. EVANS: Well, I misunderstood what he was supposed to talk about. He was here to talk about the NPRM and the scientific basis for it.

And, that's what the gist of my question is about.

JUDGE JULIUS: It's been sustained, sir.

MR. EVANS: Excuse me?

JUDGE JULIUS: The objection was sustained.

MR. EVANS: In this NPRM, did you say anything about pregnant women?

THE WITNESS: We did not write the NPRM in the drug evaluation that we did. We did not have any breakout evaluations specific to pregnant women.

BY MR. EVANS:

Q Why not?

A We base our concerns on the population

as a whole.

Q Are pregnant women part of the population of the whole?

A They are.

Q So, why didn't you consider them?

A They are part of the whole, which we considered.

Q The FDA, isn't it true that the FDA considers the effect of medicines on women in practically everything they do, pregnant women? Isn't that true?

A We were not reviewing a drug for potential approval by the FDA. We were doing a drug evaluation for drug scheduling purposes. And, our objective was to consider epidemiological databases that are representative of harms to the population.

Q Why didn't you consider harms to pregnant women and their unborn child?

MS. MAN: Objection. Asked and answered.

JUDGE JULIUS: I'll allow him to see if it, the rephrasing of the question allows. Go ahead, sir.

MR. EVANS: You didn't do it, did you?

THE WITNESS: We did not. No.

BY MR. EVANS:

Q Okay. Okay. Are you aware that since this NPRM came out that the American College of Obstetricians and Gynecologists has said that under no circumstances, there's no medical reason for a woman to use marijuana?

Are you aware of that?

MS. MAN: Objection. Outside the scope of Touhy.

JUDGE JULIUS: Do you have an argument for hearing testimony that's outside the scope of what he's authorized to disclose?

MR. EVANS: Yes. Again, he has testified that he's gone through these diligent searches, and he left a very important thing out that is in every FDA label, every FDA package insert, they talk about pregnancy, lactation, and so forth.

He was talking about how he had done this great thorough job and he didn't.

JUDGE JULIUS: Well, sir, my question - -

MR. EVANS: I'm not arguing against the two-part test. I'm arguing against the method

that they derived at.

And, they left out a key thing in deciding medical use.

JUDGE JULIUS: Sir, I understand what you're talking about. You're not answering my question.

My question was whether you have an argument for how I can get information from a witness that is beyond what he is authorized to disclose to this tribunal under his Touhy letter.

MR. EVANS: Well, the information would be a, I mean, am I not allowed to ask him any questions about what he's done over the last two years?

Doesn't he have some obligation to have continued to study this and look at it? Am I just --

JUDGE JULIUS: Under 28 CFR, Section 16, those are the Touhy regulations for the Department of Justice. And, well, he would be under FDA Touhy regs?

MS. MAN: It's the FDA Touhy regs, yes.

JUDGE JULIUS: Okay. And, can you clarify the scope of the Touhy letter? What is

he allowed to discuss?

MS. MAN: Yes. He's allowed to testify to and disclosure, included in the Government's pre-hearing statement.

JUDGE JULIUS: Thank you.

MS. MAN: He's authorized to give testimony about the scientific and medical basis underlying the eight factor analyses, which went into whether or not the substance should be controlled or scheduled.

He can testify as to the scientific and medical determinations underlying the analysis performed and conclusions drawn by the FDA in its August 28, 2023 report, which is Government's Exhibit, or excuse me, ALJ Exhibit Number 1.

And, he is also allowed to testify to FDA's recommendation that marijuana be placed in Schedule III under 21 USC 812(b)(3). That is the scope of Dr. Chiapperino, as the FDA has permitted him to testify.

MR. EVANS: Your Honor, it clearly says that he is to testify about medical determinations. And, I think the fact that he did not do a medical interpretation or a medical

determination, is something that we should be able to inquire about.

If they were negligent, we need to know about that. And, why were they?

JUDGE JULIUS: What is the date of the study that you're talking about?

MR. EVANS: The Gynecologists came out, I think it was in last fall.

JUDGE JULIUS: So, that it post-dates, the recommendation that was made in 2023.

MR. EVANS: Right. So, I'm asking him about his determinations. Well, let me ask you this --

JUDGE JULIUS: So, are you withdrawing that question for now?

MR. EVANS: Well, no. I think I should be allowed to see if he has since continued with his medical evaluation.

Clearly I can talk about that. That is relevant here on, did he continue to do this?

JUDGE JULIUS: After the recommendation was made?

MR. EVANS: Yes. Isn't that his job to do that? And, can he make a recommendation that leaves out a very important thing?

And, he left out other things also that are in here that he was supposed to report it on that he did not, like diversion. He completely waffled on that answer to diversion.

And, there's been a DEA report, it just came out earlier this year, about widespread diversion of marijuana.

JUDGE JULIUS: So, how is he supposed to incorporate an article that did not exist at the time he made the recommendation or that the FDA made the recommendation in 2023?

MR. EVANS: Your Honor, there's a thing in tort law that if you do something negligent and you correct it, okay, that's what you're supposed to do.

And, I think it was his duty to continue to evaluate this, because they're recommending this for a medicine that can be used by practitioners. And, they have consistently used the name practitioners. They have not said physicians. They said practitioners.

And, under federal law, practitioners includes family counselors and social workers. They are defined as healthcare professional

practitioners under federal law.

So, is that what they meant to do? Did they intend to give that to family counselors and social workers to give them that power to do that?

Under that definition, school nurses could do this. So, I think the Government has a continuing obligation to continue to look into the accuracy of what they've done, because people's lives depend on this.

You can't just wash your hands and then ignore everything that happens after that. It would be reckless and all that information should have been produced.

They could have amended this NPRM. They could have included the additional, they could have issued a report on this to be able to straighten that out.

The DEA, just earlier this year, came out with a report in their drug assessment, talking about massive diversion of marijuana from the legal marijuana states to the non-legal marijuana states. And, in the NPRM, he said, well, you know, we're going to need more information on that.

There's several times in this NPRM where they said, we need further studies, we need more work on it. They opened the door to that and they gave themselves that obligation to continue to study it. Okay?

If the FDA approves a drug and it turns out to be a stinker, one of the complaints against the FDA is you didn't study this thing enough. Okay?

And, I think they have an obligation, they could have corrected it. They could have issued something about the NPRM and medical use for women. But, they didn't do it.

The other issue here, Your Honor, is that just because something has in this narrow definition of medical use, doesn't mean that it can be used medically, because there's a whole bunch of other hoops that they have to jump over that require clinical studies, FDA quality ~~criminal~~ clinical studies, marketing, labeling, and so forth.

Package inserts all require under FDA law. And, I have them right here. So, you're allowing a drug to have the accepted medical use, but yet you're ignoring all of your

requirements for the second stage of that whole thing.

And, I can go through this list here.

JUDGE JULIUS: I don't need you to go through all of that. This is going on and on. I think my concern is, I don't want to compel him to give testimony that is in violation of the Touhy limits that he is authorized to give testimony on.

So, what is the Government's position with regard to the scope of the Touhy letter with regard to documents that could have been reviewed after the Food and Drug Administration and HHS put forward their recommendation in 2023?

MS. MAN: The Government reiterates Dr. Chiapperino's testimony, reiterates that Dr. Chiapperino's testimony under the Touhy letter does not permit him to do so. His testimony ends at the August 28, 2023 recommendation.

MR. EVANS: Your Honor, this is why people are so cynical about the Government, because they rely on a technicality and expose people to danger.

JUDGE JULIUS: Okay. Sir, please

refrain from editorializing.

MR. EVANS: Okay. All right. Well, let's go through the NPRM and see what you say that you left out.

THE WITNESS: Sir, you keep saying you say. I just want to clarify, this is a DEA NPRM paraphrasing in sections of the HHS evaluation.

And, the HHS evaluation is a broad team of people. But, I do take responsibility for my role in producing the final documents that were signed by the signatory, the Assistant Secretary for Health. Thanks.

MR. EVANS: I'm glad. Okay. Let's go to, on the Government's Exhibit 1, page six. Looking at the highlighted item there that deals with diversion.

MS. MAN: I'm sorry, Mr. Evans, could you point to --

MR. EVANS: You said DEA --

MS. MAN: I'm sorry to interrupt you, sir. Could you point me to where you're referring to, please?

MR. EVANS: Oh, Yeah. It's on page six of your Exhibit 1.

MS. MAN: Okay.

MR. EVANS: And, it is the first full paragraph on the left.

MS. MAN: Thank you, sir.

MR. EVANS: Let me see if I have a copy for you. Yeah, here you go. Sorry, I should have given these to you.

MS. MAN: Thank you, there it is. Already have the highlights marked as well?

MR. EVANS: Yeah. Okay. So, I will again read the sentence here that DEA anticipates that additional data on seizures of marijuana by law enforcement, cannabis-related ED visits as well as an updated etiological survey data since 2022, may be appropriate for consideration.

THE WITNESS: Um-hum.

MR. EVANS: Do I make my point? Go down to the bottom paragraph.

MS. MAN: Objection. Asked and answered.

JUDGE JULIUS: Yeah, he didn't answer the question.

MR. EVANS: Oh.

THE WITNESS: May I explain a process point?

MR. EVANS: Did you feel that you had to get updated epidemiological survey data since 2022?

THE WITNESS: Let me clarify a process point that seems to be leading to confusion in this discussion.

So, initially the evaluation was requested at the Secretary level in the Department. We did that evaluation. It is a completed project from my perspective.

The fact that DEA has written an NPRM where they are citing places where they think additional information should be considered, if DEA would like a reevaluation that involves additional analyses, the agencies would communicate on that matter.

So, there is a mechanism for additional consideration. But, until someone tells me, or any other part of FDA in this chain, that this is an active project again, we are not going to be doing work that is not going to serve an active evaluation.

MR. EVANS: Well, you opened the door and I think you ought to do it. I think you ought to do that evaluation and modify this

NPRM, because you're leaving out pregnant women.

You're leaving out data on diversion.

MS. MAN: Objection.

MR. EVANS: All right. And, let's get to the diversion point.

JUDGE JULIUS: Sorry, sir, was there a question in there?

MR. EVANS: Yes. Will you pursue this on your own as the head of CDER? Your responsibility to protect the public, will you pursue this, go to your supervisors and say, look, we need to modify this.

We need to add something and work with the DEA to get that correct.

MS. MAN: Objection. Outside the scope of Touhy.

JUDGE JULIUS: It is. I think your point is understood. I would just remind counsel examination is for purposes of asking questions, not for making statements or arguments.

MR. EVANS: Right.

JUDGE JULIUS: Thank you.

MR. EVANS: Okay. Let's look at, down at the bottom it says, "given the unique

landscape, DEA believes that the lack of data indicating diversion of marijuana from federally sanctioned drug channels to the illegal market is not indicative of a lack of potential for abuse.

DEA anticipates that additional data on diversion from state programs and DEA registered manufacturers, may aid in determining whether diversion is taking place."

So, again, do you think that you should recommend to the DEA that they add to this NPRM, the recent data they published on diversion?

MS. MAN: Objection. Same objection.

MR. EVANS: Okay.

JUDGE JULIUS: The scope of Touhy?

MS. MAN: Correct.

JUDGE JULIUS: Sustained. Do you want to rephrase your question in a way?

MR. EVANS: Okay. Go to the upper right-hand corner. It says, "in addition to the data considered and the HHS basis recommendation by HHS and DEA in their eight-part analysis, DEA anticipates that updated epidemiological survey data since 2022, may be appropriate for consideration."

So, Your Honor, I am going to make a motion for the purpose of the record that this NPRM be rejected, because they have not fulfilled and done what they said they were going to do. They opened the door to it and they didn't do it.

Now, looking also, going down to page seven.

JUDGE JULIUS: Are you moving on from the motion that you just made? Do I need to rule on that first?

MR. EVANS: No, I'll make the motion.

JUDGE JULIUS: Okay.

MR. EVANS: I think that, yeah, let them respond to it.

JUDGE JULIUS: Okay.

MR. EVANS: But, I want to get it on the record that --

JUDGE JULIUS: I understand.

MR. EVANS: We feel this whole thing should be done away with, because they did a shoddy job and there's new data coming up. And, I think they have a duty to incorporate the new data.

JUDGE JULIUS: Okay. Let's deal with

the motion first.

MR. EVANS: Okay.

JUDGE JULIUS: Government, your position on a motion to, how did you phrase it? Terminate or --

MR. EVANS: Well, I think that the, I'll make it easy for them. The motion is that the Court should order that the DEA and the FDA update the data that they said they were going to update in this NPRM, and publish it and take a look at it.

And, I've got another point on this that it will further make this motion. Look at page seven, the very last paragraph on the bottom.

It says, "in 2016, DEA found that marijuana has a high potential for abuse. Preclinical and clinical data shows that it has reinforcing characteristics of drugs of abuse.

Data on marijuana seizures shows widespread availability and trafficking. DEA believes that additional data in this area may be appropriate for consideration in assessing marijuana's actual or relative potential for abuse."

Doctor, do you think that's a good idea since you testified on the issue of marijuana's abuse?

And, this talks here about getting additional data on that? Would you be receptive to additional data?

THE WITNESS: The paragraph references --

MS. MAN: Objection to the question. But, I thought we were still talking about the motion.

JUDGE JULIUS: I did too as well.

MS. MAN: I'm not sure which one the Court would like me to address.

MR. EVANS: I'm done advocating for the motion. I think I have other points to show why this --

JUDGE JULIUS: Well, then I need to rule on the motion.

MR. EVANS: Yes.

JUDGE JULIUS: Government, your position on this motion regarding the NPRM?

MS. MAN: Your Honor, the NPRM is intended to provide notice of proposed rulemaking. This is not the avenue for, with

all due respect to the Court, the Court does not have the authority to strike the NPRM.

It's been issued by DEA already. And, it is what it is. It stands for what it stands for.

So, asking for a revised NPRM, I don't think that would get the result Mr. Evans is hoping for. But, that is also not an appropriate, this is not the appropriate venue for him to do so.

And, with all due respect to the Court, the Court does not have the authority to strike the NPRM.

JUDGE JULIUS: Okay. And, Mr. Evans, anything in reply in support of your motion?

MR. EVANS: Your Honor, again, this is for a notice of potential rulemaking, for which people have the ability to comment on and things should be accepted. They have admitted, several times, I can go on, that they need additional data in making these decisions.

So, how can they go on to make a final rule when they're admitting they don't have enough data? That's their admission.

I got another admission right here

having to do with pharmacological effects. DEA believes that additional data on marijuana's pharmacological effects may be appropriate for consideration in assessing this factor.

You know, if I was responding to this and trying to guide myself in this, and I'm arguing the motion right now, as I'm a physician or somebody else, I would look at this and say, well, I'm not quite sure what to do here, because they say there's stuff missing.

And, how do you guide people when you say, you know, you should do this. But, we're not exactly sure that you should do it.

And, it's faulty on its face. I don't think I have to make any other argument. I think this should be withdrawn and they should go back to the drawing board and start all over again.

JUDGE JULIUS: Okay.

MR. EVANS: And, do a proper job.

JUDGE JULIUS: Understood, counsel. I do not have authority to cancel this notice of proposed rulemaking. It is what it is.

I'm holding a hearing on whether, what recommendations to make. You can make whatever

arguments you would like in terms of whether you think the Government has met its burden in getting this rule passed.

I don't have authority to cancel, terminate, order them to withdraw this. If the Government chooses to do that, that's their prerogative.

I also note that the instances where you are pointing to say, may be needed, additional may be needed. I don't in any way mean to suggest that I don't think it's important that we have thorough an examination of medical products. We absolutely should.

But, I don't see a basis for me to even grant your motion based on the authorities that are vested in me with this hearing. I also don't, there's a process by which if DEA wanted, as I understand it, if DEA wanted to reopen and seek additional guidance that they could.

So, the motion is denied.

MR. EVANS: Your Honor, you do have the authority to send it back to the Director of DEA. Judge Mulrooney did that. There was a motion and his response to that motion was to send it back to the Director of the DEA, because

something had to be resolved.

These are crucial issues that have to be resolved, pregnant women, diversion, pharmacological effect, considerable variability in cannabis, cannabinoids, considerations, and so forth. This thing is faulty on its face.

And, you can send it back and say, do a better job, guys.

JUDGE JULIUS: Well, sir, I'm denying the motion. So, please proceed.

MR. EVANS: I understand. Okay. Doctor, you said that you, as part of the evaluation, you wanted to do, you wanted to consider clinical studies.

Is that correct?

THE WITNESS: Yes.

BY MR. EVANS:

Q Okay. Did you consider clinical studies on marijuana, the medical use of marijuana?

A Yes.

Q Okay. Did each and every one of those studies meet the requirements of 21 CFR 314.126 adequate and well controlled studies?

This is an FDA rule on what goes into

adequate and well controlled studies. May I approach the bench?

JUDGE JULIUS: You may.

THE WITNESS: Thank you.

MR. EVANS: Now, Doctor, isn't it true that when a pharmacological company submits clinical studies to you about their product, did you make them adhere to this?

THE WITNESS: Pivotal Phase 3 trials should adhere to these requirements in a new drug application submission.

BY MR. EVANS:

Q Have you done that in considering the clinical trials about marijuana?

A This was not a review of a drug application, nor was the conclusion a finding of safety and efficacy that led to any form of FDA approval.

This was an acknowledgment of medical use already going on in the states, and subjecting the clinical data that's available to attest and evaluate whether there is credible scientific support for any of those uses.

I've talked before about the quality of evidence. It is not the same quality of

evidence of a Phase 3 trial. There was no attempt to mislead on that statement.

We stated it in the documents in multiple places.

Q Okay. Doctor, if this NPRM goes through, will a practitioner be able to prescribe marijuana now?

Let's say this is in effect right now, --

MS. MAN: Objection. Calls for speculation.

JUDGE JULIUS: Do you have a response?

MR. EVANS: Well, I think that when you look at accepted medical use, you're thinking about this item may be used medically. And, I think that you need to go beyond that initial determination into the ultimate situation.

You have already done that. You've looked at four where you looked at the research, you looked at the effectiveness, you were convinced, you followed it all the way through from first use to whatever.

And, you know, I think I'm asking a very legitimate question. Based on what you came up with, could somebody prescribe marijuana

for anorexia?

