UNITED STATES DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION

Hearing

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

Tuesday,
June 30, 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
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[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 Smart Approaches to Marijuana:

JOHN M. McNICHOLS, ESQ.
~~PATRICK F. PHILBIN, ESQ.~~
CHASE T. HARRINGTON, ESQ.
T. ZACHARY HORTON, ESQ.
Torridon Law PLLC
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APPEARANCES: (continued)

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

JOHN M. McNICHOLS, 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
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DAVID G. EVANS, ESQ.
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On Behalf of Kenneth Finn, M.D.:

PATRICK D. KENNEALLY, ESQ.
Burke Law Group, PLLC
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DAVID G. EVANS, ESQ.
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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

CONTENTS

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

(9:00 a.m.)

JUDGE JULIUS: We'll just start this morning with a few housekeeping matters, and then we'll resume with the cross-examination.

As I indicated yesterday, I'll take -- not attendance, but just make sure we have a clear record of who is in the courtroom and is not with regards to the interested parties and designated parties.

Mr. Schwartz, could you state who is present for the Government today?

MR. SCHWARTZ: Yes, Your Honor. This morning, myself, ~~A.J.~~James J. Schwartz; Stacy Race~~;~~, and Lisa Man.

JUDGE JULIUS: Good morning, Government counsel.

Sir, if you could identify yourself and what parties you're here on behalf of and who all is with you.

MR. McNICHOLS: Certainly, Your Honor. John McNichols from Torridon Law on behalf of Smart Approaches to Marijuana, accompanied by Chase Harrington, Zach Horton, and Luke Niforatos. And three of us -- myself, Mr.

Harrington, and Mr. Horton -- are also here on behalf of the opposed states of Nebraska, Indiana, and Idaho.

JUDGE JULIUS: Okay. Any other representation from opposed states, or is that everybody?

MR. McNICHOLS: That's everybody.

JUDGE JULIUS: Okay. Thank you. It's a lot to keep track of in this case.

DUID Voices counsel?

MR. KENNEALLY: Good morning, Your Honor. Patrick Kenneally, for the record, K E N N E A L L Y, from Burke Law Group. I'm here on behalf of Dr. Ken Finn this morning, as well as on behalf of DUID Voices.

JUDGE JULIUS: Thank you very much, sir.

I noted yesterday that Pharmacist Drum, the pro se interested party, had indicated he would not be attending, I think, other than the day he's presenting his case in chief, which, again, is consistent with the preliminary order.

I also don't see Mr. Evans here present today on behalf of his organization. We'll see if he shows up today.

But that is everyone I see in the gallery -- strike that -- in the well, for who's here on behalf of the participating and designated parties.

I remember yesterday we discussed the possibility of maybe shuffling order of cross examination. Counsel, do you have a response on whether you're going to maintain the order in the preliminary order or if you're going to switch?

MR. McNICHOLS: We thought it made the most sense, Your Honor, to have Mr. Kenneally finish his examination on behalf of his other client, at which point I will then examine on behalf of my clients.

JUDGE JULIUS: Sounds good. Thank you, Counsel.

Any other preliminary matters before we resume cross examination?

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

MR. McNICHOLS: Not for us, Your Honor.

MR. KENNEALLY: Thank you, Your Honor. No.

JUDGE JULIUS: Thank you all. I

appreciate the efficiency with the procedural matters.

Sir, if you would please retake the witness stand. Please be reminded that you remain under oath and are obligated to tell the truth, the whole truth, and nothing but the truth.

WHEREUPON,

DR. DOMINIC CHIAPPERINO

was recalled as a witness by Counsel for the Government, and having been previously duly sworn, resumed the witness stand, was further examined and testified as follows:

JUDGE JULIUS: And, Counsel, if you'd like to take the podium and do your cross examination on behalf of Dr. Finn, just begin whenever you're ready, sir.

MR. KENNEALLY: Thank you.

CROSS EXAMINATION

BY MR. KENNEALLY:

Q Good morning, Doctor.

A Good morning.

Q All right. This morning, let me just pull back generally. And you and I talked about a number of stats as well as databases yesterday

with respect to factors 4, 5, and 6 of your eight-factor analysis. Is that correct?

A Some, yes.

Q Okay. And when you're going through that, just generally speaking --

A Mm hmm.

Q -- is it fair to say that what we're trying to do by looking at all these databases and these stats is we're trying to get a sense of what -- the public health impact marijuana has on United States citizens? Is that --

A Yes. Relative to other controlled substances, yes.

Q Okay. And we basically want to know, comparatively, as you said --

A Mm hmm.

Q -- how many people are being killed, injured, or otherwise affected by marijuana in the United States. Is that fair to say?

A Yes.

Q Okay. And for some part of your analysis, you considered smoking cigarettes and compared nicotine to marijuana for addictive purposes. Is that correct?

A Yes.

Q Okay. And you would agree with me that smoking is a public health risk?
A Yes.
Q It's about as bad as it gets.
A Sure. Yes.
Q Okay. And though it doesn't immediately kill you, such as an overdose, and though it may not cause you to call Poison Control, it causes disease, correct?
A Yes, it does.
Q Okay. And it's ultimately the disease that kills you.
A Yes.
Q Okay. And it's ultimately the disease that harms you and injures you.
A Yes.
Q Okay. And a lot of times it causes chronic diseases. Right?
A Yes, it does.
Q All right. And, like, in terms of the impact on the health system, chronic diseases is one of the -- is one of the biggest impacts. Would you agree with that?
A Yes.
Q So would you agree with me that the

rate at which scheduled substances cause or are associated with chronic diseases is something that bears upon public health?

MS. MAN: Objection. This is outside the bounds of Dr. Chiapperino's Touhy about the impact of scheduled substances on public health. He can ask about marijuana and the comparators, but this is outside the bounds of his eight-factor analysis he performed on marijuana specifically.

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

MR. KENNEALLY: I literally asked what the effect scheduled substances has upon public health. It's directly in line with his testimony, Your Honor.

JUDGE JULIUS: I'll overrule the objection within the scope of the Touhy, understanding that was the scope of your question.

MR. KENNEALLY: Thank you.

JUDGE JULIUS: Proceed, sir. If you need it repeated, just let me know.

BY MR. KENNEALLY:

Q Do you need me to repeat the question?

A Sure. Please.
Q Okay. Would you agree with me that the rate at which scheduled substances cause or are associated with chronic diseases, that -- that that's something that bears upon public health?
A Yes. It bears upon public health.
Q Okay. In fact, you would agree with me that that's a very important consideration.
A Are you speaking specifically about drug scheduling --
Q No. I'm just talking about --
A -- evaluations?
Q -- the rate -- I'm sorry to cut you off. Go ahead. Finish your thought.
A Thank you. Are you speaking about drug scheduling comparative analyses?
Q Yeah. And I'm speaking about the rate at which scheduled drugs cause disease. That's something that bears upon public health --
A Sure.
Q -- and that's an important consideration.
A I think it is an important consideration. I think we do tend to focus more on acute toxicities and acute harms because the

range of substances, for many reasons, that develop that cause long term harms -- we could talk about a lot of things, both controlled substances and other substances that over time might lead to disease conditions. It's hard to weigh those data when we don't have good data for many of the comparators in terms of long term outcomes, so we do focus more on acute toxicities.