JUDGE JULIUS: Wait. I need to rule on the objection before you answer.

MR. EVANS: Okay.

JUDGE JULIUS: I will allow the question. Overruled.

MS. MAN: I would like to add to my objection too. Number one, this is still outside his Touhy letter.

What Dr. Chiapperino testified to on direct was that this was considered to have a currently accepted medical use for drug scheduling purposes only.

It did not go to the safety and efficacy of marijuana once it hits the market. That's a completely different analysis. This is credible scientific support.

So, the Government reiterates that asking him to speculate about whether or not somebody could prescribe it in the future, calls for speculation and is outside the bounds of his Touhy letter.

MR. EVANS: Your Honor, the DEA has answered my question. They've made it clear that rescheduling it does not mean that it can

be distributed as a medicine. That they still have to go through the FDA procedures.

That's exactly the point that I wanted to make and I'm grateful for it.

JUDGE JULIUS: Just to clarify, is that what you were saying? I don't want to --

MS. MAN: No. No, Your Honor. It was not.

JUDGE JULIUS: Okay. Can you just maybe succinctly clarify what the Government's position is in its statement?

MS. MAN: Right. Your Honor, the scope of the Court's hearing today is whether or not it's appropriate for rescheduling, not what happens next.

And so, the currently accepted medical use is for a very limited purpose, rescheduling only.

MR. EVANS: Your Honor, the whole purpose of this is to determine whether something is accepted for medical use. How do we accept something for medical use?

Is it the two-part thing only? Could a doctor prescribe something based on the two-part? Of course not.

Of course not. There are a whole string of things having to do with labeling, clinical studies, and so forth that would have to be done.

So, if their position is that you're only doing this for rescheduling, rescheduling does not mean that it can be used as a medicine. It means it might have some medical value, but it still has to go through the FDA.

Our position has always been, we have no problem with anything that goes through the FDA and follows those rules. One of our clients is MMJ, a manufacturing company that manufactures marijuana, who agrees with us. Okay.

That's all we want. I'm a cancer survivor, I might use marijuana at some point, or CBD.

And, if I can just show the Court something, I would like, and this is further in this motion, and I'll give a copy to the thing.

MS. MAN: Please do.

JUDGE JULIUS: And, when you say further in this motion, what do you mean?

MR. EVANS: Well, it's another piece of

evidence showing, you know, my argument about --

JUDGE JULIUS: Wait until you -- sir, if you could wait until you get back to the podium, it's not picking you up.

MR. EVANS: Oh, sorry. My point is that this is a very grave decision. It can affect millions.

JUDGE JULIUS: Sir, if you wouldn't mind just describing what it is that you handed to Government counsel and to the Court?

MR. EVANS: Okay. Doctor, have you got a copy of it?

JUDGE JULIUS: We haven't provided him a copy yet. We didn't know if you wanted him to look at this.

MR. EVANS: Yes. Yes, Of course. I want him to identify it. I want him to authenticate it.

MS. MAN: Your Honor, the Government's going to object to this. Dr. Chiapperino cannot testify this. He's also not a medical doctor.

And so, he's about to ask him about dosages and like, potency, but with all of Dr. Chiapperino's credentials, he's not a medical doctor, so.

MR. EVANS: Your Honor, he's head of CDER.

THE WITNESS: I'm not head of CDER.

MR. EVANS: Well, you're in CDER. CDER decides all that issue. CDER's what wrote that. Could you identify that for the Judge please?

MS. MAN: If he can. But, Your Honor, the Government reiterates that this is well outside the scope of Dr. Chiapperino's Touhy letter, and that he's not a medical doctor.

JUDGE JULIUS: I'll allow him to answer the question if he can.

MS. MAN: Okay.

THE WITNESS: Thank you. You have handed me a copy of the prescribing information approved for the drug Epidiolex.

MR. EVANS: Correct. Yeah. Is this an example of the -- now, you did all this research on medical use of marijuana.

THE WITNESS: Um-hum.

MR. EVANS: Okay. You were looking at the whole medical use of marijuana things.

THE WITNESS: Um-hum.

MR. EVANS: And, you were looking at scientific evidence, studies and so forth. Did

you ever think to look at what the FDA finds interesting, and what should be published about something used as a medicine that's outlined in this?

MS. MAN: Objection. Outside the scope.

MR. EVANS: It's not outside.

MS. MAN: And, it's also vague and nonspecific.

MR. EVANS: It's not outside the scope.

JUDGE JULIUS: Hold on.

MR. EVANS: Yeah.

JUDGE JULIUS: Can you explain how, clarify how it's outside the scope, just so that the record is clear on your objection.

MS. MAN: Very well. Counsel said that this is titration information for a substance that Dr. Chiapperino never brought up in his direct. That would be for starters.

MR. EVANS: I'm sorry, I didn't hear the last part. And, you're speaking, can you speak louder?

MS. MAN: I'm sorry. I'm talking too fast.

MR. EVANS: No, no, louder.

MS. MAN: Oh, okay. Oh gosh, I feel loud. So, this is about a drug that Dr. Chiapperino never brought up in his direct examination.

So, it's outside the scope of his direct.

JUDGE JULIUS: Right. So, --

MR. EVANS: And, I'm not asking him about the drug. I'm asking him about the information that goes into a package insert about the drug that he says --

JUDGE JULIUS: So, sir, I understand that you have points that you would like to make. But, I am the Judge in this courtroom.

So, when I start talking, I would appreciate it if you would please refrain.

MR. EVANS: I'm sorry. I'm rather passionate on this issue.

JUDGE JULIUS: I'm trying to -- I absolutely understand. I think lots of people are very passionate on both sides about this issue.

MR. EVANS: I'm sorry.

JUDGE JULIUS: I absolutely understand and I commend you for being a cancer survivor.

All of that.

MR. EVANS: Right.

JUDGE JULIUS: But, I do need to make sure that the record is very clear about what the objections are.

MR. EVANS: I apologize, Your Honor.

JUDGE JULIUS: And, what the responses are.

MR. EVANS: I apologize.

JUDGE JULIUS: Thank you. So, you're saying it's outside the scope of direct or outside the scope of the Touhy? I didn't quite understand.

MS. MAN: It's outside the scope of both, Your Honor.

JUDGE JULIUS: Oh, okay.

MS. MAN: It's my understanding that this is about Epidiolex, I'm sorry I butchered it. But, this was a drug that never came up in Dr. Chiapperino's direct about which drugs he examined as part of his study. And, this is outside, so thus it's outside the scope of the Touhy letter.

JUDGE JULIUS: Okay.

MR. EVANS: Now, Judge, I don't care to

discuss Epidiolex. This is an example of a cannabinoid medicine, cannabidiol that the FDA has approved.

And, we would hope that if marijuana goes down to a Schedule III, that they do this kind of investigation.

Now, I'm asking him, when you look at all these items that are here, when he did his research on marijuana as a medicine, did he look at getting answers to these items?

JUDGE JULIUS: Hold on. I believe that question would be allowable. So, I'll overrule it as to that objection.

And, you may ask the question.

MR. EVANS: Okay.

JUDGE JULIUS: Thank you.

THE WITNESS: So, --

JUDGE JULIUS: Do you need it repeated?

THE WITNESS: Yes. Please repeat your question.

MR. EVANS: Okay. There's several things that go into a package insert. The Epidiolex is an example of it. Okay.

It includes pregnancy, lactation.

THE WITNESS: Um-hum.

BY MR. EVANS:

Q It includes mental illness, geriatric care. Okay. And, you know, all those have to be considered. You know that.

So, if you're looking at marijuana as a possible thing that could be accepted as a medicine, okay, did you consider all these things?

I mean, I'll give you an example. I'm a lawyer.

A Okay.

Q So, I look at jury instructions when I start a case. What do I have to do to prove my case? Okay? And, I steer my case around those jury instructions.

This tells everybody in the world what the FDA is interested in, in finding out about a medicine before they release it to the public. And, did you look at all these issues?

A No, because we are not releasing a drug to the public. The drug is already in release under state programs.

I want to clarify my role with respect to drug labeling, because the controlled substance staff does have a role in drug

labeling. We give advice on labeling for Section 9, abuse and dependence, and any Section 5 warnings and precautions that may be warranted.

Other Sections that you're describing, which are very important safety matters, have other subject matter experts. So, yes, in the context of a new drug approval, all of these things would be addressed.

If someone brings a new drug application for marijuana to the FDA, the label, if it is approved, would address all of these issues, or it would not receive approval.

We are not commenting though on state regulated medical use, which this action is basically leaving alone, because it is not finding of FDA sanctioned medical use under a drug approval. It is just acknowledging that the medical use is already happening and we applied the two-part test to see if there was any credible scientific support for it.

Q Okay. Doctor, ~~does~~ is giving something accepted medical use the same thing as the FDA declaring that it's safe and effective?

A No.

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Q Okay. Doctor, are you aware, can you think of a situation where the FDA safe and effective laws, or the CAMU, should be waived by the FDA?

MS. MAN: Objection. Calls for speculation.

MR. EVANS: Well, how about a situation? Should the Director of the FDA just decide I'm not doing the two-part test?

MS. MAN: Objection. Calls for speculation.

JUDGE JULIUS: Do you have a response to the objection?

MR. EVANS: Well, I think we're looking at the CAMU test. And, again, the liability, the effectiveness of it. Are they willing to stand behind it?

Could there be situations where the FDA would give up? Under the labeling law, the head of CDER has the authority to waive labeling requirements.

MS. MAN: Objection. Assumes facts not in evidence.

MR. EVANS: So, I just want to know, is it possible that a situation after we go through

all these trials, and the head of the FDA upon orders from President Trump says, we don't need no stinking FDA rules. Is that possible?

Could that happen?

MS. MAN: My objection --

JUDGE JULIUS: Hold on. I think there's an objection pending.

MR. EVANS: Okay.

MS. MAN: And, my objection first was --

JUDGE JULIUS: And then, still, there was more questioning.

MR. EVANS: Okay.

MS. MAN: There were many parts to this. And, I'm going to try to figure out which one to respond to first.

Is there a situation where the head of FDA, Dr. Chiapperino is not the head of the FDA. So, I think it is outside the bounds of his direct testimony for him to talk about that.

But, also, he can't speculate to what somebody else is going to do. And, also, that speculation is outside what he's permitted to testify about, what another Government entity, or it's his Government entity, but it's another

human being would do in response to something else that hasn't happened.

This calls for speculation on multiple fronts.

MR. EVANS: Your Honor, I would assert that the head of the FDA, waiving the FDA safe and effective rules is not speculation. It just was done.

Concerning again, not this topic, but on the thing the Attorney General came out, the head of the FDA said, we're not applying our safe and effective rules. And, on labeling, the Attorney General said, we're not applying the FDA prescription rules or labeling rules. We're going to leave that all up to the states.

It's trying to put you out of business.

JUDGE JULIUS: Okay, sir, let me rule on this objection. There's been a lot of back and forth, --

MR. EVANS: Right.

JUDGE JULIUS: Which I find difficult to follow. And, it's muddying the record. So, I would just continue to admonish the parties to please keep any arguments concise, and let me rule on objections before moving on and adding

additional.

MR. EVANS: Very good, Your Honor.

JUDGE JULIUS: I do find that it would be speculative to ask whether someone else out, not him individually, would waive certain requirements. I do find it does seem outside the bounds of the Touhy authorization.

And, I suppose there could be a reformulation of that question about historical events. But, asking him to speculate about potential future would be objectionable.

So, I will sustain that objection.

MR. EVANS: Let me ask it in a way. Doctor, are you aware of a situation where the head of the FDA waived the FDA's requirements that a medicine be safe and effective?

Are you aware that that has ever happened?

MS. MAN: Objection. Outside the scope of the Touhy letter.

JUDGE JULIUS: Do you have any response to that?

MR. EVANS: Well, again, looking at the, do we trust the FDA?

JUDGE JULIUS: That is beyond the scope

of this hearing.

MR. EVANS: Well, it really isn't, Your Honor. Because, they're coming up with a standard here that they're going to make everybody adhere to, okay?

And, they're reserving the right to just throw it all away. And, this medical use, accepted medical use, you know, is it something that we should support?

If they retain the power too just completely unsupport women, I think that's worth finding out. Are they going to be subjected to political influences?

Why did the, you know, if the President ordered you to stop doing labeling, would you do it?

MS. MAN: Objection. That is absolutely outside the scope of this hearing and absolutely outside the scope of Dr. Chiapperino's Touhy.

I'm sorry, I had to jump in before -- I know you still haven't ruled, Your Honor, on that last objection. But, I wanted to get ahead of this one.

JUDGE JULIUS: Your response to the

outside the scope of the Touhy authorizations?

MR. EVANS: Well, I think it is. I think that if somebody creates something and you have to consider the future of the creation. The accepted medical use implies that this is accepted for medical use and it could be used medically.

So, I'm looking at, you know, if we have something accepted for medical use, but it turns out that there's other things in here that would make that moot or impossible to implement, why are we doing this exercise?

If the accepted medical use could, you know, go forward, do we just make the decision then do nothing about it and never rely on it in the future and never think about it?

No, of course not. We have to think ahead. Okay? And, we need to examine their thoughts. Did they think ahead when they did this?

Are they aware of the consequences that could result from this? Because it appears that they didn't think about that.

That the President told them to do something. Admiral, what's his name, told them

to do something, and they did it. It's certainly the marijuana industry was very happy about it because they've been pushing for this for years.

My job, my organization represents the victims of the marijuana industry. I get phone calls once a week from a mother who's lost their child. It's like opening up the gates of hell. Okay?

I see the consequences every day. And, you know, would you be willing, any of you, willing to sit down and talk to some of these mothers, continue your clinical studies by talking to the victims sometimes?

Would you be willing to do that?

JUDGE JULIUS: Is that a rhetorical question?

MR. EVANS: No.

JUDGE JULIUS: At this point, sir, I think your argument is going beyond the scope of this hearing.

MR. EVANS: Okay.

(Simultaneous speaking.)

JUDGE JULIUS: I understand that you have to --

MR. EVANS: I know why I think it's important to pursue this, because we have to examine the consequences of the decision. Was a consequence thought out or it wasn't thought out?

Okay? And, you know, I'm not asking for, you know, repainting the, what is it, the wading pool down here. That wasn't very well thought out.

But, that's an example of something that wasn't well thought out. And, this is something that could potentially kill people.

Marijuana interacts with other prescription drugs in a negative way. If you're taking blood thinners, it will cause you to bleed.

JUDGE JULIUS: Okay. Sir, I very much take your point. I understand that you are very passionate about this.

But, I think the scope of this hearing is what went into the notice of proposed rulemaking, which was the recommendation from HHS. To the extent that he has answers to give about what went into that, he can provide those.

To the extent that we're spiraling out

and asking questions about tests that should be applied prospectively in other cases, that's beyond the scope of this hearing.

I understand that you have concerns about that.

MR. EVANS: Okay. Your Honor, I --

JUDGE JULIUS: I will sustain the objections to the questions based on outside the scope of direct, outside the scope of Touhy, and also speculative as to whether certain --

MR. EVANS: Fine, Your Honor.

JUDGE JULIUS: Aspects have not been proven.

MR. EVANS: The NPRM mentions diversion and that they need more data about diversion. Did you feel at the time you had enough data about diversion to make a rational decision about it?

THE WITNESS: DEA provided some data which we reproduced in our factor. DEA would be the agency to collect further diversion data.

If there were another review of marijuana, a full new project to review it, then there could be updated diversion data. Or, DEA can choose to supplement for this rule without

HHS's views.

MR. EVANS: May I ask you, in terms of your updating it, would you consider this? I'm going to read a statement to you.

Domestically produced marijuana is transported via U.S. interstate highways in personally owned vehicle, semi-trucks, and tractor-trailers. Facilitators working for the Chinese TCO and/or Mexican cartels, transport large amounts of marijuana directly from legal states to states that have not legalized recreational use, and those where state level recreational approval is sufficiently reason to have not yet established a registered industry.

A shotgun approach involves sending multiple vehicles, usually carrying no more than a couple hundred pounds of marijuana to the same destination to avoid the loss of a single large shipment.

Would you be willing to consider that in your --

MS. MAN: Objection. Calls for speculation. There is no active rule or there's been no active request to reopen this.

So, this calls for speculation of what

he would do in the past if that were to happen. This is also outside the bounds of his Touhy letter, which ends in 2023.

MR. EVANS: Your Honor, it's on the NPRM. He left it out and I'm pointing out --

JUDGE JULIUS: I don't even know what you're reading, sir. What is that?

MR. EVANS: This is the Drug Enforcement Administration 2025 Drug Threat Assessment. That's what they said.

JUDGE JULIUS: Okay. Well, I sustain the objection. It is outside the scope of his direct and his Touhy.

MR. EVANS: All right.

JUDGE JULIUS: I understand that you asked the question. But, you know, if you like, you may --

(Simultaneous speaking.)

MR. EVANS: May I make --

JUDGE JULIUS: A new --

MR. EVANS: The point of this whole argument is they all should update what they did, because it's now faulty of full holes.

JUDGE JULIUS: I understand your point, sir. Thank you.

MR. EVANS: How are we doing on time?
JUDGE JULIUS: It looks like you have almost 35 minutes left.
MR. EVANS: Thirty-five minutes, wow.
JUDGE JULIUS: Well, the objection time doesn't count against you. We stop the clock on that.
MR. EVANS: Oh, okay.
MS. MAN: Okay.
MR. EVANS: All right. Well, let me, now, you did talk about the eight-part analysis, correct?
So, is it permissible that I ask him about the eight-part analysis?
MS. MAN: You can ask him whatever you like, sir.
MR. EVANS: Okay. Do you know who Luli R. Akinfiresoye is?
THE WITNESS: Yes.
JUDGE JULIUS: Could you spell that for the record, just so that we're clear?
Oh, Court Reporter has it. Thank you.
MR. EVANS: Okay. Do you want me to spell it?
JUDGE JULIUS: The Court Reporter has

it. Thank you.

MR. EVANS: Okay. Okay. This is an Exhibit. I think that several of the parties have this as an Exhibit.

Do you know who she is?

THE WITNESS: Yes.

BY MR. EVANS:

Q Was she a witness the first time this NPRM was considered?

A I believe she was.

Q Did you read her affidavit?

A No, not completely.

Q Okay.