Q Did you look at the data of the association between marijuana and its association with psychosis and schizophrenia?

A We did, yes.

Q Okay. And where in your eight part analysis is that?

A It is not documented in the eight factor analysis, I agree. There are some adverse events reported that are related to psychiatric events, which would capture psychosis. We had the evaluation from the Office of Surveillance and Epidemiology that did look at that. There were --

Q That did look at what?

A Psychosis and causality, whether it was demonstrated.

Q And is that in the eight --
A No, it is not in the evaluation.
Q Okay. So it's -- so it's not in the eight part analysis.
A It is not written about in the eight part analysis.
Q Okay. So there were things that you considered --
A Mm hmm.
Q -- as part of your rescheduling decision --
A Mm hmm.
Q -- that you did not include in the analysis.
A Yes.
Q Is that --
A Yes.
Q Okay.
A Yes.
Q And how -- and did you disclose the other things that you considered as part of your rescheduling decision to Dr. Ken Finn prior to the hearing today?
A I'm sorry. To whom?
Q Dr. Ken Finn. Prior to the hearing

today.

A No.

Q Okay. Did you disclose the other things that you considered that were not part of the HHS analysis to any of the other parties to this hearing prior to this hearing today?

A No, we did not.

Q Okay. In your eight part analysis, what you wrote about --

A Mm hmm.

Q -- and what you advised us about that you considered, did you ever consider or write about how marijuana is associated with depression?

A Yes. It is captured, I think, in some of the adverse event tallies and reported adverse events among users in surveys.

Q Okay. So what is the -- so what is the association? How much does marijuana increase the risk of depression, chronic use?

A I cannot give you that number off the top of my head. If you'd like me to focus on one of the analyses, I'm happy to.

Q Sure. Where in the HHS analyses do you talk about the rate at which marijuana causes

depression --

A I don't think we --

Q -- from an epidemiological --

A -- might have broken it out --

Q Can I finish my question?

A Oh, yes. My apologies.

Q From an epidemiological standpoint, where in the HHS analysis do you talk about that?

A We don't.

Q Okay.

A Not as a rate.

Q All right.

A Of that specific outcome.

Q Would you agree with me that the rate at which a Schedule I substance and Schedule I substance use causes adverse cardiac events, would you agree with me that that's something that's important to public health?

A Yes.

Q Okay. And you would agree with me that nowhere in your eight part analysis do you specifically focus on or do you consider the association between chronic marijuana use and adverse cardiac events?

A Honestly, it's such a dense document of data that I am not sure what tables are included in it at this point.

Q Okay. But as you sit here today, you're not aware of whether or not HHS --

A I cannot be sure whether we have discussed those specific statistics.

Q Would you agree with me that if a Schedule I drug, after chronic -- after chronic use, reduced brain activity, lowered intelligence, reduced domains of memory and learning, and significantly lowered baseline motivation, would you agree with me that if a Schedule I substance was associated with those things, that that would be important to public health?

MS. MAN: Objection as to compound question.

MR. KENNEALLY: I'll rephrase.

JUDGE JULIUS: Thank you.

MR. KENNEALLY: Yeah. I appreciate that.

BY MR. KENNEALLY:

Q Would you agree with me that if a Schedule I substance was associated with reduced

brain activity --

A Mm hmm.

Q -- in users --

A Yeah.

Q -- would you agree with me that that would be an important public health consideration?

A Yes. I think it would be.

Q Okay. Would you agree with me that if a Schedule I drug, after chronic use, lowered the intelligence of the people using the drug, would you agree with me that that would be an important public health consideration?

A Yes.

Q Okay. Would you agree with me that if a Schedule I drug, after chronic use, reduced domains of memory, the ability to remember, as well as the ability to learn, would you agree with me that that would be an important public health consideration?

A Yes.

Q Okay. Nowhere did you write about, in your eight part analysis, the association between chronic cannabis use and reduced brain activity, correct?

A I think it is captured in terms of adverse event outcomes. I don't think we have paragraphs devoted to that individual topic.

Q Okay. Nowhere in your eight part analysis did you consider the association between chronic cannabis use and lowered intelligence, correct?

A Correct.

Q Okay. Nowhere in your eight part analysis did you consider the association between chronic cannabis use and reduced domains of memory and learning, correct?

A Correct.

Q Okay. Do you have Exhibit 1, ALJ Exhibit 1, Doctor?

MR. KENNEALLY: And could we provide him with that, please?

JUDGE JULIUS: Just for the record, the law clerk is handing him ALJ Exhibit 1.

MR. KENNEALLY: Thank you, Judge.

JUDGE JULIUS: And while we're paused, I'll also just note for the record that Mr. Evans is now present with us. Welcome, Mr. Evans.

MR. EVANS: Thank you for acknowledging

my presence, Your Honor.

JUDGE JULIUS: Absolutely.

MR. EVANS: It's always nice when someone acknowledges your presence.

JUDGE JULIUS: Of course.

BY MR. KENNEALLY:

Q Doctor, could you turn with me to page 50 of the August letter, please.

A I am there.

Q Okay. And middle of the page, do you see the subheading Risk of Driving Under the Influence of Alcohol?

A Yes, I do.

Q Excuse me. Do you see the Risk of Driving Under the Influence of Drugs?

A Yes.

Q I misspoke.

A Sorry.

Q Okay.

A Me, too.

Q Okay. And this talks about NSDUH data from 2021.

A Yes.

Q And we talked about yesterday how you were not aware that -- how you were aware that

there was NSDUH data from 2024 --

A Yes.

Q -- that was not considered.

A We have not reevaluated marijuana since 2023.

Q Okay. So these are surveys that are being conducted, the NSDUH survey as well as the YRBSS survey, right?

A Right.

Q So people are calling people on the phone. Is that essentially what happens?

A For the YRBSS, yes.

Q Okay. And what about the NSDUH? How are these surveys conducted?

A You know, I don't recall. I think this is an online or -- I'm not sure.

Q Okay. And essentially the survey is asking the question: How often have you driven under the influence of either a drug or alcohol, correct?

A Yes. Yes.

Q Okay. And the accuracy of this survey depends on the people essentially admitting to the surveyor that they've driven under the influence of a drug or substance. Is that

correct?

A Sure.

Q Okay. For purposes of public health, what would you say is more important, the rate at which people are driving under the influence of, let's say, marijuana, or how many people are being injured or killed by people driving under the influence of marijuana?

MS. MAN: Objection. Calls for speculation.

JUDGE JULIUS: Counsel, response?

MR. KENNEALLY: It's not. It's which -- what's more important to a public health consideration. That's exactly what he's here to testify to.

JUDGE JULIUS: I'll overrule the objection to the extent he can answer it.

MR. KENNEALLY: I can rephrase.

JUDGE JULIUS: Okay. Thank you, Counsel.

BY MR. KENNEALLY:

Q Is the rate at which people are being killed or injured by people driving under the influence of marijuana, is that an important consideration in terms of public health?

A The rate, yes.

Q Okay. How many people in 2023 were killed by somebody driving under the influence of cannabis?

A 2023 was not a complete year of evaluation. Do you want to focus on a different year?

Q Okay. How many people in 2022?

A I think it would depend on whether we're talking about people that were testing positive for Delta 9 THC or whether there is an assessment of actual impairment.

Q How many people in 2022 were killed as a result of somebody else driving under the influence of cannabis?