A But, I think, I actually don't recall. There were documents circulated for clearance purposes.

I don't think I reviewed her full affidavit, no.

MR. EVANS: Okay. Your Honor, if I may, I don't have the ability to authenticate this document. Dr. Akinfiresoye is coming in as a witness. She can authenticate it.

So, would I be allowed to ask questions on this with the authentication pending? And if it does not get authenticated, okay.

But, you know, in the interest of moving things along, would I be able to ask questions with authentication pending?

MS. MAN: Your Honor, the date of that witness's authentic affidavit post dates, Dr. Chiapperino's 2023 recommendation.

So, this is outside the scope to ask him about something that was generated afterwards. And, it appears that you've subpoenaed her to come and she's going to testify.

So, I believe that anything that's in her declaration, Mr. Evans can ask himself when she takes the stand, which would be the more appropriate venue.

MR. EVANS: Pardon me, I didn't understand about Chiapperino and the dating. What are you talking about?

MS. MAN: The affidavit of the witness's testimony postdates Dr. Chiapperino's 2023 recommendation.

So, it was generated --

MR. EVANS: What do you mean postdates?

MS. MAN: After.

MR. EVANS: After?

MS. MAN: Yes. I believe what you're about to show him is from 2025.

MR. EVANS: No.

MS. MAN: 2024? Hang on, let me see.

MR. EVANS: 2024.

MS. MAN: Right, but it's in 2024. Dr. Chiapperino's HHS recommendation for the scheduling was dated August 2023.

And so, nothing that, he couldn't have considered something that was generated almost a year afterwards. So, I believe this is outside the scope of the Touhy letter to ask him about something that was generated in 2024.

MR. EVANS: Your Honor, my response to that, they called her as a witness in December of 2024. And, that is a specious argument.

They called her as a witness. Obviously, they were going to use her testimony. But, she is a DEA witness. I got it all right here.

JUDGE JULIUS: That hearing was terminated when that notice was withdrawn. She's not a Government witness at this time in this hearing.

It does appear to postdate the

recommendation. So, it would not have been considered in the HHS recommendation as I understand it.

Am I misunderstanding the timeline?

MR. EVANS: Well, I can tell you that this document considered and commented on the HHS document that started this whole thing. It also commented on the Office of Legal Counsel's opinion.

JUDGE JULIUS: So, this affidavit that you're discussing, is talking about the HHS recommendation and the OLC memo.

MR. EVANS: No, not the document and the affidavit in itself. But, the document that was attached to it, which says U.S. Department of Justice Drug Enforcement Administration, Marijuana Scientific Data Review as it relates to the Controlled Substances Act, prepared by the Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration.

It has no author. It has no date. We've looked at the citations in the back, we know that it was written at least after, I think, March or May of 2024.

They were going to use this as an Exhibit. And, it directly contradicts just about everything that they're talking about, this NPRM.

JUDGE JULIUS: Then it seems to me that if you're calling that author as a witness, if their affidavit relied on that document, that they would be the one to ask those questions to.

I don't know how he's going to answer questions about a document that was written after he made his recommendation.

MR. EVANS: Well, I'm not asking him to authenticate the document. I'm not asking him to vouch for it.

I'm going to ask you some questions, some statements that are in this document, ask him if he believes them to be true.

JUDGE JULIUS: Okay. Sir, did you have something to say?

MR. McNICHOLS: Very briefly, Your Honor.

JUDGE JULIUS: And, if you could just please identify yourself and what party or parties you represent.

MR. McNICHOLS: John McNichols from

Torridon, on behalf of Smart Approaches for Marijuana.

JUDGE JULIUS: Okay.

MR. McNICHOLS: The only point of clarification is that Dr. Akinfiresoye is our witness. I think under Your Honor's ruling, we'd be allowed to ask her questions, and she'd be subject to cross-examination by the Government, but not by the other parties, for the avoidance of any doubt as to how he'll authenticate that document.

JUDGE JULIUS: Thank you, sir. I appreciate the clarification.

MR. EVANS: Okay. I just want to ask him if some of the statements in there are true.

JUDGE JULIUS: I'll allow you to ask the questions. We'll see what those questions are.

MR. EVANS: Okay. Okay. This statement, do you agree or disagree with this, on April 11, 2024, the Department of Justice's Office of Legal Counsel, ~~L~~OLC, issued an opinion that among other things, concluded the existing five-part test is sufficient to determine that a drug has currently accepted medical use. But,

that limiting the analysis to the five-part test is impermissibly narrow.

Do you agree with that?

MS. MAN: Objection. The OLC opinion has already established that the two-part test is valid.

Whether or not Dr. Chiapperino is drawing a legal conclusion, I don't think he's the right party to draw a legal conclusion about whether or not the five-point test is impermissibly narrow, as I believe counsel just asked.

And, also, that is another person's opinion. And, that is outside the scope of his Touhy.

MR. EVANS: Okay. Let me ask this question then.

JUDGE JULIUS: So, are you withdrawing that question, sir?

MR. EVANS: Yeah. I'll withdraw it for now.

JUDGE JULIUS: Okay.

MR. EVANS: Is it true that when it comes to accepted medical use, that there is no single right answer to how specifically DEA

should make this determination? Is that true?

MS. MAN: Objection. That calls for speculation that Dr. Chiapperino made that recommendation for FDA, not for the DEA.

He's not a DEA employee. He's asking what another Government agency would do, or what they would find permissible, or what other standard another agency would find, calls for speculation on Dr. Chiapperino's part, and is also outside the scope of his Touhy.

JUDGE JULIUS: Mr. Evans?

MR. EVANS: Well, Doctor, are there other answers to how DEA could make a CAMU decision?

JUDGE JULIUS: Well, so sir, hold on.

MR. EVANS: Okay.

JUDGE JULIUS: I was asking if you had a response to the objection, not to ask a different question.

MR. EVANS: Oh.

JUDGE JULIUS: Are you withdrawing your prior question?

MR. EVANS: I'll withdraw it.

JUDGE JULIUS: Okay.

MR. EVANS: I'm just asking what else

other than the two-part test could be used to come up with an accepted medical use determination?

THE WITNESS: As I testified earlier, an approval by FDA of a drug. The active ingredient in that drug would be considered to have a currently accepted medical use.

Absent an NDA approval, the five-point test could be used to establish that a drug has a currently accepted medical use, or also the two-part test can be used.

MR. EVANS: Okay, great. Doctor, when you were making your determinations about marijuana and the medical use of marijuana, accepted medical use, did you do any research, and you were, you know, looking at the impact, people using it, did you do any research on dosing?

Did you ask any questions about what is a dose? I mean, how many joints would you smoke to get over anorexia?

Did you ask any of those questions that would deal with that? Did you look at the type of marijuana, --

THE WITNESS: Yes.

MR. EVANS: The potency, gummy bears, soft drinks, delivery systems? Did you look at how the practitioners did that?

In other words --

(Simultaneous speaking.)

THE WITNESS: This is captured in the --

MR. EVANS: Somebody may respond to smoke marijuana differently than they respond to a gummy bear.

MS. MAN: Objection.

MR. EVANS: And, that would be part of your analysis of what would be accepted medical use. You might find out that gummy bears don't fit in there.

MS. MAN: Objection. It's a compound question. I'm not quite sure.

MR. EVANS: Did you look at -- I'll, let me clarify the question. Did you look at differentiations between types of cannabis and how they would be delivered, in making your decision about accepted medical use?

THE WITNESS: Yes.

BY MR. EVANS:

Q And, what did you do?

A Within the clinical studies that were included in the systematic review, those clinical studies would have specified dosing regimens.

So, it really depends on the individual study, what form of marijuana was used. In some cases, people were using smoked marijuana, probably with directions of how much and how to smoke, because it is a variable way of administering the drug.

There were also people who vaped marijuana in some studies. There were also edible forms in some studies.

Q And, did you notice differentiations between the effect?

A The point of the review was to consider, within that clinical study the way it was designed, the endpoints, et cetera, did the resulting data about efficacy and safety in that study show a beneficial effect?

So, we did not consider the fact that multiple studies in the systematic review may have used alternative dosing regimens. Again, the goal was to determine that there was credible scientific support for that therapeutic

use.

So, a positive study that showed there's at least one way to administer marijuana effectively that provided some patient benefit, if that quality of evidence was moderate, it was considered a study with some credible scientific support for the use.

Q Okay. Doctor, the accepted medical use two-part test mentions the --

JUDGE JULIUS: Could you speak in the mic?

MR. EVANS: Oh, I'm sorry. The two-part test mentions current experience. How did you define current?

THE WITNESS: Do you mean of the healthcare practitioners?

BY MR. EVANS:

Q Well, it said that you're looking at the current experience. What does current mean?

A I think you'd have to direct me in the documents to, I need some context for that question.

And, I'm sorry, also by the way, I don't have that Exhibit anymore in front of me.

Q This quote's right from the OLC

opinion. Part one, this is a quote from the OLC opinion, part one of the inquiry asks whether licensed healthcare providers have widespread current experience with medical use of the drug.

You investigated that. How did you, what scope of currency did you use for this?

MS. MAN: Objection. Dr. Chiapperino did not generate the OLC opinion, nor does he know what went into the OLC opinion.

It is also outside the scope of his Touhy letter to be testifying about the OLC opinion.

JUDGE ~~JULIAN~~ JULIUS: My understanding of the question was, how did he apply that? Not what it means in the OLC memo, but how did he apply that. And, was that question?

MR. EVANS: Yes, Your Honor, that's right. How did he, when he went and looked at this, did he decide that some were not current and discontinue them?

Or, decide that some were current and he investigated them? I'm just looking at the range of time that you were looking at there.

JUDGE JULIUS: And, I'm going to overrule that objection to the extent it's a

question about what went into the two factor analyses that he and FDA performed.

MR. EVANS: Right.

MS. MAN: Thank you, Your Honor.

THE WITNESS: So, I think you're referring to an excerpt from the part one memo, right?

MR. EVANS: Um-hum.

THE WITNESS: Okay. So, the part one memo was produced by the office of the Assistant Secretary for Health. They provided that memo to us already completed, and directed us to apply part two.

So, I don't think I could answer how they interpreted current healthcare practitioner experience. But, we did our own landscape analysis, and of course, it varied from state to state. But, there were states with implemented programs over a long period of time.

So, I assume some of those programs were ten years, some of them were eight years, and yeah.

BY MR. EVANS:

Q Well, in applying this then, how am I to be guided if I submit a study to you, in

terms of could the study be ten years old, one year old, a day old?

If I'm a practitioner and I make a report on something that happened five years ago, I mean, did you set any kind of timeframe for making these evaluations?

A The programs have all been implemented since 2009. There's probably not all. I mean, they began implementation starting in the low 2000 teens.

Programs came online in different states at different times, right up until 2022, which would have been the last year that we would have been able to include consideration.

But, again, the two-part test really has, there is no part of the two-part test, part two that draws on the state programs in great detail other than the patient surveys, to understand adverse events experienced, or, you know, from some of the surveys that we did consider under part two.

The experience level of healthcare practitioners was not one of the considerations in part two.

Q Okay. Doctor, it says widespread

current experience. Does the FDA normally look at negative and positive experience?

A Usually, with an FDA approved medication, a medical professional would use the prescribing information to begin using a new medicine.

So, it's a very different context. These are medical programs already established with their own regulations. FDA does not have any role in regulating state medical programs.

We also didn't comment anywhere in our documents on the characteristics or quality of those. We really focused on patient use of it and the clinical trial data that may have provided some credible scientific support for some of that.

Q Okay. Did you ask people about negative experience?

A Can you ask that? You know, I'm not sure what you're asking.

Q One example of negative experience that you might want to consider?

A Negative experience --

Q With medical marijuana?

A Among a patient?

Q You're doing the research.

A Yeah. If a patient felt that using marijuana made them so nauseous that they no longer wanted to use it for pain, I assume they would stop.

Q And, did you ask those questions?

A We looked at survey data.

Q Did you equally focus on negative as well as positive?

A Well, the clinical trials would document if there were adverse events reported, not maybe as robust as a Phase 3 clinical trial submitted to FDA.

But, we used data where it was available in the published studies. Published clinical trials don't have as much detail as what we get from FDA when it's submitted under a drug application.

The adverse events reported by patients would show up in some of the surveys that we did analyze. As I said in my testimony, most of the adverse events reported were mild.

Q Okay. You say that the use of the drug in accordance with implemented state authorized programs were medical uses recognized by

entities that regulate the practice of medicine.

What was your understanding of entities that regulate the practice of medicine?

A State medical boards, boards set up by the state programs for marijuana that sometimes included health professionals making decisions about a new indication that they would consider eligible.

Q Okay. Now, I'm a little confused about the ambiguity here, because you talk about healthcare providers and, I think, we've established that a lot of them are not going to be physicians. They're not going to be subject to any kind of medical practice authority.

MS. MAN: Objection. Assumes facts not in evidence. I don't think that ever came out.

MR. EVANS: It's what?

MS. MAN: Assumes facts not in evidence.

MR. EVANS: I'm asking for clarification. There seems to be a, you know, what is the field that you're looking at, the people that you're going to provide this to?

Is it just people that are regulated by medical boards? Which this seems to imply. Or,

is it people that are practitioners? And, practitioners already are a wide group.

JUDGE JULIUS: So, is the question essentially what they interpret or how they view what healthcare providers includes?

What is that universe? Essentially, is that your question?

MR. EVANS: Well, yes. What was that universe? And, they seem to be limiting it to people that are, you know, entities that regulate the practice of medicine.

Healthcare providers, there's a lot of healthcare providers that are not physicians. A lot of healthcare providers are, and I've given you the federal definition of practitioner. It can include social workers, marriage counselors. They're not regulated by a medical board.

So, I'm just trying to look at what is the, you know, are you restricting it to just medical board regulated people, and warning all the other people?

There's all kinds of states that have given the power to recommend marijuana to a lot of practitioners. Did you look at all of that?

MS. MAN: May I respond briefly?

JUDGE JULIUS: Yeah, please.

MS. MAN: I don't believe Dr. Chiapperino can testify to that because the FDA does not regulate practitioners. That's the DEA's role.

And so, when counsel is asking about who's regulated and who's not, who falls into that pool, that's not something that Dr. Chiapperino can testify to. He has no personal knowledge.

And, it is also outside the scope of the Touhy letter about who's regulated under state boards. That is a DEA authority and not the FDA's.

MR. EVANS: The definition of, excuse me, I'll respond to that. The definition of practitioner is part of the Federal Public Health Service Act, which I would assume was in the HHS.

JUDGE JULIUS: So, my understanding of the question is essentially, when conducting their review of the studies, et cetera, what did they interpret healthcare practitioners to include in making their evaluation?

MR. EVANS: That's exactly right.

JUDGE JULIUS: To the extent that is the question, I will overrule the objection and allow that.

MR. EVANS: What did they include? And, was it just narrowed to people that are regulated by boards of medicine?

We need to know that.

THE WITNESS: Yeah. I think that that would be determined in the individual state programs.

State regulations for their own programs would probably address who is eligible to be a healthcare practitioner with the ability to recommend marijuana to their patients.

I would assume there's variability. I do not have detailed information on that myself. It was not something that we were responsible for addressing.

JUDGE JULIUS: Just as a reminder, Mr. Evans, I think we're having a little bit of difficulty at times hearing you.

If you could just always make sure to speak into the mic.

MR. EVANS: I'm sorry, Your Honor.

JUDGE JULIUS: It's not your fault. I

think you just are very tall.

MR. EVANS: I'm sorry, Your Honor.

JUDGE JULIUS: This is not a problem I experience.

MR. EVANS: Your Honor, one of the reasons that I'm asking these questions about --

JUDGE JULIUS: Yeah, if you could just maybe tilt it as close, I don't want to make you bend down. I don't want to cause any problems.

But, if you could just, yeah, direct it as best.

MR. EVANS: I'm trying to have some fun, Your Honor. It's very boring being a lawyer sometimes.

JUDGE JULIUS: I don't disagree, sir.

MR. EVANS: And, you got to listen to it all day long. All right.

JUDGE JULIUS: I think that's better. Thank you so much, sir, for accommodating us.

MR. EVANS: Yeah. Yeah. All right. So, I tried to, I'll tell you what I'm driving at, Your Honor. And, maybe this is out of the scope.

But, this Court cannot look at ambiguity issues regarding the two-part test.

It's the law as far as you're concerned.

But, there's going to be an appeal in this case. If we win, they're going to appeal. If we lose, we're going to appeal.

The federal court can consider ambiguities in legislation. They do not have to consider that anymore. They don't have to just lockstep do what a federal agency says is an interpretation.

So, I'm trying to understand again, they've put this forward, he acted on it, he did the research. What were you looking for?

Every practitioner plus people regulated by the medical board? Or, just people regulated by medical boards?

When you went out to practitioners who said, give us your experience. We want to know what's going on, who did you look at?

Did you talk to social workers? Did you talk to podiatrists? Did you talk to veterinarians? Some states give it to veterinarians.

When you're looking at the experience, did you talk to the American Psychiatric Association? I mean, the other thing that you

did not put in the NPRM was anything about psychoses.

We're having a tsunami of cannabis induced psychosis right now showing up in the ERs. That would go directly to deciding accepted medical use, because something may have accepted medical use, but the risk of it is too high. Okay?

So, giving somebody who's got PTSD, for example, can cause them to become violent. And, that's not me saying that, that's the Veterans Administration saying that. I'd be happy to read it to you.

So, I'm trying to understand how thorough you were, what were you considering? What was the whole field of data and information that you're looking at?

And, did you ever think to talk to parents who have lost children and hear from them about the devastating effect this has on their families?

And, I can give you several negative results from medical marijuana. None of these people were ever approached by the FDA or anybody else.

Kids using medical marijuana, blowing their brains out, jumping off bridges, standing in front of trains, all --

MS. MAN: Objection.

(Simultaneous speaking.)

MR. EVANS: Psychoses could --

MS. MAN: At this juncture --

MR. EVANS: Potentially be known.

MS. MAN: There is no question pending before the tribunal.

MR. EVANS: Okay.

JUDGE JULIUS: So, what is your question?

MR. EVANS: So, I want to know, exactly what you looked at?

THE WITNESS: I'm sorry. I would ask you to please, like, back up to the first question you'd like to ask.