A I don't have the exact number, because what you're suggesting is that we know which fatalities were caused by impairment with marijuana as opposed to testing positive. The data that I have seen would place that number somewhere, I think, between 2,000 and 5,000 individuals.

Q Okay. And between 2022 and 2015 -- no, between 2022 and 2012, would you agree that the number of people who have been killed in a

accident involving somebody testing positive for cannabis increased?

A I think there are increases in those numbers.

MR. EVANS: Your Honor, if I may, could I give my co counsel a note?

JUDGE JULIUS: Yes. Just make sure to speak into the microphone, but --

MR. EVANS: Oh. Your Honor, if I may, I would like permission to give my co counsel a note.

JUDGE JULIUS: That's fine. Thank you.

BY MR. KENNEALLY:

Q What's your definition of "medicine"?

MS. MAN: Objection. Dr. Chiapperino is not a medical doctor.

JUDGE JULIUS: Response to the objection?

MR. KENNEALLY: Well, he's here to talk about the fact that marijuana has a CAMU, which has a medical application. I just want to know what he thinks "medicine" is.

MS. MAN: Objection as to the question being impermissibly broad and vague.

MR. KENNEALLY: I don't know how it --

I'll allow Your Honor to rule.

JUDGE JULIUS: I'll overrule the objection. If he needs further parameters, he can ask you to contextualize, if he needs, but go ahead and ask the question.

MR. KENNEALLY: Thank you, Judge.

BY MR. KENNEALLY:

Q Doctor, what's your definition of "medicine"?

A I would refer to the Food, Drug, and Cosmetic Act definition of a drug to treat, diagnose -- I'm not sure of the exact language off the top of my head, but I think it is to treat, diagnose -- I should know this, and I apologize.

Q It's okay.

A But --

Q Can I try to help you out a little bit?

A Sure. Thank you.

Q Okay. Would you agree that it's something that stops or prevents a medical condition or a disorder?

A Prevents or heals, yes.

Q Okay.

A Yes.

Q And it can also --
A Treats a condition.
Q It can also be something that relieves the symptoms --
A Yes.
Q -- of a medical condition or a disorder?
A Yes.
Q Okay. Would you agree that pain is a medical condition?
A Yes.
Q All right. And would you agree that at some point in everybody's life they suffer from pain?
A Speculative. There might be some lucky people, but, yes, I do believe most people would experience pain.
Q Okay. And your mental health and your outlook can affect how people experience pain. Is that correct?
MS. MAN: Objection. Outside the bounds of his Touhy letter to speculate about mental health and its effects.
JUDGE JULIUS: Counsel?
MR. KENNEALLY: He explicitly spoke

about pain, as well as the literature that supports marijuana having an application with respect to pain. I'd like to explore that. I'd ask for a little bit of rope, Your Honor.

JUDGE JULIUS: I'll overrule the objection. Thank you, Counsel.

THE WITNESS: Can you repeat the question?

BY MR. KENNEALLY:

Q Would you agree that your mental health or your outlook can affect how people experience pain?

A How people experience pain based on their mental health, I can't give you an answer on that. I think it's possible, yes.

Q Will you turn with me to page 24 of the HHS document, please?

A Yes, I'm there.

Q All right. And this is where you talk about the CAMU test, part 1 and 2, correct?

A Yes.

Q All right. And I'm going to -- I'm on 24 in the middle.

A Mm hmm.

Q And I'm talking about part -- so part

2, right in the middle of the second paragraph under the subheading Currently Accepted Medical Use of Marijuana.

A Yes.

Q All right. Do you see the sentence that starts with "Part 2 of the CAMU test evaluated where -- whether there exists credible scientific support for at least one of the medical conditions for which part 1 test is satisfied."

A Yes.

Q Do you see that sentence?

A Yes.

Q Okay. So that's -- that's part 2 of the CAMU test.

A Correct.

Q All right. And you're trying to figure out whether or not there's credible medical evidence to support that.

A Credible scientific support, yes.

Q All right. And now would you turn with me to page 25?

A I'm there.

Q All right. Now, there's a way to evaluate whether or not the medical support is

credible. There's factors that you're supposed to consider, correct?

A Correct.

Q Okay. And I'm in the second full paragraph. It states, "In evaluating whether there exists some credible scientific support under part 2 of the CAMU test for a particular use, factors considered in favor of a positive finding included: number 1, favorable clinical studies of the medical use of marijuana, although not necessarily adequate and well controlled clinical studies, that would support approval of an NDA, have been published in peer reviewed journals," correct?

A Yes.

Q Okay. So in order to qualify under that first factor as credible scientific support, it has to be favorable, and favorable in that it has some sort of medical application. It either prevents the disorder, stops the disorder, alleviates the symptoms. Is that correct?

A Yes.

Q Okay. And it says -- it says "favorable clinical studies." Can one study do

it or do you need two studies?

A That's a loaded question right now because FDA has recently discussed guidance of moving from a two-pivotal-trial standard to a one pivotal trial. I would say that you need -- I think it is always better to have replicated results of a clinical trial.

Q But in order to satisfy this test, do you need one clinical trial or do you need two?

A You don't need two because the standard for the test is not a finding of safety and efficacy. It's credible scientific support.

Q Okay. So one study would do it.

A Yes.

Q Okay. So it has to be favorable. It has to be clinical. And what does "clinical" mean?

A A study in humans.

Q Okay. So just studying humans, not like an in vitro study, not a study of rats, right?

A Correct.

Q Okay. And it needs to be published in a scientific journal, correct?

A Yes.

Q Okay. So it doesn't have to be

adequate under this test.

A We focused on randomized clinical trials, which means there is a control group. "Adequate" gets more at the size of the study and other design features. It did not have to be a large trial.

Q Okay. The language here says it doesn't have to be adequate. Is that correct?

A Correct.

Q Okay. And the language here says it doesn't have to be well controlled. Is that correct?

A You -- I think I would read the full sentence there. "Although not necessarily adequate and well controlled clinical studies that would support approval of an NDA." I think the phrase is intended to use the entire phrase used to describe a clinical study that would support an NDA.

Q So it doesn't have to --

A I wouldn't separate that out as it doesn't have to be adequate and it doesn't have to be controlled. We did focus on controlled trials, regardless of how you're interpreting that sentence.

Q Okay. But I -- I'm just talking about this sentence. Okay? And under this sentence it says, "It does not necessarily have to be adequate and well controlled clinical studies." Am I reading that correct?

A Grammatically, you are reading it correct.

Q Okay. Thank you. It doesn't have to be repeatable, correct?

A Correct.

Q Okay.

A There might only be a couple of studies. If one was positive and one was not, we would still consider the results in the first study.

Q Can we -- so -- and when -- and when we're talking about well controlled, we're talking about it has a placebo. Is that -- is that one of the ways that you control --

A It has a comparator group. It could be an active comparator or a placebo. Most of them were placebo studies --

Q Okay.

A -- for control.

Q All right. Now, when you have a

placebo study and you're dealing with Delta 9 THC, right, generally what happens is you're comparing -- you give somebody Delta 9 THC, correct?

A Mm hmm.

Q And then you compare it to not giving somebody Delta 9 THC.

A Correct.

Q Okay. Do you see -- well, let me ask this question. When you're given Delta 9 THC, you know you're given Delta 9 THC because it has an effect on your cognition, right?