BY MR. EVANS:

Q Okay. Did you limit your practitioner's experience investigations only to people regulated by medical boards?

That's pretty clear.

A Yes, it is. There was not a part of the process that FDA was involved in to look at

the structure of -- the healthcare practitioner's phrasing that you're referring to is part of the explanation of part one of the two-part tests, which was conducted by another office, not FDA.

FDA considered the clinical studies and considered survey data from the states. We did not look at the way each individual state structured their regulatory program, and what healthcare practitioners were permitted to recommend use of marijuana medically.

There was one other point. Sorry, there was, I, that's all I recall what I was going to say.

Q Doctor, in doing this research on people regulated by medical boards, did you inquire on the quality of those state programs in making your decision?

A We did not do a review to address the quality of the state programs.

Q Okay.

(Simultaneous speaking.)

A We actually could --

Q Did you rely on the quality or did you just assume --

A Excuse me, if I can --

Q That they were, did you just assume?

A Now that I --

JUDGE JULIUS: Hold on, sir. Let him finish his --

MR. EVANS: I'm sorry.

THE WITNESS: I'm sorry. I was trying to back up, because I do remember there was some consideration of certain features of the state program.

But, it was, I think, addressed in the part one memo not by FDA.

MR. EVANS: Okay. I would like to give you an invitation and the DEA an invitation, we have a witness coming in that is going to give you direct evidence about what's really going on in the states.

And, I can assume --

MS. MAN: Objection as to this question. There is no question pending here.

MR. EVANS: Okay.

JUDGE JULIUS: Sustained.

MS. MAN: Thank you.

MR. EVANS: I'm running out of time, and I appreciate you're a very good witness and

you're very courteous to me and I appreciate it. You've been very professional.

Did you look at the, you said that a lot of older people that are using a lot of this marijuana, was there any inquiry when you looked at the risk to older people to looking into how marijuana negatively interacts with prescription medications?

Could that have been something that would have affected your risk balance determination?

THE WITNESS: We did not have a granularity of data in the kind of information that we looked at. We had survey data where there would not necessarily be a connection of the individual and their demographics relative to an adverse event reported.

In an NDA submission of safety reports in a clinical trial, you'd be able to identify an individual patient that reported an adverse event. We certainly didn't have that level of detail in the studies that were reviewed, whether they were the clinical trials, which also don't have individual patients accounted for in their demographics, and the survey data

also would not make connections like that.

So, we could not really look at that issue.

MR. EVANS: Okay. So, again, I, you know, I raise the issue with, do you feel you need to do more work on this?

MS. MAN: Objection.

JUDGE JULIUS: The basis?

MS. MAN: Outside the bounds of the Touhy letter.

MR. EVANS: I'm sorry, what did you say?

MS. MAN: It's outside the bounds of the Touhy letter.

MR. EVANS: No, I'm asking, he did the evaluation, the NPRM says they needed more data. And, I'm asking him, I think, a very legitimate question of a Government employee.

Would you be willing to accept additional information?

JUDGE JULIUS: Sir, my reading of the NPRM is that DEA said that there may be additional information that would be sought, not FDA.

Am I misreading the NPRM?

MR. EVANS: The FDA was the one that was providing, the role of the FDA, the DEA is not allowed to question the scientific medical thing that comes from HHS. They're bound by it.

So, anything to do with all this stuff has got to come from the FDA.

JUDGE JULIUS: Or, I believe he testified that DEA reached out and asked for additional analysis based on further evidence.

MR. EVANS: We're going to supply it to them. I'm just bringing it up here in the hopes that they'll do something.

MS. MAN: Objection. This is outside the scope of this hearing for, and --

MR. EVANS: Okay.

JUDGE JULIUS: Sustained. Please proceed, Mr. Evans.

MR. EVANS: Yeah. You seem to have been focusing a lot on when you did your evaluation on overdoses and the DEA emphasized overdoses and it's like are there dangers of drug use other than overdoses?

THE WITNESS: Yes.

BY MR. EVANS:

Q Okay. Could, for example, use of

marijuana, although it may be not an overdose, but could the use of marijuana directly or indirectly result in death?

A Yes.

Q Okay. Could it result in psychosis that would cause somebody to kill somebody else?

A You're thinking of -- I think you're characterizing a psychotic episode versus psychotic disorder, right?

Q Yeah.

A I believe there are cases of people who have had psychiatric adverse events that have led to self-harm, yeah.

Q Okay. Are you familiar with the case of Bryn Spejcher?

A No.

Q She was an audiologist and my question is would you be willing to talk with her? She was an audiologist, PhD, I believe, went over to somebody's house to use a bong. The guy had souped it up with high potency marijuana. She went into a psychosis and stabbed him over 100 times.

MS. MAN: Objection.

MR. EVANS: Killed her dog and stabbed

herself in the neck when the police arrived. Would you be willing to talk with her to see what kind of harm marijuana can cause?

MS. MAN: Objection, Dr. Chiapperino has testified he does not know her and counsel is unclear about how Dr. Chiapperino could talk to a woman who Mr. Evans said has died.

MR. EVANS: No, she's fully alive. Part of her probation is to go out and tell people -- or her parole, to go out and tell people what happened to her and the constant problem that I get from --

MS. MAN: Objection. There's no question pending at this juncture.

MR. EVANS: I'm making an argument here.

MS. MAN: And this is not the appropriate time to do so.

(Simultaneous speaking.)

JUDGE JULIUS: Okay, again, do not speak to each other. I do tend to agree with the government that this is venturing into argument, not responding to objections to questions asked.

MR. EVANS: Okay.

JUDGE JULIUS: You're asking him if he would be willing to speak to someone who --

MR. EVANS: To get further data.

JUDGE JULIUS: When did this event allegedly occur? I don't have anything in evidence at this point that shows what occurred. You're making this proffer of evidence. Whether this would have been available at the time he made the recommendation, again, it doesn't sound like under their rules that they go out and canvas the nation asking for peoples' --

(Simultaneous speaking.)

MR. EVANS: What I'm really trying to establish here, Your Honor, is how --

JUDGE JULIUS: Experiences and please do not talk over me.

MR. EVANS: I'm sorry. I'm sorry. I thought you were finished.

JUDGE JULIUS: Go ahead.

MR. EVANS: What I'm trying to establish here is the degree of negligence that this NPRM represents and the refusal seems to be a refusal of the government to accept new evidence. I think that affects the validity of

this. It affects the credibility of it. If you make a mistake and you say I don't want to hear anything about the mistake I made, that effects your credibility.

I have yet to hear anybody including the DEA that's supposed to be protecting those kids, there's a whole wall down there of kids that have died. I would just like and the families would just like for them to answer the question. Are you willing to talk to the families? Get more information. They'll tell you their position on all of this.

JUDGE JULIUS: For the record, I believe you're referring to the Faces of Fentanyl, which is not before this Court or this rescheduling action.

MR. EVANS: I'll give you the Faces of Marijuana. I have a whole collection, Your Honor. I can bring them in.

JUDGE JULIUS: That's your prerogative, sir.

MR. EVANS: Thank you.

JUDGE JULIUS: That's not where we're at right now.

MR. EVANS: I understand.

JUDGE JULIUS: And asking --

MR. EVANS: What I'm trying to understand looking at the validity of a government action, okay, that I have pointed out several areas where they have been negligent or refused to look at information, that affects the whole -- everything they did. Okay? If they make one mistake, fine. Make two mistakes, three mistakes, four mistakes, five mistakes, or they leave stuff out they refuse to consider, you have to question whether they did a proper evaluation.

My role here today is really just to point out and via these questions to the good Doctor, and I don't blame you. I mean I was a bureaucrat once, I get it. This is what we're looking at. Did they do this NPRM properly? Did they look at it properly? Did they consider things? Have they launched the ship that's full of leaky holes or a ship that's going to withstand the storm? All we want is a ship that can withstand the storm.

We want the FDA to step in and do something about this and we're very happy that they've decided to do the research and so forth.

We want them to do it. We would love to have the FDA approve cannabinoid drugs. We have no problem with it. Nobody is against that. I'm personally not against it. I'm responsible for the American Bar Association being in favor of medical marijuana.

You put something out there, it's defective, you should own up to it. You should admit your mistake and protect the public and look at things properly. Do not be swayed by public opinion or donations from the marijuana industry. I've demonstrated to you several ways that the public has not been protected by this and I believe that the Doctor wants to do that. He wants to do the right thing. I'm convinced of it.

I worked with Doug Throckmorton before he left and good man.

JUDGE JULIUS: All right, sir. I'm sorry to cut you off.

MR. EVANS: Okay.

JUDGE JULIUS: But we are venturing again into argument. This is a cross examination.

MR. EVANS: Right.

JUDGE JULIUS: I need you to please limit your comments --

MR. EVANS: Your Honor, I --

JUDGE JULIUS: To what's relevant to the objections to your questions.

MR. EVANS: My goal in the cross examination was to show where there are defects. Okay? I think that I have done that. I could go on with more. There are more things that didn't happen here, but I think I've raised more than a reasonable doubt that there is something here that they need to take a look at.

They can't just say we're going to go forward with this because the President wants us to do it.

JUDGE JULIUS: Again, sir --

MR. EVANS: Okay.

JUDGE JULIUS: You're engaging in argument. I need you to either ask questions --

MR. EVANS: I'm closing. This is my closing statement.

JUDGE JULIUS: On cross -- yes.

MR. EVANS: Okay.

JUDGE JULIUS: It's going to be available to you to write in the written

statement. If you have additional questions to ask on cross examination, you are more than free to ask them --

MR. EVANS: No, I think --

JUDGE JULIUS: You still have time.

MR. EVANS: I think at this point, I don't. Let me just see if -- oh, I do have another couple -- one or two questions. Do you agree with this statement, medical practitioners who are not experts in evaluating drugs, are not qualified to determine whether a drug is generally recognized as safe and effective or meets NDA requirements? Currently --

MS. MAN: Objection.

MR. EVANS: There is no consensus concerning the medical utility of marijuana for use in treating specific recognized disorders. To date, the FDA has not approved the marketing application for cannabis for the treatment of any disease or condition. Do you agree with that?

MS. MAN: Objection as to outside the scope of his testimony.

MR. EVANS: No, it isn't. It's --

JUDGE JULIUS: Sir, please let her get

her objection out.

MR. EVANS: Sorry, okay.

MS. MAN: It's outside the scope of the Touhy letter, unless that statement comes from one of these documents that Dr. Chiapperino has testified to, it is outside the scope of the Touhy letter and he cannot testify to that.

JUDGE JULIUS: Where is that statement coming from, Mr. Evans?

MR. EVANS: From the Dr. Akinfiresoye statement and it's relevant because they have chosen to make medical practitioners the people who decide whether or not something is a medicine or not, whether it has an accepted medical practice. Okay? This doctor is saying looking medical practitioners, the first part of this two-part thing says hey, we're going to let the doctors tell us, not the FDA, not anybody else, we're going to let the practitioners tell us what goes on.

This point is counter to that, medical practitioners who are not experts in evaluating drugs are not qualified to determine if a drug is generally recognized as being safe and effective. So, they are relying on the

practitioners that was the statement contrary to their reliance and I'm asking him was the statement that I read to you true.

JUDGE JULIUS: Is it true or does --

MR. EVANS: It's true.

JUDGE JULIUS: He agree with it?

MR. EVANS: Does he agree with it?

JUDGE JULIUS: Those are two different questions.

MR. EVANS: Do you agree with that statement that medical practitioners are not qualified, just plain medical practitioners, not qualified to decide whether a drug is safe and effective?

MS. MAN: And the government's objection remains that he's taken that statement from a 2025 declaration that has been generated after his recommendation was issued and his testimony to that would be outside the bounds of his Touhy letter on both fronts; is it true and does he agree. The same objection remains.

MR. EVANS: If I may respond, Your Honor?

JUDGE JULIUS: Go ahead.

MR. EVANS: Again, it was not 2025. It

was December of ‘24, right before we were going to go trial. That’s when we --

JUDGE JULIUS: Either way, it was after FDA made the recommendation to --

MR. EVANS: Yeah.

JUDGE JULIUS: Reschedule?

MR. EVANS: Yeah.

JUDGE JULIUS: Correct?

MR. EVANS: Yeah. So, if he agreed with that statement, that would mean that that cuts to the credibility of the analysis that he did. If he agrees that medical practitioners are not qualified to decide a drug is safe and effective on their own, that is a direct contradiction, cross examination of his position that they are.

JUDGE JULIUS: I’ll allow him to answer the question.

MR. EVANS: Okay.

THE WITNESS: I think that to answer your question, we should look at the full context of the criteria in the part one memo, because we’re talking about the phrasing of the criteria of part one that is in the two-part test. Healthcare practitioners are not deciding that something is a medicine. They are working

within a regulatory system that the state set up because the state decided that marijuana would be accessible as a medicine.

If the state creates a regulatory program that allows access to marijuana medically and part of their program is to allow certain healthcare professionals, the state decides what the structure of that program is going to be. If the state so decides that it's only doctors that could write a recommendation or it's doctors and nurse practitioners or doctors and clinical social workers, that is the state's program, that is the determination that marijuana can be used as a medicine.

The actual healthcare practitioners didn't make the decision, but they are then eligible to be participants in the system to decide when a patient can get access to marijuana.

BY MR. EVANS:

Q Doctor, you used a term that they're writing prescriptions.

A I'm sorry then I misspoke. I should have said recommendation.

Q Right, yeah, why aren't they writing

prescriptions?

MS. MAN: Objection, calls for speculation. He's asking him to speculate about why somebody else isn't doing something and that is calling for speculation.

JUDGE JULIUS: Mr. Evans?

MR. EVANS: I'm asking him a question. He evaluated this. He seemed to know that they are writing recommendations. Oh, I'll ask to rephrase it. Why did you say that they're writing recommendations?

THE WITNESS: Is this resolved to answer?

JUDGE JULIUS: He's rephrased the question, I understand the original phrasing to be withdrawn.

MR. EVANS: You said that they were not writing prescriptions, that they were writing recommendations. What does that mean, they were writing recommendations?

THE WITNESS: Because prescribing, I think, requires DEA registration for one. For two, prescriptions are filled at pharmacies and the state programs have largely set up a parallel structure as a dispensary. I don't

think any marijuana is being distributed from a conventional pharmacy. So, I think it would be inaccurate to call what doctors or healthcare practitioners do as writing a prescription and that's all I could say on that. It goes beyond my expertise beyond that.

BY MR. EVANS:

Q Okay, when the doctor writes a recommendation, to your knowledge, are they specific about what type of marijuana, the dose, how many strains, smoking, gummy bears? Do you know what they're doing?

A I do not.

Q Okay. Are you familiar with the term medical marijuana dispensaries?

A Yes.

Q Okay. The people that are deciding the dosage, the type of marijuana, and so forth are called budtenders. They're usually people who are marijuana users --

MS. MAN: Objection as to the question --

MR. EVANS: And they come in -- I'm asking if he knows this.

(Simultaneous speaking.)

JUDGE JULIUS: Let him get the full question out before we hear the objection.

MS. MAN: All right.

MR. EVANS: Okay. Do you know that that is happening? That most of the medical marijuana, the decisions about this are made by budtenders, who have had no medical training. The recommendation comes in, give the person marijuana and a budtender says well, I think you ought to try Gorilla Glue here or I think you ought to try Wacko Lightning. Are you aware -- did you inquire about that happening?

MS. MAN: Objection assumes facts not in evidence.

JUDGE JULIUS: Mr. Evans --

MR. EVANS: I'm just asking him if -- I'm saying did you look at that? I'm saying that this is something that's going on.

JUDGE JULIUS: Well, sir, again, I believe your question is very complex and assumes facts not in evidence about who is making these determinations. I think if you want to ask a more straightforward question that may be a different story.

MR. EVANS: Okay. You have relied on

evidence from practitioners, correct?

THE WITNESS: Actually, no, not in part two of the two-part test. We've relied on data from clinical trials, some survey data. As I said, we considered the FDA approved drugs, but I think what you're talking about is the dynamic of a healthcare practitioner writing a recommendation, what is the form of that recommendation, how specific is it and how does the patient acquire cannabis.

All of those interactions were not part of our recommendation. We did not review what I would consider the broad structure or quality of each individual state program.

BY MR. EVANS:

Q Well, that's interesting to know you didn't consider the quality of the state programs when you made this decision. I hope that -- would you be interested in getting more information on what's actually going on in the states?

MS. MAN: Objection as to --

MR. EVANS: Would that help you making future evaluations?

MS. MAN: Objection.

JUDGE JULIUS: Basis?

MS. MAN: Outside the scope of the Touhy and calls for speculation.

MR. EVANS: No, it's about his evaluation. I'm looking at the data, the research that he did, how thorough it was and in deciding this issue that's directly related to the damage and the harm that's being caused by people without any medical training, dispensing marijuana. That's part of the harm.

We talk about the issue that you're supposed to be involved in which was distribution issues. Is marijuana being illegally distributed? Almost every marijuana dispensary does it that way and they don't have doctors, they don't have pharmacists making decisions. I'm asking you were you aware of that when you made these evaluations?

JUDGE JULIUS: So, sir, I'm going to ask you again, when there's an objection and you're responding to the objection, please do not ask additional questions --

MR. EVANS: Oh, I'm sorry.

JUDGE JULIUS: To the witness.

MR. EVANS: Okay.

JUDGE JULIUS: I need you to address the basis of the objection --

MR. EVANS: Okay, sorry.

JUDGE JULIUS: So that we can resolve it.

MR. EVANS: Okay, would you repeat the objection, please?

MS. MAN: It was whether or not -- the question was whether or not you would be willing to consider outside information to go to your recommendation and the objection to that question was it is outside the scope of his Touhy letter. He cannot testify to anything that is outside of after he finished making his recommendation in 2023. So, any questions about whether or Dr. Chiapperino would be willing to consider additional information is outside the bounds of the Touhy letter.

MR. EVANS: She got my question wrong. I asked did he consider this in doing his evaluations. The evaluation he's talking about, 2024, did he consider what's actually happening and the harm that's being caused by these dispensaries. Did you consider that?

THE WITNESS: I can answer that

question by pointing out that we looked at adverse events reported from the use, so to the extent that data was available about what patient experiences were, and the data that were available did not suggest serious adverse events. That's what we reviewed.