A Depending on the dose, yes.

Q Okay.

A It could.

Q Well, what --

A A lot of therapeutic doses are subtherapeutic for -- for inducing euphoria and other effects associated with marijuana.

Q Okay. But one of the effects of Delta 9 THC is that it has an effect on your cognition, correct?

A Yes.

Q And one of the effects of Delta 9 THC is that it creates euphoria, correct?

A Yes.
Q And that's something that you can feel, correct?
A At a -- at a certain dose, yes.
Q Okay. Now, did every study that you considered as part of your CAMU, was it a subtherapeutic dose such that you could not feel the euphoric effects? Is that what you're saying?
A No. The doses in these studies were wide ranging, as low as 2 milligrams, and I think up as high as 80 milligrams, which should certainly be a CNS intoxicating dose.
Q In fact, about 5 milligrams is generally what could get you high.
A I would consider that a low dose as to what could get you high. But, yes, some people might feel effects at 5 milligrams.
Q And some people might feel effects at 2 milligrams.
A Rarely.
Q Okay. And you would agree with me that there's something called the "placebo effect"?
A Yes.
Q So if you know you're getting a

medication, there's an expectation that you're going to feel better, and a lot of times you feel better even though there's no actual effect that the drug is having, correct?

A Yes.

Q Now, grammatically, under this test, the study, the clinical study, doesn't have to be well designed, correct?

A Well, that would certainly count against it when we consider quality of evidence.

Q But I'm not -- I'm not talking about what you did. I'm talking about the test here itself. Grammatically, under this test, there's no requirement that the study be well designed, correct?

A I disagree with the way you're characterizing it. We are going to consider the quality of a trial. If you want to parse the language we used in this paragraph, I'll allow that grammatically it may read as though we're not concerned about the quality.

Q Well, I'm just talking about the requirement.

A Yeah.

Q So there's no requirement in this study

that the study -- that the clinical trial be well designed.

A There's no requirement to include the study in the analysis.

Q Okay.

A Yeah.

Q And anywhere else in this document or the July document, did you --

A Mm hmm.

Q -- elaborate on all of the other requirements that satisfy clinical trials and other things that the -- and other factors the clinical trials had to meet?

A I think the CAMU part 2 document and the supporting documents that we got as a report from the University of Florida, I think there is -- there is a lot of discussion about the quality of the studies or what might be wrong about the studies that led to a low quality of evidence or lower quality of evidence.

Q But you and I seem to be talking past each other.

A Yeah.

Q I'm not talking about what you did.

A Yeah.

Q Okay?
A Okay.
Q And I'm not talking about the responsibility that you took on for your group. I'm talking about the CAMU test generally that you used, okay?
A Generally, okay.
Q Okay. That's what I'm talking about. And so -- and under the test --
A Uh huh.
Q -- there's no requirement that the clinical study, in order to be considered, be well designed. That's my question.
A I answered that. Yes. Yeah.
Q Okay. There's no requirement under the CAMU test that the clinical trial has to have been done recently, correct?
A Not as written in that paragraph. We did have a date cutoff for our analysis, though. It had to be -- I don't know the exact date, but I think it was in 2010 or later.
Q Okay. But under the CAMU test as it was provided to you --
A Yeah.
Q -- and that you were directed to follow

--

A Mm hmm.

Q -- you independently made the decision to do a cutoff test in 2010, but there's no requirement under the CAMU test itself. Would you agree with that?

A Yes. I would agree that as written here it doesn't cover those details.

Q Okay. And the clinical trial under the CAMU test here, it doesn't have to have a specific sample size.

A No, it doesn't.

Q All right. And it has to be published in a medical journal, correct?

A I think that was a criteria, yes.

Q Any medical journal will do.

A Yes. The -- the goal is that it's publicly available, yes.

Q Now the second factor is the -- the second factor that weighs in favor of part 2 of the CAMU --

A Mm hmm.

Q -- is a qualified expert organization, e.g., academic groups, peer review journals and/or qualified -- excuse me, academic groups,

professional societies, or government agencies have opined in favor of medical use or provided guidance to HCPs. Is that healthcare professionals?

A Yes.

Q Okay. HCPs on the medical use.

A Or practitioners. I'm sorry. It's healthcare practitioners, I think.

Q Okay. Who decides whether or not the organization is qualified? Is that you?

A I'm sorry. So you're talking about the phrasing "academic groups, professional societies, or government agencies"?

Q Well, it says --

A Professional societies. That's what you're talking about, professional?

Q So I'm looking at number 2. It says, "Qualified expert organizations," and it gives a few examples of what --

A Oh.

Q -- could be qualified --

A I see. Yeah.

Q Okay. So who decides whether or not the organizations are qualified and expert? Is that you?

A I think the team, yes.

Q Okay. So the people making the rescheduling decision are the ones who make the determination as to whether or not the organization is qualified and expert. Is that correct?

A We're not deciding that they are qualified. We are -- we are basing it on them being well known medical associations for a certain clinical specialty, such as the American Psychiatric Association. Within the states, there might be a medical board that determines -- that makes decisions regarding practice of medicine in the state. These would be well known government health departments or professional societies that are well known for that specialty.

Q And the people making the determination of whether or not they're qualified, well known, sufficient, that's you and your team. Is that correct?

A The team is choosing which organizations.

Q Okay. And they could be professional societies. Is that correct?

A Yes.
Q Okay. And, again, focusing on the test --
A Mm hmm.
Q -- and the language --
A Mm hmm.
Q -- there's no requirement that one of these professional organizations not have a vested interest in the scheduling decision. Is that correct?
A I don't actually know what societies have to declare in terms of their conflicts of interest, so I can't really answer that question.
Q I'm just talking about the language. There's no requirement in the language that the expert organization not have a vested interest in the rescheduling decision. Is that correct?
A Correct.
Q And it can be a professional society.
A That's what the words say, yes.
Q And a professional society in support of an industry, correct?
A Not necessarily an industry. In the treatment of a disease condition, they might be

focused on making -- on the science and medicine associated with treating their specialty condition.

Q But it -- and is there any requirement that it's limited to that?

A No. But we do have in our CAMU part 2 document the actual organizations that we used and their views, and most of them were not favoring marijuana as medicine, so --

Q And it says that they had to have opined. Do they need to currently be opining as to a medical application for cannabis, or could they have opined in the past?

A If they have a published position that is still in effect. Many of these have been positions that they've held for years, but they might still be in effect, we would assume, if they're still on their websites.

Q Okay. And if that decision has been overturned by a subsequent rule, or if they no longer hold the position but didn't necessarily make a formal edict with respect to overturning the decision, would that still count?

A Can you repeat that?

Q Sure. So there's a lot of

organizations that make determinations, and some of those determinations can go stale. Would you agree with that?

A That's speculative. I mean, you'd have to give me some examples. I assume that things change over time with science and medical advances. They might have to change their views on what is the best treatment for a disease based on new therapies being available. So I assume, yes, there's room for change.

Q Do you agree that -- that alcohol has an analgesic effect?

A I cannot agree to that. I don't know the science of alcohol with respect to reducing pain condition.

Q Would you agree that there's clinical trials in favor of alcohol having an analgesic effect?

A Excuse me?

MS. MAN: Objection. Calls -- this is outside the scope of what was --

MR. KENNEALLY: I'll rephrase.