BY MR. EVANS:

Q Okay, so that means that you did not look at budtenders because everything seemed to be going okay. Is that right?

A The five elements that we included did not include reviewing the quality of state regulatory programs including how each of them are designed.

Q Well, again, you know, I'm finished with my rather contentious cross examination. I apologize to the Court if I was rude in any way. I have a great deal of passion about this. I interacted with so many parents, it drives me crazy what's going on. I think that it would be appropriate for the Court just based on this testimony to refer this back to the DEA and say, guys, take another look at this. This is faulty. You have no idea what's going on the state level and you need to investigate that.

We've been trying for years to get the DEA, FDA to take a look at what's going on. It is outrageous what's going on. I did my own investigation. I was treated for a spinal cord injury and I had cancer and I went into a pot doctor in Plattsburgh, New York. I had my medical records with me and he walked in and said, okay, we're going to give you your medical card today.

JUDGE JULIUS: So, sir --

MR. EVANS: Okay.

JUDGE JULIUS: I see that your time has expired. I also believe that you were beginning to testify on your own behalf --

MR. EVANS: I have --

JUDGE JULIUS: On your own personal experience. I very much appreciate that you have very strong feelings about this.

MR. EVANS: Your Honor --

JUDGE JULIUS: I absolutely appreciate the advocacy. I did not detect or perceive any rudeness whatsoever. I understand where you're coming from and I thank you for cross examination, sir.

MR. EVANS: Your Honor, I have always

looked upon litigation as an opportunity to educate people and I'd be happy to talk to any of you if you're interested in any of the information I have to share with you. So far, nobody's been interested.

JUDGE JULIUS: Thank you very much, sir. Let's go ahead and take our break now, if that's okay with Tennessee Bureau of Investigations. We'll take a 15-minute break. Let's come back at 3:05. We'll be in recess.

(Whereupon, the above-entitled matter went off the record at 2:50 p.m. and resumed at 3:08 p.m.)

JUDGE JULIUS: All right, so next up, we have cross examination by Tennessee Bureau of Investigations. One moment, please, while I get logged back in.

Just for all counsels' awareness, I acknowledge that we said that time spent addressing objections would not count against your time, but I would please ask that arguments with regard to objections, responses to objections remain as concise as possible and not use those as an opportunity to enter full blown argument. Those should be reserved for the

closing statements that will be allowed after the end of the hearing. Okay? I just want to make sure that we remain on schedule as much as we can. Bear with me one moment.

Mr. Smith, whenever you're ready, sir.

CROSS EXAMINATION

MR. SMITH: Thank you, Your Honor. Mr. Chiapperino, good afternoon. My name is Reed Smith and I represent the Tennessee Bureau of Investigation in this matter.

You're testifying about HHS's recommendation that marijuana be moved to Schedule III of the Controlled Substances Act. Is that correct?

THE WITNESS: Yes.

BY MR. SMITH:

Q Is the basis for that recommendation found in ALJ Exhibit 1?

A The HHS evaluation documents, yes. I don't have that in front of me anymore.

Q Yeah, Your Honor, I'd like to present the witness with ALJ Exhibit 1.

JUDGE JULIUS: You may do so. Mr. Phillips, if you could provide that to him.

THE WITNESS: Do you want me to give

these back or yes?

JUDGE JULIUS: If you could. We're just, for the record, we're going to clear the table in front of the witness, except for what's been entered into the record as ALJ 1. Go ahead, sir.

MR. SMITH: Thank you, Your Honor. Did HHS disclose its entire basis for recommending that marijuana be rescheduled to Schedule III in ALJ Exhibit 1?

THE WITNESS: Can you describe what you mean by the entire basis? I mean this is the complete 8-factor evaluation and the part two memo, it's a supporting document, but it would fit within factor 3, currently accepted medical use is just an expanded section of factor 3 essentially, but that is the whole basis for the recommendation.

BY MR. SMITH:

Q Okay. Are there any basis for HHS' recommendation that are not disclosed in ALJ Exhibit 1?

A Again, I'm not sure what you mean by that. Other source documents or things that function as citations or?

Q Well, when I say disclose, I mean if HHS was relying on a document, that document is disclosed in ALJ Exhibit 1, correct?

A All of the citations are listed for what we're relying on. Some may not be publicly available.

Q HHS didn't conceal any basis for its --

A No.

Q Recommendation?

A No.

Q Okay. When you were testifying earlier, you testified that alcohol was considered as a part of the HHS analysis. Is that correct?

A Correct.

Q You testified that the reason alcohol was included was because marijuana is legal in many states and alcohol provided useful context for marijuana as opposed to other substances that are not legally available in the states?

A That's a paraphrase, but yes, it captures my point, yes.

Q You can turn with me to page -- well, maybe you can answer this without turning to it. When HHS considered the diversion of marijuana

under factor 1, did it consider state licensed marijuana?

A Okay, so under factor 1B, I think you're referring to --

Q It's on page 8 of Exhibit 1.

A Thank you. Yes, we did not have data related to state dispensaries and if those may be experiencing diversion, we considered diversion from legitimate sources under federal law. Legitimate activities related to marijuana under federal law are manufacturing to support research, to make sure there are adequate supplies for research and the conduct of non-clinical and clinical studies with marijuana which would be under DEA's regulated system and any diversion from supplying those studies or from the studies being conducted, if any supplies are diverted. We had no evidence of diversion to speak of.

Q Did you have evidence that marijuana was not being diverted from state-licensed dispensaries or growers?

A I do not recall what data may have been available for that issue. I don't think we discussed in our documents diversion from state

entities with marijuana programs.

Q So, nothing in this document would speak to diversion from state-licensed marijuana programs?

A I think that's correct.

Q Did FDA consider any connections between violent crime and marijuana when it was performing the 8-factor analysis?

A Violent crimes related to trafficking? Violent crimes related to people using marijuana?

Q Did it consider any connection whatsoever between violent crimes and marijuana when it was performing its analysis?

A No, we generally focus on scientific and medical considerations, ~~help~~ health outcomes from people using marijuana and medical use of marijuana and try to form an assessment of marijuana's safety profile or lack thereof.

Q But marijuana-related crime could be a public safety issue, correct?

A Yes.

Q Looking at page 1 of ALJ Exhibit 1, it says that the recommendation that marijuana be controlled in Schedule III of the Controlled

Substances Act refers to botanical cannabis, cannabis sativa L., that is within the definition of marijuana or marijuana depending on if you spell it with an H or a J in the Controlled Substances Act. Is that correct?

A Correct.

Q And this was a recommendation from August 29th, 2023?

A Yes.

Q And so it would be based on the definition of marijuana in the Controlled Substances Act as of that date?

A Yes.

Q And this is the definition that HHS relied on when it evaluated marijuana under the 8-factor analysis?

A Yes.

Q And this is the definition that HHS relied on when it recommended that marijuana be rescheduled to Schedule III?

A Yes.

Q And it's the basis for the 3-factor analysis on page 62 that was the definition used?

A Yes, the 3 findings that we make based on the 8 factors, yes.

Q Thank you. On page 1, it indicates that the definition is based on cannabis sativa, correct?

A Yes.

Q If we turn to page 18 of ALJ Exhibit 1.

A I'm there.

JUDGE JULIUS: I'm sorry, Counsel, what page did you say?

MR. SMITH: Page 18, Your Honor.

JUDGE JULIUS: Thank you, Counsel.

MR. SMITH: Are we there?

THE WITNESS: Yes.

BY MR. SMITH:

Q Page 18 indicates that -- may I just call it cannabis?

A I think so.

Q Okay. Page 18 indicates that cannabis is a highly polymorphic species, correct?

A Yes.

Q And that means it can have widely varying composition and chemical components?

A Yes, we've noted in the document the existence of many different chemovars with different profiles.

Q And one of those cannabinoids is delta-

8-THC. Is that correct?

A Yes, it is.

Q Did HHS analyze the psychoactive effects of delta-8-THC as a part of the analysis it performed in Exhibit 1?

A We are aware of delta-8 as being a cannabinoid receptor type 1 agonist. We did not describe delta-8 in this evaluation. It is a much less abundant isomer of THC, but we are aware it's a CB1 agonist.

Q Did HHS consider any concentrates of delta-8 as a part of its analysis?

A Not specifically. I think that if there were harmful outcomes from use of a delta-8 concentrate, those might be showing up in the same databases as it may be confused for a delta-9 product, but we may not know that.

Q HHS specifically focused on delta-9 as a part of those analyses. Is that correct?

A We focused on marijuana products that have delta-9 in them at a level that would make it marijuana and not hemp. We acknowledge there's a profile of cannabinoids in the plant that would also be in a marijuana natural botanical form. The focus on delta-9 is due to

its far greater abundance and it's most likely being determinative of the effects of the user unless the product was manipulated in some way to have less delta-9 and more of something else which might be more the hemp domain.

Q Okay, did HHS analyze whether any groups were modifying cannabis to create high potency delta-8 strains?

A We did not write about it in this document. We've made statements in the document in the background section to acknowledge the existence of hemp products and the fact that there are products that might be excluded from the definition of marijuana based on the hemp definition; but that may also be leading to drug effects that would find its way into the epidemiological data as a health interventions.

Q Does anything in this analysis deny the existence of high potency delta-8 products?

A No, we don't have any statements in the document specific to delta-8.

Q Did you analyze the possibility of delta-8 high potency products?

A We did not, not for this evaluation.

Q On page 19 of Exhibit 1, HHS found that

marijuana plants are heterogenous in nature and contain a complex chemical profile. Is that correct?

A Yes.

Q And then it determines that the potential for high variability of marijuana and marijuana derived products both in product composition and in purity profile are major considerations for the potential variability of drug effects and safety. Is that correct?

A I would have to scroll this for a minute, if you'll give me a minute. Yes, that is toward the bottom of the page. I don't know if you read it explicitly, but it sounds like what we wrote near the bottom of page 19.

Q When it says the potential for high variability of marijuana, marijuana is not merely hypothetically highly variable. Is that correct?

A No, it is known to be variable.

Q Okay, so there are real world examples of high variability of marijuana?

A Yes.

Q And of cannabis?

A Yes.

Q If we turn to page 21, towards the middle of the page, it would be the last paragraph, over human pharmacokinetics. It says marijuana is not a single chemical with a consistent and reproducible chemical profile or predictable and consistent clinical effects. Is that correct?

A Correct.

Q Has HHS recognized a CAMU, or commonly accepted medical use, for any other products that it determined had a high variability in both product composition and impurity profile?

A We have not made a finding of CAMU for any other substance except marijuana.

Q Has HHS found a CAMU for any substance that does not have a consistent and reproducible chemical profile other than marijuana?

A Outside the context or drug scheduling, there are, I think, two FDA approved botanical drugs. Those would be somewhat variable, but there drug control specifications to keep the parameters appropriate to be reproducible enough to rely upon for the safety and efficacy.

Q Does this analysis contain similar parameters for marijuana?

A The considerations for CAMU do not consider the variability of cannabis available in medical marijuana dispensaries. We consider that part of the regulatory program structure in what they permit or how they permit healthcare practitioners to recommend use of marijuana.

Q Does anything in your recommendation to reschedule marijuana to Schedule III limit the recommendation to state-licensed marijuana?

A No, the recommendation for Schedule III creates a schedule change under federal law. We think that the recommendation enabled the transfer to Schedule III because it met criteria, but the actual existence of the state programs and how they're regulated, are not FDA's purview as to how the individual states are running state medical marijuana programs.

Q I'm not sure that that was responsive to my question.

A Can you repeat the question?

Q Yes, does anything in this analysis that recommends marijuana be rescheduled to Schedule III under the Controlled Substances Act limit that recommendation to state-licensed marijuana?

A No.

Q Does HHS consider every substance that meets the definition of marijuana used in Exhibit 1 as having a commonly accepted medical use?

A Our evaluation is for marijuana as a category. We did not make individual findings for individual types of marijuana products.

Q So, is it fair to say that that answer is a no?

A Yes.

Q I'd like to return to ALJ Exhibit 1, if we turn to page 2.

A I'm there.

Q Towards the middle of the page, it discusses an analysis that HHS performed regarding the scheduling of marijuana in 2015. Is that correct?

A Yes.

Q HHS's recommendation at the time was that marijuana should not be rescheduled, correct?

A Correct.

Q Then it goes on to say, an important difference between the analysis that HHS

performed in 2015 and the one that HHS performed in ALJ Exhibit 1 is that Congress amended the definition of marijuana in the Controlled Substances Act in 2018. Is that correct?

A That's correct.

Q When Congress amended the definition of marijuana under the Controlled Substances Act, did it botanically change cannabis sativa in any way?

A No.

Q Reading on further on page 2, it says the reason that there was an important difference was that when Congress amended the definition of marijuana, it narrowed the scope of what is considered marijuana under the Controlled Substances Act by removing hemp and chemical derivatives of hemp as discussed below. Is that correct?

A Yes.

Q Would delta-8 be considered hemp under the definition of marijuana?

A That is a complex finding that I think it addressed in DEA's 2020 Federal Register Notice implementing hemp. If there was a delta-8 product that was botanically derived and not

synthetically derived and contained less than 0.3 percent THC, delta-9-THC, I don't know that anyone has confirmed legally that that is hemp, but that is probably the issue that you're trying to identify. I can't speak to that because I don't have legal authority to make that determination, but I think that's the issue that you are getting at.

Q Under the definition of that HHS was working with in ALJ Exhibit 1 --

A Yep.

Q A product that was 0.3 percent or less THC delta-9 by dry weight, but say for example, 30 percent delta-8 by dry weight, would be considered hemp. Is that correct?

A A naturally derived product like that would not exist so I suppose if someone could convince a judge that that product is naturally derived, they might get a finding that it is hemp. I would say it is most likely enhanced with a synthetic preparation of delta-8 to obtain that kind of differential concentration relative to delta-9-THC.

Q Is there any analysis that would preclude that possibility performed in ALJ

Exhibit 1?

A No, we did not get into the complexities of delta-8 in this evaluation which was of natural botanical marijuana.

Q Is the definition of marijuana under the Controlled Substances Act limited to natural botanical marijuana?

A It's the plant cannabis sativa. I think there's always been ambiguity about the word derivatives that are part of the definition, but I don't have an answer for you as to how that is resolved legally.

Q If you will turn with me to page 20 of ALJ Exhibit 1.

A I'm there.

Q At the bottom of the page, it says marijuana or derived products can generally be categorized as one of four types -- flowers, concentrates, edibles and topicals. Is that correct?

A Yes.

Q Are concentrates botanical marijuana?

A Yeah, I believe so.

Q So, a hash or rosin via vaping is just simply dried cannabis sativa leaves?

A I believe those products are obtained by extracting from the cannabis plant and then concentrating that extract down to a residue that would become firm and that would be hashish, so I believe that's botanical as long as all unnatural solvents are removed, but yeah.

Q Okay, so it doesn't matter what potency is used you're saying as long as chemical solvents are not used?

A I'm saying my knowledge of how hashish is produced is that it is still considered a botanically derived product, but I don't actually know that for certain. I'm not that familiar with all of the manufacturing steps leading to hashish.

Q What about vape oils? Are vape oils considered botanical marijuana?

A No, I don't think so.

Q Would they meet the definition as derivatives of marijuana?

A Well, when you say vape oils, I'm sorry, I may have misunderstood you. Did you mean the solvent that is used to make it into a vape or did you mean the entire like marijuana in a vape oil product?

Q I mean the THC-infused vape oils.
A If the THC is a botanical product, I believe it would be a marijuana product.
Q Did HHS do any analysis of potency of THC-infused vape products as a part of this analysis?
A We focused on potency of plant material, not vape oils. I don't think we did a detailed analysis in our chemistry section of all the types of marijuana products including vape oils.
Q Did HHS do an analysis at all as to the health effects of THC-infused vape oils?
A No, not distinct from our general evaluation, not as special consideration if that's what you're asking.
Q Did HHS do any analysis as to the use of THC vapes or vaping cannabis as it's sometimes referred to?
A I think there were some survey data that described products people use and I believe vapes are among the products people use, so to the extent that those surveys collected safety-related adverse events, that might provide information about vapes, but we did not have the

data in a granular way to know which events were produced by which dosage forms.

Q The method of administration can be important, correct?

A Did you say can or can't?

Q It can.

A It can be important, yes.

Q And the definition of cannabis that's on page 1, it's important to know what the definition is, correct?

A Yes.

Q Was one of the reasons that HHS considered the change in law an important difference, is it because it defined marijuana by delta-9 and so therefore eliminated consideration of other THC components?

A Not quite. I think the concern that made us want to highlight the hemp provisions from 2018 was the fact that it created what we now see as a cannabis marketplace that is quite large. It is also sometimes a delivery system for cannabinoids that are CB1 agonists like delta-9-THC and delta-8, so the contribution of those products that are not actually marijuana by the legal definition may be feeding into some

of the same epidemiological databases in terms of health interventions.

Q But for purposes of your definition of marijuana, you excluded hemp for this analysis, correct?

A We did to the greatest extent possible, but we acknowledge that some hemp products may be represented among the events that we're lumping in as marijuana, because we can't know what people are using. But if a person reported using a cannabis product and they presented with the effects of a marijuana product, it was probably considered a marijuana product.

Q If HHS were using a different definition of marijuana that could impact its analysis, correct?

A I cannot give you an answer to that. I don't know what different definition we might use. We were asked to evaluate marijuana so I don't know what other definition we would use.

Q Well, let's say for example the 2015 definition of marijuana. The definition that was used when HHS performed that analysis in 2015.

A Yeah.

Q That could reach different results, correct?

A That's speculative because we don't know what the universe of all cannabis users looks like and without the 2018 legislation and the hemp-related cannabis market. I can't answer what the world would like today if there was no change in the marijuana definition.

Q Has HHS taken the position that marijuana, as defined in 2015, should be moved to Schedule III?

A I'm sorry, can you repeat that?

Q Has HHS taken the position that marijuana, as defined in the 2015 version of the Controlled Substances Act, should be moved to Schedule III?

MS. MAN: Objection, outside the scope of the Touhy letter. The 2015 HHS recommendation is not on Dr. Chiapperino's list of approved topics for testimony.

MR. SMITH: It's certainly something that he can consider. Your Honor, it's something that HHS could consider as to what they analyzed and he can say whether or not they can rule out the 2015 definition or not.

MR. McNICHOLS: Your Honor, can I be heard on this?