MS. MAN: -- what went into the test. Thank you.

MR. KENNEALLY: I'll rephrase.

BY MR. KENNEALLY:

Q Are you aware, yourself, of any clinical trials that have found that alcohol has an analgesic effect?

MS. MAN: Objection as to relevance.

JUDGE JULIUS: Counsel?

MR. KENNEALLY: Can I ask a few follow up questions, Judge, to lay the foundation?

JUDGE JULIUS: I'll allow that, yes.

MR. KENNEALLY: Thank you.

BY MR. KENNEALLY:

Q As part of your evaluation, did you compare alcohol to marijuana? Was alcohol one of the comparator substances?

A In abuse related harms, yes.

Q Okay. So would you agree with me that -- okay. So would you agree with me that alcohol has an analgesic effect?

MS. MAN: Objection. Asked and answered.

THE WITNESS: I don't know.

JUDGE JULIUS: Yeah. Just remember to wait --

THE WITNESS: Sorry. Sorry.

JUDGE JULIUS: -- when there's an

objection.

MS. MAN: Dr. Chiapperino previously said he didn't know.

JUDGE JULIUS: Yeah. I mean, his answer was that alcohol was used as a comparator for some purposes. I don't know that he testified that it was used as a comparator for medical or analgesic.

MR. KENNEALLY: Judge, I'm trying to get at the sufficiency of the test as well as the analysis through analogy. And so I'd just like to explore this line of questions. And we've -- and we've talked about pain as part of this entire -- I mean, that was a feature of the Government's case. I think they've opened the door to it.

MS. MAN: That's pain, but what the question was, was alcohol an analgesic or analgesic effect. And Dr. Chiapperino said he did not know about the exact science behind alcohol, which is why I started objecting to the alcohol by itself questions. If it's questions about the comparators, that's a different question, but alcohol alone, he's already answered that he does not know the science

behind alcohol.

JUDGE JULIUS: He did give that answer, but I'll allow you to ask the question. I --

MR. KENNEALLY: Thank you, Judge.

BY MR. KENNEALLY:

Q Doctor, are you aware of any clinical evidence showing that alcohol has an analgesic effect?

A No.

Q Okay. Have you ever read the study Thompson, et al., 2017, Analgesic Effects of Alcohol: A Systematic Review and Meta Analysis of Controlled Experiment Studies in Healthy Participants? It's published in the Journal of Pain, and it pooled 18 controlled experiments, and it shows that a mean blood alcohol content of about 0.08 produced a small elevation of pain threshold, and increasing BAC produced increasing analgesia with each 0.2 increment, raising the effect size of pain threshold and reducing pain intensity further. Have you ever read that study?

MS. MAN: Objection. This is outside the bounds of the Touhy unless it's referenced in any of his analysis. And, also, he is

treating Dr. Chiapperino like an expert witness. Dr. Chiapperino is here as a fact witness, not an expert witness.

JUDGE JULIUS: Understood. I understand that he is here as a fact witness. I think if you want to ask if that was incorporated in the evaluation and the recommendation, that might be permissible. I think the way that you phrased the question is outside the scope of the Touhy letter. I pulled it up and I'm looking at -- at what's allowed. If you want to ask about what went into the recommendation, that may be a different line of inquiry.

BY MR. KENNEALLY:

Q Did you consider that study as part of your eight part analysis in this case?

A We did not.

Q Okay. Would you agree with me that heroin, which is another Schedule I drug, would you agree that that has an analgesic effect? "Analgesic" meaning it reduces pain.

MS. MAN: Objection. It's outside the bounds of this Touhy unless it was used as part of the comparator analysis, and that's what he

wants to get into.

JUDGE JULIUS: Counsel?

MR. KENNEALLY: Well, it's a comparator, Judge. And, again, I'm trying to get to the sufficiency of the test by way of analogy. They've talked about pain. I'd like to go through whether or not, in this case, a consideration that -- that what exactly is the deciding factor in this CAMU test, as well as factors 1 and 2, and so to compare, as he's done in his testing, marijuana to some of the other drugs as it relates to the CAMU test.

MS. MAN: Your Honor, I'd like to be heard briefly.

JUDGE JULIUS: Go ahead.

MS. MAN: Dr. Chiapperino testified that heroin was a comparator for other categories, not the analgesic effect. And that's where I think we're splitting hairs, where if there are other comparators for other categories that aren't mentioned here, heroin wasn't used as a comparator for analgesics. It was for relative abuse and relative abuse potential and, I think, harms, but not for analgesic effect. And that's where I think

we're getting into dangerous territory, and it is outside the bounds of the Touhy letter.

JUDGE JULIUS: Sir?

MR. KENNEALLY: Judge, understanding how pain was considered as part of the CAMU test, one of the things that we can do is we can look at how they did marijuana, and then we can compare it to other drugs. I'd ask for a little bit of leeway just around this question. I only have three or four questions that relate to heroin. I think it goes to the sufficiency of the CAMU test by way of analogy.

JUDGE JULIUS: I don't know that that logic follows. I think it depends on how the comparators were used. So I'll sustain the objection for now.

I'll ask a question just so that we're clear. If you could please explain how the comparators were used in your recommendation and analysis --

THE WITNESS: Yes.

JUDGE JULIUS: -- for what purposes and what purposes they were not used for.

THE WITNESS: Happy to. So counsel is correct that a substance like heroin and a

substance like alcohol are part of the abuse related harms analysis we did. The currently accepted medical use has no requirement for a comparative finding among the other drugs being evaluated or being used in the comparative analyses of abuse liability.

So, no, we did not look at any studies to see if marijuana had a better or worse effect than other substances. Their ability to treat a disease condition was never a question in this drug evaluation.

MR. KENNEALLY: Judge, I would just ask to make an offer of proof at this time.

JUDGE JULIUS: And what is that?

MR. KENNEALLY: May I do so?

JUDGE JULIUS: Yes.

MR. KENNEALLY: Okay. And may I make an offer of proof in terms of my questioning of the doctor?

JUDGE JULIUS: You can offer it. We'll see where it goes from there.

MR. KENNEALLY: Okay. Well, I -- okay.

BY MR. KENNEALLY:

Q Doctor, would you agree with me that heroin is another Schedule I drug, correct?

A Yes.

Q Okay. And would you agree with me that there's clear clinical evidence that heroin treats pain short term very effectively? You don't dispute that, correct?

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

MR. KENNEALLY: This is my offer of proof, Your Honor.

JUDGE JULIUS: Well, it's also -- it is outside the scope of Touhy, if it wasn't part of the analysis. If that wasn't how the comparator was used, it would be outside the scope of the Touhy authorization.

MR. KENNEALLY: And I'm asking to make an offer of proof in view of the fact that the objection has been sustained.

JUDGE JULIUS: I mean, I -- I don't know how you're going to get him to answer questions that are beyond the scope of his Touhy authorization.