JUDGE JULIUS: Yes, if you could just again note your name and party you represent.

MR. McNICHOLS: Yeah, John McNichols on behalf of Smart Approaches to Marijuana. I intervene only because I might ask some similar questions of the doctor also.

Just to reiterate this issue, the 2015 HHS recommendation is discussed by Dr. Chiapperino on page 1 of ALJ 1. It's also discussed on page 2 of ALJ Exhibit 1. There's been some testimony already as well in this case about the differences between the 5-factor analysis and the 2-factor analysis that were elicited by the government's counsel. Clearly, it's fair game at this point because I'm sure that Ms. Man did not ask any questions that would exceed the scope.

JUDGE JULIUS: Understood. I will allow the question to the extent that it is about how the 2015 definition and the reference to that influenced or was evaluated as part of the 2023 recommendation. So, with that caveat, overruled and I'll allow the question.

MR. SMITH: Has HHS taken the position that marijuana, as defined in 2015, should be moved to Schedule III in this analysis?

THE WITNESS: This meaning the 2023?

BY MR. SMITH:

Q That's correct.

A I'm sorry, I'm just really not understanding the question. So, the 2015 definition is different from the definition at the time we did the 2023, so our recommendation for Schedule III in 2023 uses the definition that was relevant in 2023. What are you asking about the 2015?

Q I'm asking does this analysis demonstrate whether the marijuana as defined in 2015 should be moved to Schedule III of the Controlled Substances Act?

A I think that the present definition of marijuana in our findings for placing it in Schedule III is essentially judging marijuana with significant amounts of THC, so I do think it is a different finding for a similar substance as 2015.

Q But it is a different finding, correct?

A What's that?

Q It is a --
A Yes.
Q Different finding, correct?
A Yes. Yeah, we recommended Schedule III in 2023, HHS recommended Schedule I in 2015.
Q And if the definition of hemp were to change to be more narrow and therefore marijuana would include more substances, that could also require an addition analysis, correct?
MS. MAN: Objection, calls for speculation.
JUDGE JULIUS: Sir, do you have a response to the objection?
MR. SMITH: The objection is again -- I'm asking him how they performed the analysis and part of it is the definition. So, I think it's fair to ask, what are they including in the 2023 analysis and what are they not including in the 2023 analysis.
JUDGE JULIUS: Well, the way I understood your question was whether if the definition of hemp were altered in the future, if that would change the recommendation from the 2023 letter.
(Simultaneous speaking.)

MR. SMITH: Right and I --

JUDGE JULIUS: Did I misunderstand?

MR. SMITH: I think that's important because again, I'm just trying to establish, Your Honor, because as the Court may well know, the definition of hemp is actually scheduled to change in November of this year. So, I'm just trying to establish what HHS is claiming that this recommendation covers.

JUDGE JULIUS: I'm going to sustain the objection. I think it is speculative and it doesn't inform what was used at the time of the 2023 recommendation.

MR. SMITH: Okay, thank you, Your Honor.

JUDGE JULIUS: Thank you.

MR. SMITH: Did HHS consider when it made its recommendation marijuana that would include substances that had less than 0.3 percent THC 9, but greater than 0.3 percent total THC?

THE WITNESS: Again, we tried to exclude the category hemp, so what you just described is a little bit different from what the definition of hemp was at the time. I

realize if there are changes to hemp, including total THC, I think that it's hard to know because I know that the hemp market continues to grow. I don't know how that affects cannabis users overall in terms of the proportion of them using a product still within the definition of marijuana and some within the definition of hemp, whether it's the one from 2022 or the one from the new legislation.

I think our evaluation would consider the epidemiological data that's still showing up, that is probably going to be influenced by the cannabinoids in the cannabis plant whether it is mostly delta-9 or delta-9 and delta-8 or whatever they were using that led to a health intervention that we would be evaluating.

BY MR. SMITH:

Q But that change in definition could have resulted the impact of this analysis, correct?

A That I don't know, that's speculative.

Q You don't know one way or the other, correct?

A Correct?

MS. MAN: Objection asked and answered.

JUDGE JULIUS: Overruled.

~~MS. MAN~~ MR. SMITH: Withdrawn.

JUDGE JULIUS: Thank you.

MR. SMITH: With that, I have no further questions, Your Honor.

JUDGE JULIUS: Thank you very much, Counsel. Okay, next on the schedule, we have opportunity for cross examination by DUID Victim Voices. Remind me of your name again, sir?

MR. KENNEALLY: Of course, Judge. For the record, first name Patrick, last name Kenneally, K-E-N-N-E-A-L-L-Y.

JUDGE JULIUS: Thank you very much, sir. Feel free to conduct your cross examination whenever you're ready.

CROSS EXAMINATION

MR. KENNEALLY: Okay, appreciate it. Good afternoon, Doctor.

THE WITNESS: Good afternoon.

BY MR. KENNEALLY:

Q Doctor, my name is Pat Kenneally, I represent DUID Victim Voices. If I ask you a question and you don't understand it, please feel free to ask me to rephrase it. If I ask a question that you can't hear, please let me know

and I'll repeat it, okay?

A Yes.

Q Okay. Som, this is FDA's recommendation that cannabis should be rescheduled. Is that correct?

A Correct.

Q All right and just so I'm clear especially with regard to the Touhy letter, you're recommending that cannabis be rescheduled in 2026, not recommending that it be rescheduled in 2023, correct?

A Well, the recommendation is for marijuana, I think cannabis is a broader term.

Q I'll rephrase.

A Okay.

Q Your recommending that marijuana be rescheduled in 2026 as opposed to 2023. Is that correct?

A We made our recommendation in 2023, sometimes these processes take a long time to play out.

Q Do you still recommend that cannabis be rescheduled?

A Yes, the recommendation is still in effect.

Q Okay, so then my question, you're recommending that cannabis be rescheduled in 2026. Is that answer to that question yes?

A Marijuana, yes.

Q Marijuana, excuse me.

A Yeah.

Q Is the answer yes?

A Yes.

Q I want to pick up on something that Mr. Evans had started on, but you didn't answer. Mr. Evans asked, as part of your 8-part analysis, he asked whether or not you've spoken, as part of that analysis in 2023, to one or more parents whose children had suffered from psychosis as a result of cannabis use.

A No.

Q Did you do that?

A No, we did not.

Q Okay. As part of your analysis in 2023, did you speak to a single parent or family member of somebody who committed suicide as a result of their cannabis use?

A No, we did not.

Q Okay. Did you speak to a single family member of somebody who died or was injured in a

car crash where the other driver was under the influence of cannabis?

A No, we did not.

Q Do you have Exhibit 1 in front of you, ALJ Exhibit 1?

A Yes.

Q All right. Now, you had mentioned that when you were conducting the analysis you had limited resources in 2023. Is that correct?

A We considered our resources and made sure we had enough to cover the evaluation.

Q Okay.

A Yes.

Q So, is there anything that you wanted to evaluate that you weren't able to evaluate?

A I feel that we did a comprehensive job, so the answer is no.

Q Okay. Did you evaluate, did you compare marijuana use and its danger to the public health as well as individual health to every single Schedule I drug?

A No, we did not.

Q Okay. That would have been relevant, correct?

A It is very typical to only include a

few comparables --

Q That wasn't my question. My question was, comparing marijuana to all other Schedule I drugs would have been relevant. Is that correct?

A No, I think that the use of the Schedule I, there are a lot of substances listed in Schedule I. There are not health agencies equipped with testing standards for all of those. We would get a lot of confounded data to say that we're looking at, I don't know, 90 substances and reporting statistics when only a dozen of them are part of testing standards.

Q So, you're saying that it wouldn't have been helpful because you wouldn't have had the data?

A We wouldn't have had the data. It would have been a very ~~unweildly~~ unwieldy review to try to conduct.

Q If you had the data, would it have been relevant?

A It wouldn't have been irrelevant. It would have been useful.

Q Okay, so if it's not irrelevant, then it's relevant, correct?

A Yes.

Q Okay. Thank you. All right, so you set out to make these three findings, correct?

A Yes.

Q All right and your findings are only as good as the data that you use, correct?

A Yes.

Q All right and so we're trying to figure out whether or not we have the data here today to make a finding that in 2026, we should reschedule marijuana from a I to a III. Is that correct?

A Yes.

Q Okay and we want to be relying when we make that decision on the most reliable data. Would you agree with that?

A Yes.

Q Okay and we would want to make that finding based on the most recent data. Would you agree with that?

A I think 2023 is actually fairly recent data in the larger scheme of things.

Q Well, if you look at factor 1 and you look at the NSDUH survey data, that only goes to 2019, correct?

A Which survey? I'm sorry, which?
Q Go to page 6.
A Yeah. Okay.
Q All right, I'm on page 6 of ALJ Exhibit 1 and I'm at the very bottom. This describes factor 1. Is that correct?
A Yes.
Q All right and there's the first factor under factor 1 that you're supposed to consider at the bottom of the page. It's marked subsection A and it says, there's evidence that individuals are taking the substance in an amount sufficient to create a hazard to their health or to the health and safety of other individuals or the community.
It goes on to state, evidence shows that some individuals are taking marijuana in amounts sufficient to create a hazard to their health and to the safety of other individuals and the community. I'm turning to page 7, Doctor.
A Yes.
Q However, evidence also exists showing that the vast majority of individuals who use marijuana are doing so in a manner that does not

lead to dangerous outcomes to themselves or others. All right, that NSDUH data the most recent year that that data was collected was 2019, correct?

A NSDUH, –S-D-U-H?

Q Yes.

A Is that what you said?

Q Yes.

A Yes.

Q Okay. So, 2016, HHS makes the finding --

A I'm sorry, I would like to refer to some of the tables of NSDUH data or some of the descriptions because I think 2019, there was a break in trends due to COVID, but I do believe it resumed and reported some results up to 2021.

Q Okay and where is that in Exhibit 1?

A I would have to look, give me a minute.

Q I'm going to withdraw the question. I'm going to refer you to page 7 of Exhibit 1.

A Okay.

Q This is the second full paragraph and it says, to provide context, from 2015 to 2019, the prevalence of past year use of alcohol was 5 to 6 times greater than the past year of non-

medical use of marijuana. In contrast, the prevalence of past year non-medical use of heroin, cocaine, oxycodone, hydrocodone, tramadol, benzodiazepines and zolpidem was 4 to 5 times less than that for marijuana.

When we're talking about those statistics with regard to past year use, this is between the years 2015 and 2019, correct?

A Correct.

Q Okay. Now, in 2016, HHS made a recommendation not to reschedule cannabis, correct?

A Yes.

Q Okay and they made that decision based on the information that they had in 2016.

A Actually, the review was completed in 2015, which suggests that the databases used probably had a data lock around 2014, but yes.

Q Okay, so around 2014-2015 is when they used that information?

A Yes.

Q Okay, so now we're in 2026, right?

A Uh-huh.

Q And in 2023, only 8 years later, that analysis completely flipped, where now it's

being rescheduled based on new information that we have by 2023?

A Completely flipped is let's put it into a more complete context.

Q Okay, well let me rephrase the question. In 2015, there was an opinion by HHS that said don't reschedule marijuana, correct?

A Yes.

Q Okay. In 2023, that opinion flipped because there was an opinion that said, let's reschedule marijuana. Is that correct?

A Correct.

Q Okay so --

A Three different findings in both evaluations.

Q And it was based on the information that they had at the time?

A Yes.

Q Okay and we're now in 2026 and the information that we're relying on to make the decision in 2023 at least some of that information is from 2019, correct?

A Yes.

Q Okay and we don't have any data available to us when we're making this decision

in 2026 about what happened in 2024, correct?

A Correct.

Q What happened in 2025, correct?

A Correct, yes.

Q And we certainly don't know what's happening now?

A Yes.

Q In 2026?

A That's the length of the rulemaking process sometimes.

Q Okay. So, would you agree with me that when we're thinking about public health and individual health, how much people are using on a yearly basis, would you agree with me that, that would be something that could affect public health?

A Yes.

Q Okay and would you agree with me that the number of states that have legalized cannabis, that that will affect use rates?

A I think the trend has been increasing use over those years, but we don't know exactly, but yes.

Q So, the answer to the question is yes?

A I would assume that state programs --

(Simultaneous speaking.)

Q That the number of, excuse me, excuse me.

A Yes.

Q That the number of states that have legalized cannabis that that would affect use rates?

A I cannot say, that's speculative. There are people using cannabis in states that do not have recreational marijuana. These are national surveys. We have --

(Simultaneous speaking.)

Q So, it's your testimony --

A Yeah.

Q That you don't think --

MS. MAN: Objection, Your Honor. I'd like you to ask, let Dr. Chiapperino finish his thought before his next question.

JUDGE JULIUS: If you could just make sure that we get a full answer before moving onto your next question, but go ahead and if you want to restart your most recent question, we'll just reset from there.

MR. KENNEALLY: Of course, Judge.

JUDGE JULIUS: Thank you.

MR. KENNEALLY: Thank you. Your testimony here today is that you, as a doctor, who works for the FDA, you don't know whether or not states legalization of cannabis for recreational purpose, will affect use rates?

THE WITNESS: I would predict that it would, but I do not know. I feel -- that's enough, yeah.

BY MR. KENNEALLY:

Q Okay. Would you agree with me that the number of dispensaries in the United States would affect annual use rates?

A They could, I don't -- I don't know.

Q Okay, so let me give you a hypothetical. If there are five dispensaries in the United States versus 10,000 dispensaries in the United States, do you think the fact that there's 10,000 dispensaries in the United States would affect use rates?

MS. MAN: Objection, calls for speculation. Also, outside the bounds of the Touhy.

MR. KENNEALLY: Judge, he's been called as an expert in this case.

MS. MAN: We haven't qualified him as

an expert, sir.

MR. KENNEALLY: He's been called as an expert in this case. He has an impressive CV which qualifies him for an expert. If they haven't qualified him as an expert, then I would make the motion to qualify him as an expert at this point based on his CV. I'm not asking him to speculate, I'm asking for his opinion.

JUDGE JULIUS: Well, as I read the pre-hearing statements, he's offered as a fact witness by the government, not an expert, and he has a Touhy letter from the FDA that limits what he's allowed to say, so, I don't know what your ability to qualify him as an expert and ask any questions beyond the scope of the Touhy. Government, what --

MS. MAN: That was the government's argument, that it's outside the scope of the Touhy letter and we designated him as a fact witness. We did not ask to designate him as an expert witness.

MR. KENNEALLY: Well, the third factor of the Touhy test is that he is recommending that this Court as well as the DEA reschedule cannabis. That's not a fact that he's

testifying to, that's an opinion that he's given based on all of the evidence that he's had. So, I'd like to delve into that opinion, Your Honor.

JUDGE JULIUS: Well, he's not been qualified as an expert in this. He's not been proffered as an expert by the government, who is the one who called him today. He's been testifying as to what is contained in this report. The recommendation is what the report says it is, so he's not an expert at this point.

MR. KENNEALLY: Okay, I understand, Your Honor.

JUDGE JULIUS: Okay.

MR. KENNEALLY: I appreciate it.

JUDGE JULIUS: Sure.

MR. KENNEALLY: In 2019, do you know how many states had legalized cannabis or I should say marijuana recreationally? Was that part of your 8-factor analysis?

THE WITNESS: I don't know the data for 2019. I know what it was when we completed the evaluation, it was 23 states with recreational use plus D.C.

BY MR. KENNEALLY:

Q That's in 2026, correct?

A I don't think there have been any changes, so yes in 2026 that is still the case.

Q Would you dispute that in 2019 there were 7 recreational marijuana cannabis --

MS. MAN: Objection, asked and answered. The witness says he does not know.

MR. KENNEALLY: And I asked a new question which was would he dispute that there were 7.

JUDGE JULIUS: I'll overrule the objection and allow this question.

MR. KENNEALLY: Would you dispute that?

THE WITNESS: So, you're saying that you think that in 2019, the number of recreational adult use programs was only 7 and you're asking if I would believe that?

BY MR. KENNEALLY:

Q I'm asking the questions and my question was do you dispute that in 2019, there were 7 recreational cannabis markets that were operational?

A I don't know, so I have no basis to dispute.

Q Okay, going back to page 7 and again I'm in that second paragraph.

A Yes.

Q You compared the annual use rates of marijuana to heroin and cocaine, those are the only two Schedule I drugs that you compared them to?

A Cocaine is actually Schedule II, it does have an approved medical use.

Q Okay, so then heroin that's the only Schedule I drug that you --

A Correct.

Q Compared it to?

A Correct.

Q You didn't compare it to any other Schedule I drugs?

A Yes, that's correct.

Q Did you have the data for annual use rates for any other Schedule I drugs? Do you know?

A There are a lot of Schedule I drugs. I would say if we had selected some others, there would be some, such as psilocybin or MDMA. We did not consider those appropriate comparators.

Q Isn't one of the factors that you're supposed to consider is to compare the public health as well as the individual health of

marijuana which is a Schedule I drug to other Schedule I drugs? Isn't that part of the analysis?

A Yes.

Q Okay and the only Schedule I drug that you compared it to is heroin?

A Yes, that's correct.

Q Okay, despite the fact that you had data with respect to other Schedule I drugs?

A Our decisions to include comparators are based on many things, not just whether there is data available. We can --

(Simultaneous speaking.)

Q Yeah, but my question&--

A Yeah.

Q And I'd object as an unresponsive and I apologize for cutting off the witness. My question was you had data for other Schedule I drugs, correct?

A We did not have it collected. If we had it in our plans to include as a comparator, it would have been added for data collection and we would have had it, but we did not have it in hand.

Q Okay, but you had access to it. Is

that fair to say?

A I think some Schedule I drugs are tested for in these databases.

Q I'm moving on to page 8, Doctor.

A Uh-huh.

Q And I'm looking at the second sort of sub factor under factor 1, number B. Do you see that?

A Yes.

Q Okay and it says there's a significant diversion of the substance from legitimate drug channels and I'm going to read a paragraph and then we're going to talk about it. Is that okay?

A Sure.