MR. KENNEALLY: We don't think it is, Your Honor, and we respectfully disagree. I'd like to make a record with respect to the limits of --

JUDGE JULIUS: Okay.
MR. KENNEALLY: -- cross examination in this hearing.
JUDGE JULIUS: Okay.
MR. KENNEALLY: And as a result of that, I'd like to make an offer of proof.
JUDGE JULIUS: Understood.
MR. KENNEALLY: Okay?
JUDGE JULIUS: Okay.
BY MR. KENNEALLY:
Q All right. So you would agree with me that there's clear clinical evidence that heroin treats pain short term very effectively.
MS. MAN: Objection.
JUDGE JULIUS: Basis?
MS. MAN: It is outside the bounds of Touhy, and also objection on the grounds of relevance, especially when it comes to the rescheduling of marijuana. What heroin's effects are when it comes to treating chronic pain, unless it went into the eight factor or the HHS recommendation, is, number 1, not relevant, and, number 2, outside the bounds of Dr. Chiapperino's Touhy letter.
JUDGE JULIUS: I'll sustain that

objection.

MR. KENNEALLY: Okay.

JUDGE JULIUS: Go ahead.

MR. KENNEALLY: And I -- and I understand the objection has been sustained. So what I'm trying to do is to make a record.

JUDGE JULIUS: Understood.

MR. KENNEALLY: And so at this point -- okay. All right.

BY MR. KENNEALLY:

Q So, Doctor, you would agree with me that there's clear clinical evidence that heroin treats pain short term very effectively. Would you agree with that?

MS. MAN: Objection.

JUDGE JULIUS: Basis?

MS. MAN: Same basis as before. I'll make it again. I understand counsel is trying to make his record, but I cannot allow the witness to answer if you ask the same question and the objection was previously sustained.

The effects of heroin on chronic pain are outside the bounds of this hearing, so there's a question -- an objection of relevance. It's also outside the bounds of Dr.

Chiapperino's Touhy letter because, unless heroin to treat the use of chronic pain was factored into his eight factor analysis or the HHS recommendation, it's outside the bounds of what he's permitted to testify about.

So if counsel persists in asking the same question again, I will be forced to make the same objection again for the record.

JUDGE JULIUS: Understood. And I'll sustain the objection.

MR. KENNEALLY: Okay. And at this point, Judge, in order to establish my record, I understand the objection has been made.

JUDGE JULIUS: Mm hmm.

MR. KENNEALLY: I understand the objection has been sustained. At this time, I'd like to make an offer of proof asking the witness to answer the question, so that we can get it on the record, and Your Honor can consider, after we've done that, whether or not the objection still holds.

I'd also like to preserve these answers because if I don't preserve these answers on the record, there's -- and the -- and if the reviewing court isn't able to see what the

answers are and determine their relevance, we're not going to be able to sufficiently preserve the issue for review.

JUDGE JULIUS: I understand. But I also understand that the witness has limits on what he's allowed to answer, so I'm not sure where this is going. I mean, you can ask the questions, and there's an objection, but if he's not allowed to answer and he's going to go beyond the scope of the Touhy, then we're running into a very serious problem.

MR. KENNEALLY: We would ask to preserve that issue --

JUDGE JULIUS: Okay.

MR. KENNEALLY: -- for appeal. So that's -- that's all we're trying to do is I agree -- is that, as of this time, I understand counsel's objection. I understand that what the answers to this question are will not be made part of the record for purposes of this hearing.

JUDGE JULIUS: Okay.

MR. KENNEALLY: But they will be made part of the record, so that it can be reviewed, Your Honor. That's all I'm trying to do.

MS. MAN: And, Your Honor, the

Government's response is that Dr. Chiapperino cannot answer that question. So I'm not sure how an order of proof -- an offer of an order of proof is going to prompt the witness to give an answer that he cannot legally give.

And so the witness's answer is not going to be preserved for appeal because the witness cannot answer. So I'm a little confused by counsel's motion and how he expects to get an actual answer out of the witness when that objection has been sustained.

MR. KENNEALLY: Judge, whether or not the witness can answer a question is a legal determination that you make. We respectfully disagree with that legal determination. It's also a legal determination that's subject to review.

If I'm not able to establish -- if I'm not able to discuss with the doctor what exactly it is that's being objected to, and sustained, and not made part of the record, we're not going to be able to get it to be able to be reviewed, irrespective of Your Honor's decision and irrespective of the fact that Your Honor may sustain the objection for purposes of this

hearing.

JUDGE JULIUS: I have the same concerns as Government counsel. I don't understand how he's going to be allowed to give answers that are beyond the scope of his -- I understand we may be -- we may be talking past each other at this point.

Again, as I read the Touhy letter, if it's not part of the analysis and the recommendation, and that's not how these things were used, I don't see how he would be authorized to give these answers.

MR. KENNEALLY: Which would - and I -- I don't want to belabor the point, Your Honor, but -- and I guess what I'm saying is that's a determination that you're -- that's an evidentiary and a legal determination that you're making that's subject to review.

JUDGE JULIUS: I understand that.

MR. KENNEALLY: The reviewing court is not going to be able to sufficiently review that unless they're able to see what the evidence is that's being excluded.

JUDGE JULIUS: Well, he explained how the comparators were used, and my understanding

of your question is getting at things that are outside of how he explained that the comparators were used. Am I missing something here?

MR. KENNEALLY: What I'm trying to get at is, by analogy, the sufficiency of the CAMU test. So one of the things that Your Honor is considering is whether or not the CAMU test is sufficient. What I'm trying to get at is the fact that essentially any Schedule I drug would pass the CAMU test, such that it's no - such that it's no test at all.

So I'd like to discuss -- so by way of analogy, I'd like to discuss other comparator Schedule I drugs and run through the analysis with the doctor in order to establish that we're not really dealing with a sufficient or adequate test or a sufficient or adequate analysis, Your Honor.

MS. MAN: Your Honor, may I respond?

JUDGE JULIUS: Go ahead, Counsel.

MS. MAN: Government's Exhibit 4 is the OLC opinion, which has already -- is binding upon the Department that states that the part 2 test is legally sufficient. The issue before the Court, with all due respect, is not the

sufficiency of the two part test. And that's what counsel is trying to argue by analogy, other -- analogy, a roundabout way, that I'm not quite sure I quite understand.

But the sufficiency of the two part test is not the issue before the Court today. The OLC opinion is binding on the Department that the two part test is legally sound and sufficient. And that's also not an opinion that Dr. Chiapperino can opine on, the sufficiency of the two part CAMU test. That is outside the bounds of his Touhy and has been established by OLC opinion that it's binding.

JUDGE JULIUS: Counsel?

MR. KENNEALLY: Judge, I'm getting to the sufficiency of his analysis under the CAMU test.

JUDGE JULIUS: Well, I understand that you can ask questions regarding the sufficiency of the analysis, but as I understood your question, you're asking about a hypothetical of another substance, not the substance he actually was analyzing and making a recommendation for rescheduling on. So that would not be -- unless he acknowledges or answers that that was part of

the analysis, I don't know how he can opine on the question that you -- that I understood you to be asking.

MR. KENNEALLY: Judge, I have no further questions.

JUDGE JULIUS: Okay. Thank you, Counsel.

MR. McNICHOLS: May I take the podium?

JUDGE JULIUS: Yes, please. And you are taking it on behalf of the opposing states at this time?

MR. McNICHOLS: At first, Your Honor.

JUDGE JULIUS: Okay. And those are Nebraska, Idaho, and Indiana, correct?

MR. McNICHOLS: That's correct.

JUDGE JULIUS: Okay.

MR. McNICHOLS: We have some -- a binder of documents that may -- we may use with Dr. Chiapperino during the course of this examination.

JUDGE JULIUS: Okay.

MR. McNICHOLS: We have a copy for the Court, as well as one for Government counsel, and one for the witness.

CROSS-EXAMINATION

BY MR. McNICHOLS:

Q Good morning, sir.

A Good morning.

Q My name is John McNichols, and I'm here on behalf of the opposed states of Nebraska, Idaho, and Indiana. One of the points you made in your report was that this particular eight factor analysis that you did that provides the basis for this rescheduling was, in fact, the fourth one the FDA has done since the year 2000. Is that correct?

A Yes.

Q And the most recent one was the one that you did in 2015. Is that correct?

A Correct.

Q And in the 2015 eight factor analysis that FDA did, and in the previous one as well, the FDA concluded that marijuana should remain in Schedule I, correct?

A Correct.

Q And in concluding so, the FDA concluded in 2015 that marijuana had a high potential for abuse, correct?

A Yes.

Q And in 2015, the FDA also concluded

that marijuana did not have a currently accepted medical use, correct?

A Correct.

Q And the FDA also concluded that marijuana could not be used safely under medical supervision, correct?

A Correct.

Q And in 2023, in the eight factor analysis that you supervised, the FDA reversed its position as to all three findings, correct?

A Correct.

Q Is that correct?

A Yes, correct.

Q Now, Doctor, am I correct that since 2015 and the previous eight factor analysis, that the number of FDA approved botanical products is zero, correct?

A Yes.

Q Is that yes?

A Yes. I'm sorry. I don't think the microphone is picking up my voice. How about this? Yes.

Q Thank you, sir.

JUDGE JULIUS: It sounds like the court reporter can hear him, but I do acknowledge that

sometimes it sounds like it's not broadcasting throughout, so just let him know if you have a difficult time hearing him.

MR. McNICHOLS: Yes, Your Honor.

JUDGE JULIUS: Thank you.

BY MR. McNICHOLS:

Q And since 2015, when FDA concluded that marijuana had a high risk of abuse, the prevalence of non medical marijuana use in the United States has gone up, correct?

A Yes.

Q And since 2015, when FDA concluded that marijuana had a high risk of abuse, the number of emergency department visits involving marijuana disorder has gone up, correct?

A I think the NEDS data does capture as far back as 2015. I would say yes.

Q And since 2015, when the FDA concluded that marijuana had a high risk of abuse, the number of marijuana disorder hospitalizations has gone up, correct?

A I think that is correct.

Q And since 2015, when the FDA concluded that marijuana had a high risk of abuse, the potency of marijuana has also gone up, correct?

A Yes.

Q Now, one difference between the 2015 eight factor analysis that FDA prepared and the one that you supervised in 2023 was the new test for the criterion of currently accepted medical use, correct?

A Correct.

Q And having a currently accepted medical use is a prerequisite to get a drug out of Schedule I into one of the other schedules, correct?

A I would agree, yeah.

Q Okay. And you used a two part test in 2023, but the FDA used a five part test in 2015, correct?

A Yes.

Q And this came up a little bit yesterday in your examination by Ms. Man, but I think you said there are three ways that you can establish that a substance has a currently accepted medical use. Is that correct?

A Yes.

Q The first way is, of course, to get FDA approval of the drug, correct?

A Yes.

Q The second way is to pass the five factor test, correct?
A Yes.
Q And the third way is to pass the two factor test, correct?
A Correct.
Q And I think you said also yesterday that the five factor test, or the five point test, as you put it, actually resembles the test that the FDA applies to approve a drug for prescription use, correct?
A Two of the five elements are safety and efficacy, and I think they are consistent more with the FDA approval standard of safety and efficacy.
Q Okay. And the two part test that you applied in 2023, for example, does not require a showing of reproducible chemistry, correct?
A Correct.
Q And that is a part of the five part test, correct?
A It would be, yes.
Q Okay. The two part test that you applied in 2023 does not require a showing of acceptance of a group of experts, correct?

A Can you repeat that?
Q The two part test that you applied in 2023 does not require as a condition to show a currently accepted medical use that the use of the drug for a particular indication is accepted by a body of experts.
A Correct. In the five point test, every one of the five elements must be demonstrated.
Q Correct. And one of those five elements under the five part test is the acceptance by the body of experts --
A Yes.
Q -- in that particular indication, correct?
A Yes.
Q Okay. And so you -- and you would agree with me, sir -- I think you've covered this already -- that passing the two part test that you applied in 2023 does not mean that a drug is safe or effective for FDA approval, correct?
A Yes.
Q The two part test that you applied in 2023 is not as rigorous a test as the five part test, correct?

A Part 2 of the two part test is not as rigorous in the standard of evidence, yes.

Q Now, the two part test that you applied in your eight factor analysis was -- I think you testified yesterday that it was developed in 2023. Is that correct?

A Yes.

Q And you started the eight factor analysis that you did on marijuana, I think you said yesterday, in October or November of 2022. Is that correct?

A Yes.

Q Am I right, then, that by your chronology, sir, the two part test that you applied in your eight factor analysis did not exist at the time when you started work on this project, correct?

A Correct.

Q When were you informed that you would be using the two part test?

A Formally, the letter arrived in July of 2023. That's on the record in the exhibit.

Q And if you started your work in October or November of 2022, do I understand correctly that when you first started on this project, you

were working under the five part test, correct?

A I don't think I could answer your questions in this matter because in order to do so I'd have to be discussing communications among HHS agencies, and they're not documented in the exhibit.

Q Let me ask you a question that follows up on a question you got yesterday, sir.

A Yeah.

Q When Ms. Man asked you which of the tests that you applied --

A Yeah.

Q -- you said, "We were directed to use the two part test." Do you recall that testimony, sir?

A Yes.

Q Who directed you to use the two part test?

A The Assistant Secretary for Health.

Q You mentioned July 2023 a moment ago.

A Mm hmm.

Q But when were you given the direction to use the two part test?

A As I said, the formal communication was in July.

Q Which was, again, roughly three months before you finished your work?

A More like two months.

Q Most of the work that you did to analyze marijuana for this rescheduling was done before you were told about this two part test.

A The two part test was developed by HHS in 2023 over a period of months. The letter in July is the culmination of their formalizing their request that we use that test.

Q Most of the work that you did analyzing marijuana for purposes of this rescheduling was done before you were formally told --

A Mm hmm.

Q -- to use the two part test, correct?

A Yes.

Q What test were you using before you were formally told to use the two part test?

A We were analyzing the -- the clinical literature, which could have served purposes under either the five point test or the two part test.

Q Now, since 2023, when you completed your evaluation of marijuana, have you used the five point -- five part/five point test to

evaluate other drugs?

A We have applied that test, yes.

Q And I believe you testified about this yesterday on Mr. Kenneally's examination, but I think you said that you try to be consistent --

A Mm hmm.

Q -- in the content of each drug evaluation. Is that correct?

A Correct.

Q Is that correct?

A Yes.

Q I don't think it picked you up, sir.

A Yeah. Sorry.

Q It's all right. Now, since 2023, have you used the five part test in all other evaluations of drugs that you've used?

A Yes. The -- the process that we try to be consistent with is to make sure that we've considered any of the three tests that could lead to a finding. So in the absence of an NDA approval, we will consider both the relevance of the five point test and the relevance of the two part test.