Q Okay. The first paragraph. "There is a lack of evidence of significant diversion of marijuana from legitimate drug channels, i.e., marijuana that is legally marketed under United States Federal Law due to the fact that an NDA for a drug product containing botanical marijuana has not been approved for marketing in the United States. Marijuana is used by researchers for clinical research under investigational new drug (IND) applications and

there are multiple DEA registrants, who have applied and are approved to produce marijuana and derive formulations for use in DEA-authorized non-clinical and clinical research. The research and manufacturing authorizations represent only legitimate federally sanctioned drug channels in the United States and there is a lack of data indicating diversion occurring from these entities or activities. However, there are significant additional sources of marijuana in the United States, both from illicit cultivation and production, illicit importation from other countries and from state programs that permit dispensing of marijuana for medical use and, in some states, recreational adult use."

So, diversion is important because it's sort of real world proof that people are actively seeking misuse. Is that fair to say?

A Yes.

Q Okay. How much marijuana in -- do you know the year that you got this data?

A What data?

Q The data with respect to diversion. You said that --

A We say there's a lack of evidence. We did not have data to suggest that there were some amount of marijuana being diverted from these legitimate sources.

Q So, was that in 2023? Was that the year that you analyzed that?

A Yes.

Q Okay and did you compare that -- well, how much of the cannabis for research purposes was being diverted?

A We did not think any was.

Q Okay. There are other sources of marijuana in the country in 2023, specifically recreational as well as non-recreational, correct?

A Yes.

Q Okay. How much of that cannabis was being diverted?

A If you're speaking about cannabis supplies in state regulated programs --

Q Yeah.

A We did not do an assessment of diversion from those sources because we specifically said we were considering cannabis under federal law.

Q Okay, so could you have considered it from other sources?

A I think the point of mentioning this -- could we have considered it? I don't know if data are available. I don't know to what extent state authorities that run these programs collect data on diversion.

Q Did you ask?

A No.

Q It certainly would be relevant to how much cannabis is being diverted and how much cannabis is being abused, would you agree?

A I think the supplies of cannabis from these programs is considerable and I think diversion amounts would probably add to the usage, but we don't -- how much would it add to the number of users of marijuana, I don't know.

Q No, no, but it would be relevant to your purposes here of trying to figure how much, how often marijuana is being abused.

A We already know how much marijuana is being used non-medically from survey data and other sources.

Q Well, then why are considering diversion?

A Because it's part of the format of an 8-factor. We try to be comprehensive and be consistent in the content in each drug evaluation.

Q Okay, well you answered the question that the reason diversion is relevant is because it's a real world proof that people are actively seeking to abuse the drug, correct?

A Yes.

Q Okay, so if there is a significant amount of marijuana that's being diverted from state and recreational programs, that would be relevant to how often people are abusing marijuana.

A It would be relevant.

Q Okay and you did not consider that?

A No.

Q Would you agree with me that a large share of the marijuana being prescribed through state programs as medical marijuana is being used for recreational purposes?

A I would agree that a fraction of it probably is.

Q Okay.

A We know this from survey data reporting

percentages of people saying they use marijuana for non-medical reasons only.

Q Yeah and you had talked about how the largest percentage of people using medical cannabis was for anxiety, right?

A Correct.

Q And that was one of the indicators --

A In one state, yes.

Q In one state and that was one of the indicators that you used, correct?

A One of the indications, yes.

Q Okay and that after your entire analysis of looking at whether or not there's proof that marijuana treats anxiety, you found that there was no credible evidence to support that, correct?

A That's correct.

Q Okay, so if most people are using marijuana for anxiety and there is no scientific evidence that marijuana treats anxiety, it follows that those people are using marijuana recreationally?

A No, it does not.

Q Okay.

A I mean no it does not follow just ~~os~~ so

you're clear on my answer.

Q Would you agree with me that in medicine, like when you're using a medicine, the ingredients of a product matter?

A Yes.

Q Okay, so opioids, one of the things that distinguishes oxycodone and makes it less dangerous is it has this coating which is time released and it sort of decreases the speed at which it is released into your body. Would you agree with that?

MS. MAN: Objection.

JUDGE JULIUS: Basis?

MS. MAN: This is outside the bounds of the Touhy letter. Dr. Chiapperino is not authorized to testify about the effects of oxycodone.

JUDGE JULIUS: Counsel?

MR. KENNEALLY: Okay.

JUDGE JULIUS: Yeah, I'll sustain the objection if you want to approach the question in a different way.

MR. KENNEALLY: That's fine. Would you agree that dosage matters?

THE WITNESS: For knowing how to use a

medication? Of course, yes.

BY MR. KENNEALLY:

Q And for taking a medication?

A Yes.

Q And for the effect that it has?

A Yes.

Q Okay and for its ability to actually treat the ailment that it's supposed to treat?

MS. MAN: Objection, this is also outside the bounds of the Touhy. I let it go for a little bit too long because I'm a little slow right now, but my objection still remains.

JUDGE JULIUS: If you could repeat the last question that you were talking about --

MR. KENNEALLY: Dosage matters with respect to the ability of the medication to treat the underlying disorder. Would you agree with that?

JUDGE JULIUS: I'll overrule the objection to the extent he can answer that.

THE WITNESS: Yes, I agree.

MR. KENNEALLY: Okay and would you agree that the administration of -- how a medicine, particularly marijuana, is administered that can effect its medicinal

qualities as well as its medicinal effect? Would you agree with that?

THE WITNESS: Yes.

BY MR. KENNEALLY:

Q Okay. In medical marijuana states, people obtain a license or a certification, correct?

A I believe they. Do you mean people who are using it medically? People who are recommending its use?

Q Air quotes patients.

A Patients, yes.

Q Okay and medical marijuana is not given to the patient him/herself, correct?

MS. MAN: Objection, if he knows. Calls for speculation and also outside the bounds of the Touhy.

JUDGE JULIUS: Counsel, do you have any response to the objection?

MR. KENNEALLY: Did you consider medical marijuana programs as part of your 8-part analysis?

MS. MAN: That's a different question.

JUDGE JULIUS: Are you withdrawing the prior question and asking this one?

MR. KENNEALLY: I'm not. I think that that goes to why it's relevant. As part of the 8-part analysis, the nature of the medical marijuana programs that's how it's being dispensed, was part of his analysis therefore, me asking about those programs and how they work is relevant.

JUDGE JULIUS: I'll overrule the objection. I agree with Counsel.

THE WITNESS: Please repeat the question.

MR. KENNEALLY: Medical marijuana, the medical marijuana, it's not given by the doctor who prescribes the certification or the license, correct?

THE WITNESS: Not the doctor nor a pharmacy.

BY MR. KENNEALLY:

Q Okay, right. And it's not given by a pharmacist, correct?

A Correct.

Q All right. And, generally speaking, when you go to a pharmacy with a prescription, you don't really have a lot of choice in terms of what comes back after you give them the

prescription, correct?

A Correct.

MS. MAN: Objection, outside the bounds of the ~~DUID~~ Touhy.

JUDGE JULIUS: I don't know that it was in time, he -- he got the answer out.

THE WITNESS: Sorry.

JUDGE JULIUS: So, it's -- it's a general comment. I'll allow it. Overruled to the extent that it was timely made.

BY MR. KENNEALLY:

Q Okay. Somebody who has a medical marijuana card who's not going to a pharmacist, where are they going to get their cannabis?

A State dispensaries.

Q Okay. And does the doctor tell them the dose of cannabis that they need to take?

A As I had testified earlier, I do not have data about what healthcare practitioners, what their recommendations actually look like and how specific they are.

Q Do you have data that the doctor tells them the exact product that they have to take?

A No.

Q Okay.

A I don't know that.

Q Do you have data that tells them the exact administration of how they should take the marijuana?

A I don't know that they do, they may.

Q Okay. So, you have no idea with respect to these medical cannabis dispensaries, you, essentially, have no data with respect to what a medical patient can purchase when they go into a dispensary?

A Only to the extent of survey data.

Q Do you have any data with respect to the percentage of medical doctors that are prescribing cannabis certifications or licenses?

A We had absolute numbers provided in the Part 1 memo. I think it was upwards of 30,000 healthcare practitioners. That was not worked out as a percent or by state.

Q Okay. And you -- would you agree with me that it's about 2 percent of healthcare providers are providing the vast majority of these licenses and certifications?

A I'm --

MS. MAN: Objection, calls for speculation.

MR. KENNEALLY: Doesn't call for speculation at all --

JUDGE JULIUS: Yeah, it --

(Simultaneous speaking.)

MR. KENNEALLY: Would you agree with me that the vast majority of the physicians who are prescri -- that that 2 percent of the physicians in a state are providing the vast majority of the certifications and the licenses for marijuana?

MS. MAN: Objection, assumes facts not in evidence.

MR. KENNEALLY: I'm asking if he would agree with me to that fact.

JUDGE JULIUS: I will overrule the objection and he can answer what he knows.

THE WITNESS: I don't know the total number of healthcare practitioners. That's not data I've seen. So, I don't know how 30,000 relates to the total number across these programs.

BY MR. KENNEALLY:

Q So you don't know and that wasn't considered as part of your analysis?

A No.

Q Okay. And would you agree with me that the vast majority of certifications or licenses for medical marijuana is same day authorization with little to no prior treating relationship from the physician?

A As I testified earlier, we did not review the quality of or the specifics of individual marijuana programs in the states.

Q Okay. So, you don't know whether or not the vast majority of licenses or certifications that are being given to medical marijuana patients, whether there's a prior treating relationship there?

A I don't know.

Q And did you consider or do you know -- strike that.

Would you agree with me that the vast majority of the examinations that allow for certifications and licenses are not insurance but cash?

A I don't have knowledge of that.

Q Okay. All right, can you turn with me to page 32 of ALJ's Exhibit 1?

A Okay.

Q I'm at the very bottom. Are you there,

Doctor?

A Past year use?

Q Yes, yes. And I'm just going to read you a few sentences, and then we can talk about it. Okay?

A Sure.

Q Past year use of marijuana for non-medical and medical uses combined, based on NSDUH data from 2015 to 2019, past year use of marijuana for any reason, non -- open paren, non-medical and medical, close paren, among peoples 12 years and older increased from 14 to 18 percent.

This is in contrast to past year use, open paren, non-medical and medical, close paren, of comparator drugs that have FDA approved therapeutic indications, where use declined or remained relatively stable over the same timeframe, including hydrocodone, open paren, 22 to 16 percent, benzodiazepine, open paren, 12 to 11 percent, 2017 to 2019 only, close paren, oxycodone, open paren, 11 to 9 percent, close paren, tramadol, open paren, 7 to 6 percent, close paren, zolpidem, open paren, 4 to 3 percent, close paren, and ketamine, open

paren, less than 1 percent.

Okay, so, in your report, you say that last year's cannabis use in people 12 years and older increased 4 percent from 14 percent to -- to 18 percent, correct?

A Yes.

Q It's a pretty big jump? And if that trend continued, today, it would be as high as 26 percent, do you agree?

MS. MAN: Objection, calls for specu -- speculation.

MR. KENNEALLY: It calls for math, but sure, okay.

JUDGE JULIUS: Sustained.

BY MR. KENNEALLY:

Q Do you have that data and -- and you do not have this data with regard to annual use rates from 2026, right? Wasn't considered as part of your consideration?

A Correct.

Q 2025? Don't know?

A Correct.

Q 2024, don't know?

A Correct.

Q Okay. Now, 18 to 25 is an important

demographic, would you agree?

A Yes.

Q Okay. And this is especially true with regard to mental health? In fact, in the 18 to 25 demographic, that's generally when you see the onset of serious mental health disorders.

Would you agree with that?

MS. MAN: Objection, outside the bounds of ~~DUID~~ Touhy.

MR. KENNEALLY: Okay, well, I'll -- then, Judge, let me rephrase the question.

BY MR. KENNEALLY:

Q Did you consider whether or not 18 to 25 was an important demographic as part of your eight-part analysis?

A We consider all demographics important, but yes, they are important.

Q Okay. And did you consider whether or not it was important by virtue of the fact that between 18 to 25, that's when the vast majority of serious mental health disorders, that's when the onset occurs? Did you consider that as part of your analysis?

A I think our experts are aware of that issue, yeah.

Q So, yes?
A Yes.
Q Okay. And where in here do you talk about the use rates for 18 to 25-year-olds?
A Probably in several places --
Q Well, let me -- let me withdraw that question.
A Mm-hmm.
Q When you're looking at national survey on drug use and health, with respect to page 32, nowhere in here am I going to find the annual use rates for those 18 to 25, is that correct?
A In this section, I --
Q In this section?
A -- agree, yes.
Q Okay. And am I going to find the monthly use rates for that demographic?
A Yeah, this section is titled Past Year Use, so, no.
Q Okay. And am I going to find the daily use rates for this demographic or whether or not they're using 21 days or more?
A I know that that's captured elsewhere in the review, maybe not in this section.
Q Do you know -- do you know that there's

recent data from -- do you know that there's a recent NSDUH report from 2024?

MS. MAN: Objection, outside the bounds of ~~DUID~~ Touhy.

MR. KENNEALLY: Judge, he's giving a recommendation as to whether or not cannabis should be rescheduled in 2026. That includes the evidence that he considered in 2023, but it also includes a consideration of everything that ~~t~~he did not consider that's relevant to the credibility as well as the -- as well as the merits of that rescheduling recommendation.

JUDGE JULIUS: Did you have something else to add?

MS. MAN: I did. That the recommendation was made in 2023 and these rulemaking things take time. And there's been nothing else considered since because there's been no active, open matter in front of the FDA.

He cannot testify to something that happened in 2024 and whether or not that would, in fact, know something that he recommended a year ago.

MR. KENNEALLY: That goes to weight and not admissibility. If they want to make the

argument that they couldn't do anything else after 2023 because it takes time and resources, they can make that argument.

But it's still a relevant factor for purposes of Your Honor's recommendation.

JUDGE JULIUS: So, the question is, is he aware that there was an updated one?

MR. KENNEALLY: That's it.

JUDGE JULIUS: I'll allow that question.

BY MR. KENNEALLY:

Q Are you aware that there's a -- that there is a more recent 2024 NSDUH report that was from 2024?

A Yes.

Q Are you aware of that?

A Yes.

Q Okay. And that was not part of your analysis with respect to rescheduling?

A Correct.

Q Okay. And have you considered that before testifying here today?

MS. MAN: Objection --

THE WITNESS: No.

MS. MAN: No.

MR. KENNEALLY: Okay. Will you turn with me, please, Doctor, to page 34?

THE WITNESS: Okay.

BY MR. KENNEALLY:

Q All right. Now, I think this gets into the monthly use rates that you were --

A Yeah.

Q -- referring to, is that correct? So, I'm looking at the -- do you see this section entitled, Behavioral Risk Factor Surveillance System?

A Yes.

Q All right. And that's referred to as BRFSS?

A Correct.

Q Correct?

A Yes.

Q Okay. BRFSS is a national state-based, cross-sectional telephone survey by the Centers for Disease Control and Prevention, the -- and then I'm going to jump down to the second paragraph and just read the first sentence there. Okay?

A Yes.

Q It says that estimated prevalence of

past month marijuana use for any reason in the BRFSS survey was 12 percent with 88 percent reporting no marijuana use, correct?

A Correct.

Q Okay. So, this is the Center for Disease Control, which is making phone calls to people and asking them about their past marijuana use, is that correct?

A Yes.

Q Okay. Now, somebody who is in the -- in an inpatient hospital suffering from cannabis induced psychosis, do you think they're going to pick up the phone and answer the surveyor?

MS. MAN: Objection, calls for speculation.

JUDGE JULIUS: Counsel?

MR. KENNEALLY: Well, they -- it goes to the credibility of the report, which he's relying on. So, talking about some of the deficits in the report that he's certainly able to opine on, I think is relevant.

MS. MAN: I think it's also argumentative.

JUDGE JULIUS: Well, I think the question of whether he knows anybody to -- and

if that was considered may be a different question. I know that's not what you're asking, but I think maybe the way you phrased your question is objectionable.

So, I will sustain the objection, but I think, if you want to come at it from a different way, you may be able to.

BY MR. KENNEALLY:

Q Okay. Somebody who's suffering from psychosis, all right, do you think that they're likely to answer a CDC survey on the telephone?

MS. MAN: Objection, calls for speculation.

JUDGE JULIUS: Yeah, I -- it -- I think that's not any really different than the way that it was asked the first go around.

BY MR. KENNEALLY:

Q Well, do you have experience conducting -- have you ever conducted a survey?

A Yes, as a matter of fact, but many years ago.

Q Okay. And so, you have -- you have an understanding of the methodology, correct?

A Yes.

MS. MAN: Objection --

THE WITNESS: Some.

MS. MAN: Outside the bounds of the ~~DUID~~ Touhy.

JUDGE JULIUS: Yeah.

MR. KENNEALLY: Well, I mean, it's somewhat of a double-edged sword, Judge. So, I'm trying to -- so, she's basically objecting that he -- that it calls for speculation by virtue of the fact that I haven't laid -- I haven't laid a sufficient foundation with respect to his knowledge base. At this point, I'm just trying to lay a sufficient foundation.

JUDGE JULIUS: I understand what you're trying to do. I just -- I can't order someone to answer questions that are beyond the scope of what they're authorized to do.

If someone wants to ~~change DUID~~ challenge Touhy up to the Supreme Court, they are more than welcome to do that. But I'm not going to order someone to answer questions that are beyond the scope of what they're authorized to do.

I think if you want to ask him if he knows of anybody who self-reported or if that was considered, that may be a different issue.

MR. KENNEALLY: Okay.

JUDGE JULIUS: As part of the 2023 recommendation.

BY MR. KENNEALLY:

Q It -- do you consider when -- when you're going through this, do you consider the weaknesses of some of the data as part of you're eight-part analysis?

A Yes, we do have sections describing caveats about the data.

Q Okay. So, if there's a clear, glaring, commonsensical problem with respect to one of the -- with respect to one of the surveys, is that something that you and your group would consider?

A Yes.

Q Okay.

A I don't consider this one of them, but yes.

Q Okay. You don't consider what one of them?

A What you're getting at with this analysis.

Q You don't think that it's commonsensical that somebody with psychosis is not going to answer the phone and when the CDC

calls to tell them about their monthly marijuana, which you don't -- you don't see that as commonsensical?

A I think that the rate of psychosis in the general population is 1 to 2 percent. I think that the ability of the scenario you're describing to alter the number 12 significantly is not realistic.

Q Okay. Well, what about people who are severely disaffected because of their cannabis use and suffering from any form of mental illness? Do you think that makes them more or less likely to do the survey?

A That is the caveat of a phone interview, I suppose, yes.

Q So, that is -- okay, so, that is a weakness of this survey data? You would agree with that?

A It is a shortcoming of a valuable survey instrument.

Q Okay, thank you. All right, now, monthly data is important because it could be a reflection of how often -- how many people are abusing cannabis, is that fair to say?

A Yes. However, when you're looking at a

population that includes both non-medical and medical users, people using it for a medical purpose often have a reason to use it daily.

Q What percentage of -- what percentage of this 12 percent of cannabis users used it 21 more days per month?

A I would need a minute to browse through to see if we cover the kind of data you're asking about.

Q Do you know offhand whether or not you cover that type of data?

A I -- this is a very dense document. It was finalized several years ago almost. So, yeah, I'm a little in need of refreshing on some of the details of it.

Q Okay. Would you agree with me that every day use would probably be one of the most important considerations when determining whether or not somebody has cannabis use disorder?

A It is one of the factors in the DSM-5, yes.

Q But would you agree with me that it's one of the most important factors?

A It's a totality of the factors. Yes, it's an important factor.

Q Okay. And you don't know what that is offhand?

A Don't know what -- what what is?

Q You don't know what the 21-plus day use rates for marijuana users is offhand, correct?

A It is covered, I think -- I don't know offhand, no.

Q Okay. What is the percentage of past -- of year heroin users who used 21 or more days a month?

A Probably high. I don't know. Would you like to direct me somewhere in the document and we could talk about the numbers?

Q No.

A Okay. Well, then, I don't have an answer for you off the top of my head.

Q Did you consider LSD in that analysis?

A No, we did not include LSD as a comparator.

Q Mescaline?

A No.

Q MDMA?

A No.

Q All right, go with me to page 37, if you would, please?

A Okay.

Q Thank you. And I'm looking at the bottom of page 37, Factor 5, the Scope, Duration, and Significance of Abuse?

A Yes.

Q And under the fifth factor, the Secretary must consider the scope, duration, and significance of marijuana abuse, including in relation to relevant comparator substances that are abused.

And then, I'm going to jump down to the next subsection, it's called, Epidemiological Data on Consequences of Marijuana Abuse. Under that, it's the National Poison Data Center.

A Yes.

Q Okay. Are you aware that there is a more updated report from the Poison Control Center from 2024?

MS. MAN: Objection, outside the bounds of ~~DUID~~ Touhy.

JUDGE JULIUS: Counsel, any response to the objection?

MR. KENNEALLY: The same responses I had, Your Honor. I think that he's -- it's the sufficiency of the eight-part review with

respect to his recommendation in 2026 depends on what he did consider.

But I also think that it's fair game to get into what he did not consider, as it goes to the weight of his testimony, Your Honor.

JUDGE JULIUS: Counsel?

MS. MAN: May I respond? When something is recommended in 2023, and you're -- the witness is being asked if he considered something from 2024, that is something that he wouldn't have been able to ob -- consider something that happens in the future.

So, I don't have any problems with questions about what he considered to generate his report, but when it happened clearly after the report, and we know that going into the question, I object to the form of the question and to the substance of the question.

JUDGE JULIUS: Counsel?

MR. KENNEALLY: They're saying that, based on the 2023 data, they can sufficiently, using that data, make a recommendation in 2026 that that still holds true.

What data they have not considered since they've -- what data they have not

considered since they published their report is information that you can consider as to whether or not they have satisfied their burden of proof of establishing that marijuana should be rescheduled.

JUDGE JULIUS: Based on the testimony that the recommendation is to reschedule as of 2026, even though the written recommendation was in 2023, I will allow the question.

Overruled.

MR. KENNEALLY: Do you want me to repeat the question, Doctor?

THE WITNESS: No, I think the answer is, yes, I am aware there is a 2024 report from the Poison Center.

BY MR. KENNEALLY:

Q And, no, that was not considered as part of your analysis to reschedule here today?

A That is correct.

Q All right, I'm going middle of -- excuse me, second paragraph, page 38, second sentence. It's the sentence that starts with, the highest.

Are you with me, Doctor?

A Yes.

Q The highest number of PC abuse cases was observed for alcohol, open paren, ~~N 56, 143~~ N equals 56,143, close paren, followed by heroin, open paren, N equals 34,083, close paren, and by benzodiazepines, open paren, N equals 33,688, the fourth highest number of PC cases was for marijuana, open paren, N equals 22,731, with all other comparators showing even few PC cases, and you go into heroin, oxycodone, hydrocodone, fentanyl, tramadol, zolpidem, and ketamine.

Now, PC abuse, that means that the person on the phone, who answers the phone, from the Poison Control Center, believes that the user used the product in an attempt to get high, that's the abuse part of it?

A Yeah.

Q Okay. So, the idea here is that we're trying to determine how many Poison Control contacts resulted from a person trying to get high versus how many Poison Control contacts resulted from either an accident or somebody using it medically.

Is that fair to say?

A Yes, I mean, these data are only focused on the abuse cases. I don't know what

the frequency is in the other categories.

Q Do you know whether or not the person who's answering the phone is a trained substance abuse professional at the Poison Control Center?

A I assume they are. I don't review these data from the Poison Center. The Office of Surveillance and Epidemiology is. I trust our epidemiologists to provide numbers that they trust, so I would assume these are qualified people.

Q Okay. But you don't know?

A No, I don't know.

Q Okay. Do you -- so, with respect to all of the data that you received, how much assuming that it was quality did you do versus how much verification that it was quality that you did?

I'll withdraw the question.

So, the person on the phone, though, is relying on the information that they receive, is that correct?

A Yes.

Q Okay. And if you're calling Poison Control, there's usually some type of emergency going on, is that fair to say?

A Yes.

Q Okay. And the first priority is to get help?

A Yes.

Q And probably, many of these -- these calls drop prematurely, there could be a number of instances where they just don't get to the question as to whether or not this is being abused versus accidently consumed, correct?

MS. MAN: Objection, calls for speculation.

JUDGE JULIUS: Counsel, do you want to respond to that objection or rephrase your question?

MR. KENNEALLY: I'll rephrase my question, Your Honor, thank you.

Did you consider, when relying on this data, how -- whether or not the ability to report the abuse was accurate, just based on the nature of the call?

Does that question make sense?

THE WITNESS: No, say it one more time.

BY MR. KENNEALLY:

Q Okay, that's a horrible question. Okay, did you consider, when evaluating PC abuse

cases, how many PC abuse cases are there?

A Mm-hmm.

Q Did you consider how -- how accurate the transfer of information was between the person making the call versus the person receiving the call as to whether or not this was an abuse case?

A I consider this data source to be a very valuable data source that maybe has minor flaws, not flaws, but realities of circumstances. I think that the overall numbers being reported are not likely to be influenced tremendously by the kind of scenarios you're describing.

But, in any case, we wouldn't have any other data that's any better. This is the best we have.

Q Okay. So, okay, do you see where it says 41 percent of the cocaine cases were not --

A Down in the fourth paragraph, yes.

Q Yeah. So, it says, 41 percent of cocaine cases were not -- were PC abuse cases. That would mean, 59 percent of the Poison Control cases were not abuse cases?

Do you think 59 percent of the people

are accidentally snorting cocaine up their nose?

A I think you're misunderstanding that statistic. Let me -- can you say, again, what you think that the number 41 percent means?

Q The number 41 percent is the number of cases, the number of total Poison Control cases involving cocaine that are coded with abuse, correct?

A Yeah.

Q Okay. Which would mean that 59 percent of the cases are not abuse, correct?

A No, no, it's not correct. The number 41 percent is calculated by the number of reported events divided by the estimated users of cocaine based on, I'm sure we say somewhere what the utilization adjusted numbers are.

Q This is, in order to -- that's that --

A Oh, okay, I'm sorry, you are actually correct, yes.

Q Okay.

A My mistake, sorry.

Q It's okay.

A The utilization adjusted numbers are below. I was thinking we were already at that part.

Q Did you consider how many PC abuse cases there were for LSD?
A No.
Q Mescaline?
A No.
Q MDMA?
A No, these were not chosen comparators.
Q Okay. Let's jump to 39? All right, and I'm on the first full paragraph.
A Okay.
Q It's when utilization adjusted abuse rates, open paren, PC abuse cases per one million people with any past year use for a substance alone or with another substance, close paren, were calculated using data from 2015 to 2019, the highest rate was seen for heroin, increasing from 4,038 to 7,021 cases per one million people.
That's the biggest number by far, right?
A Yeah, yes.
Q Okay. The next highest rates were seen for ketamine, decreasing from 535 to 227 cases per one million people.
Cocaine remained relatively stable at

373 to 389 cases per one million people, close paren. And benzodiazepine relatively stable from 171 to 139 cases per million people, 2018 to 2019 only. But these rates were considerably lower than the rate for heroin.

The rates for marijuana were relatively stable at 75 to 70 cases per one million. So, that's the utilization-adjusted rate for PC abuse cases, and it looks like probably -- it looks like your big number is heroin, correct?

A Yes.

Q And heroin's a Schedule I?

A Yes.

Q And because it's a Schedule I, if somebody's using heroin, they're likely using it from an illicit source, correct?

A Yes.

Q All right. And because you're -- they're using it from an illicit source, there's no way to dose the product, correct?

A Yes.

Q You basically have to rely on what your dealer's telling you and the eye test, correct?

A Yes.

Q Okay. It's often used intravenously,

correct?

A Yes.

Q Which means that it goes directly into the blood, nothing to mediate or dampen the effects, correct?

A Yes.

Q All right. And cocaine is your sec -- is your third biggest number, correct?

A Yes.

Q And that's also likely received from illicit sources, would you agree with that?

A Yes.

Q And it could have other ingredients in there like fentanyl, correct?

A Yes.

Q All right. Now, marijuana, you would agree that, because of the state and medical licensing programs, much of that is sold at dispensaries, correct?

A About 40 percent, based on surveys.

Q And then, much of that is already tested to make sure there's no adulterants and people know what's in there, correct?

A There are regulations, yes.

Q Okay. But in --

A Usually.

Q I'm sorry.

A There are regulations and state programs, I don't know the detail of all state programs as to what they require in quality testing. But I assume they've set up a monograph of some sort.

Q Okay. So, do you think that some of the inherent danger or the risk of an overdose from things like cocaine and heroin being much higher, could have something to do with the fact that people don't know what's in those products when they're taking it?

A I think they're fundamentally more dangerous products and I think that some of what you're describing could be contributing to that, but they are fundamentally more dangerous, yes.

Q Because it's interesting, because oxycodone is an opiate, right?

A Yes.

Q Like heroin?

A Yes.

Q Okay. And if you look at oxycodone, generally, you get oxycodone from a pharmacist, correct?

A Correct.

Q Okay. And if you look at oxycodone, and I'm in the middle of that paragraph, that's relatively stable at 60 to 61 cases versus heroin at 4,000?

A Yes.

Q Okay. So, did you consider the fact that the fact that heroin and cocaine seem to be so much more dangerous than marijuana, did you consider the fact that probably the explanation there has to do with the fact that most people are getting it from illicit sources and don't know what's in it?

A That may be a contributing cause, yeah.

Q And was that factored into your analysis?

A The evaluation is a totality of the data. We have many more data sources than Poison Center data. The trends repeat across these databases measuring harms, regardless of why some substances and some databases appear less than others, if you look at all of the databases, the trends we've noted is that marijuana is not usually in the same category as Schedule I and II in terms of the harms.

Q Okay. But that -- that's fine, but it's -- it's just interesting that we've gone through this cross-examination on a number of things. You've acknowledged some flaws, but nowhere in your analysis do you discuss any of the shortcomings or the flaws in Factors 4 and 5 for any of the databases that you're pulling from.

A We did not comment, you're right, on those particular flaws with this data.

Q And if you didn't comment on it, chances are, you didn't consider it, correct?

A I don't think that the bottom line of the number of deaths associated with heroin relative to marijuana are the reasons for it are still that --

Q But that's not my question.

A Yeah.

Q My question is, if you didn't comment on it, chances are you didn't consider it?

A I don't know the extent to which our Office of Surveillance and Epidemiology considered that issue.

Q I'm at the bottom of page 39. It says, an analysis of medical outcomes related to

exposure based on severity, timing, and assessment of clinical effects for all single-substance PC abuse cases involving marijuana or comparator drugs shows that serious medical outcomes, open paren, a combination of moderate effect, major effect, and death, close paren, were greatest with illicit fentanyl, 81 percent, and heroin, 79 percent, followed by oxycodone, 70 percent, ketamine, 64 percent, tramadol, 62 percent, cocaine, 59 percent, hydrocodone, 43 -- 44 percent, marijuana, 41 percent, benzodiazepines, 32 percent, alcohol, 31 percent, and zolpidem, 27 percent.

What is the definition of moderate effect?

A I don't know that off the top of my head. I mean, it's relative to the health outcomes, severity or ability to cause life-threatening conditions, I assume. I don't know where they draw the line or define it formally.

Q Is that -- was that part of your analysis? Do you -- does anybody that did the analysis here know what that word means?

A Yes, I believe that the OSE evaluation does explain in their methodology section, but

that methodology section is a cited document, it's not within the ~~A~~8-Factor. It's a very dense, detailed document that we work from.

Q All right. What does major effect mean?

A I assume it means the ability to produce significant adverse outcomes, death or debilitating adverse event.

Q Okay. And for this statistic there -- this is Poison Control tracking people immediately after the event, like they're not tracking people to see if it has a moderate or major effect a year down the line, correct?

A Yes, I think these are acute cases.

Q Okay. All right, I'm going to page 40. All right, and this is National Survey on Drug Use and Health data. And I'm in the second paragraph, Doctor.

A Mm-hmm.

Q Well, first of all, let me point something out to you in the -- in the first paragraph. This data is from 2021, correct?

A Yes.

Q And it says, NSDUH data showed that among the individuals with past year heroin use

in 2021, there was an 81 percent prevalence of meeting the criteria for heroin SUD, open paren, i.e., endorsing at least 2 of the 11 criteria for SUD, according to DSM-5 severity data for heroin, not available, close paren.

In comparison, there was 30 percent prevalence of meeting criteria for marijuana SUD among individuals who use marijuana for non-medical reasons only.

So, basically, we're trying to figure how many people suffer from substance use disorder, is that correct?

A Yes.

Q Okay. So, I'm in the -- I'm in the penultimate sentence of paragraph two. And it starts with, there is also a 30 percent prevalence of meeting criteria for cocaine SUD among individuals who use cocaine in the past year, with 13 percent of those with past year cocaine use having mild SUD.

Is that correct?

A Yes, they are giving the breakdown, mild, moderate, and severe, 13, 5, and 12.

Q Okay. So, you would agree with me that many, many more people each year use cannabis

than cocaine, correct?

A Yes.

Q All right. And we don't have the substance abuse rates for any other Schedule I drug here, correct?

A Do you mean the frequency of use disorder or --

Q Yes.

A -- abuse?

Q Frequency of use disorder?

A Yeah.

Q I'm sorry if I misspoke.

A Yeah.

Q For any other Schedule I drug here, correct?

A Correct.

Q All right, all right. And the last thing I want to get to today, if I have a minute left, two minutes left. Okay --

A Can I clarify something with -- for just ten seconds? You've asked a lot of questions about heroin as the only Schedule I drug. The standard for Schedule II is also high potential for abuse.

So, the only difference between the

comparators chosen is that some have medical use and heroin does not, but they are all considered comparators of substances considered to have a higher potential for abuse.

Q How many Schedule II drugs did you consider as part of this analysis as a comparator?

A Four, four.

Q Four? Okay. And one Schedule I drug?

A Correct.

Q And marijuana is currently listed as a Schedule I drug?

A Yes, before April, yes.

MR. KENNEALLY: Okay. Judge, I might as well close it out. I think I only have a minute left and I don't think I'm going to get to my final point, especially how long-winded I am.

So, thank you for your indulgence, Your Honor.

JUDGE JULIUS: Thank you, Counsel.

We are four minutes to 5:00, which is our resolution time for the day. I don't know, Counsel, so, what we have next on the schedule is for the opposing states to do their cross

examination -- cross examination next.

Mr. Kenneally, I don't know, you're also going to be doing the questioning for Dr. Finn, is that right?

MR. KENNEALLY: Correct, Your Honor.

JUDGE JULIUS: I don't know if the two of you -- the two parties want to discuss swapping slots. I don't know if you want to continue on behalf of Dr. Finn, if the states want to go first tomorrow first thing.

I'm happy to do either one.

MR. McNICHOLS: We can discuss it after we adjourn.

JUDGE JULIUS: I'm happy to do that, just let me know tomorrow morning which way you want to go.

MR. McNICHOLS: Thank you.

JUDGE JULIUS: And, all right, thank you, everyone. I appreciate it. It was a good day one.

I'm sorry? Oh, yes, just a reminder, you're still under oath. Please don't discuss your testimony with anyone overnight. You have more --

THE WITNESS: Understood, thank you.

JUDGE JULIUS: -- parties to ask -- answer questions for on cross examination. So, I appreciate that.

We'll see everyone --

MR. McNICHOLS: Before Your Honor leaves the bench --

JUDGE JULIUS: Yes?

MR. McNICHOLS: -- my colleagues have brought some binders in here, they are strong and young, but rather than have them carry them back to our offices, I wanted to know if we could leave them here tonight. Is that suitable with Your Honor?

JUDGE JULIUS: You can leave them in one of the counsel rooms. That'll be locked and secure.

MR. McNICHOLS: Thank you.

JUDGE JULIUS: And the security can let you in in the morning when you're -- when you arrive.

MR. McNICHOLS: We'll do that.

JUDGE JULIUS: They'll be safe there, so you won't have to take them all the way to the hotel, but maybe not right there on the table.

MR. McNICHOLS: Sure, thank you.

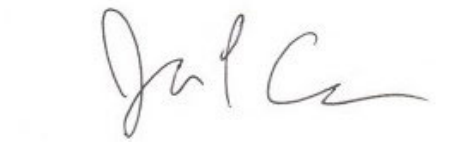
JUDGE JULIUS: Okay, thank you. We'll be in recess until 9:00 tomorrow morning.

Thank you, everyone.

(Whereupon, the above-entitled matter went off the record at 4:57 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