If one seems like a better likelihood of reaching CAMU, we would use that test and not

worry about the other. If we get a negative in any of the tests, we will move to the next one and consider. In other words, we exhaust all three methods before concluding that something doesn't have a currently accepted medical use.

Q And in the case of marijuana, you did not exhaust the prior methods before you applied the two part test, correct?

A The NDA approval, obviously, we did not have a botanical drug within the definition of marijuana, so we moved to the clinical -- the evaluation of clinical studies. I think what you're getting at --

Q Don't worry about what I'm getting at, Doctor.

A Yes. Okay.

Q My question to you, sir --

A Yeah.

Q -- is in the case of marijuana --

A Mm hmm.

Q -- you did not evaluate it under the FDA approval standard, correct?

A Correct.

Q You did not apply the five part test, correct?

A We had activities going on that could have been useful for the five part test.

Q And in your report, you did not provide a five part test analysis of marijuana, correct?

A Correct.

Q Were you directed not to do that?

A I don't think we ever got a directive not to do that. I think we had the information to continue with the two part test.

Q If I recall your testimony from yesterday correctly, Dr. Chiapperino, you have, over the course of your career, done reschedulings for between 120 and 130 different substances. Is that correct?

A Yes. I think the exact number is 127.

Q Thank you, sir. And you are very familiar with the five part test as a result of your work in all 127 of those reschedulings, correct?

A Yes.

Q Okay. And in the course of your analysis of marijuana, you reviewed all the data that you've described in your report and all that was asked about by Ms. Man, correct?

A Can you repeat that? Sorry.

Q Yeah. In the course of analyzing marijuana --

A Mm hmm.

Q -- for purposes of this rescheduling, you reviewed all the data that's described in your report, correct?

A Are you talking about me specifically or the team?

Q I apologize, sir.

A Yeah.

Q The FDA did.

A Yes.

Q The team under your supervision did, sir.

A Yes.

Q Correct?

A Yes.

Q And as someone familiar with the five part test --

A Yeah.

Q -- and someone who supervised the process of analyzing marijuana in this case, you can say, can you not, sir, that there is no way that marijuana would have passed the five part test, correct?

MS. MAN: Objection. That's not the analysis that he conducted.

MR. McNICHOLS: He can answer this, Your Honor. There's been ample attempt yesterday to show that these two tests are equivalent. This man is very familiar with all the data and the tests that he's already talked about. We should get it on the record as to whether this drug could have passed the test that the FDA has used before and since.

MS. MAN: Your Honor, may I respond?

JUDGE JULIUS: Yes. Go ahead, Counsel.

MS. MAN: I believe counsel is mischaracterizing the testimony that was yesterday, with all due respect. We talked about what they evaluated and the differences and what the two part test evaluated that the five part test did not.

Dr. Chiapperino did not conduct the analysis of the five part test for marijuana, so to ask him to speculate whether or not it would have passed the five part test is purely speculative. He conducted the analysis using the two part test, and so the Government has no issue with asking about his analysis of the two

part test.

But to ask if marijuana would have passed the five part test, that was simply not the analysis done by his team. And to ask him to speculate about whether or not marijuana would have passed the five part test, which is not an analysis that his team did, is purely speculative.

MR. McNICHOLS: What he said, Your Honor, earlier was that for the first eight months of his analysis they were reviewing the literature, which could have applied either to the five part test or the two part test. That's what he said. He's familiar with the five part test, and as we've already established, he's familiar with the data that his team reviewed. This is well within the scope of what they've asked about and what he's already testified to.

MS. MAN: Your Honor, I'd also like to be -- I'd like to point out that this is also outside the scope of his Touhy letter, which does not permit him to testify about if marijuana would have passed the five part test.

JUDGE JULIUS: So I agree that he -- he did testify that the two part came about two

months before the analysis was completed. The recommendation is based on the two part test, which is what's reflected in the recommendation that was sent from HHS. I don't believe we've had any testimony that they completed a five part or five factor analysis here. So what's --

MR. McNICHOLS: Your Honor, if he reviewed the data, and he knows the test from having applied it 127 times, and he's already told us that the two part test is less rigorous than the five part test, which is now on the record, he can tell us, based on his familiarity with the drug and the test, whether or not this would have passed the test that he always applies in every other situation. That's what he can tell us.

MS. MAN: Dr. Chiapperino is here as a fact witness. That would be expert testimony if --

MR. McNICHOLS: That is preposterous.

MS. MAN: I don't believe so.

MR. McNICHOLS: He talked about what he's done.

JUDGE JULIUS: Okay. Would you please let her finish her objection and --

MR. McNICHOLS: Yes, sir.

JUDGE JULIUS: -- maintain.

MS. MAN: Thank you. The five part -- there is no testimony so far that the five part analysis was ever complete, and that's a conclusion and a recommendation that the FDA would give, is whether or not it would have passed a five part test. Anything other than that is outside the bounds.

FDA did not recommend that -- make the recommendation using the five part test. So to ask somebody to speculate about whether or not a substance would have passed the five part test, if they had completed -- and he -- we -- he just testified that he had not completed the analysis. They were still months out from it when they used the two part test.

So the analysis was -- that's assuming, number 1, the analysis was ever complete. That's assuming facts not in evidence. And Dr. Chiapperino is here to testify about the two part test and cannot speculate to whether or not marijuana would have passed the five part test. That is absolutely outside the bounds of his Touhy letter.

JUDGE JULIUS: Okay. And now, Counsel, I'll hear your response to that.

MR. McNICHOLS: No, I think I've already covered it, Your Honor. The -- he has testified about what he did in his review of the data, which went on most -- most of the review, in other words, by his own testimony, occurred before he was directed to use the test that ended up in this report.

And he said that his review of the data could have been applied either to the two part test or to the five part test. That's also his testimony. And he's also said that he's applied the five part test more than 120 times in his career.

He can, therefore, say, based on his review of the data and his familiarity with the test, that it did -- that this drug would not have passed the test that they've always applied, both before and since.

JUDGE JULIUS: But I think this also gets to the point that he's here as a fact witness, not an expert witness to provide opinions. He's here to discuss scientific and medical determinations under the eight factor

analysis performed by FDA pursuant to paragraphs A through C of Section 201 and paragraph B of Section 202 of the Controlled Substances Act, 21 U.S.C. Sections 811, subsections A through C, and 812(b), as transmitted to DEA with HHS's August 29, 2023, recommendation.

Two, scientific and medical determinations underlying the analysis performed and conclusions drawn by FDA in its August 28, 2023, report, considerations for whether marijuana has a currently accepted medical use in the United States for purposes of Section 202B of the Controlled Substances Act, also known as FDA's part 2 of the CAMU evaluation; namely, that for purposes of the drug scheduling criteria in 21 U.S.C. Section 812(b), marijuana has a CAMU for: (i) anorexia related to a medical condition; (ii) nausea and vomiting, e.g., chemotherapy induced; and (iii) pain.

And, third, FDA's recommendation that marijuana be placed in Schedule III under 21 U.S.C. Section 812(b)(3).

I don't see how your question falls within the scope of what he's been authorized to testify about, particularly as a fact witness,

as compared to asking his expert opinion about whether the drug would have passed an alternate analysis that was not reflected and completed in the recommendation that was transmitted.

MR. McNICHOLS: It's not reflected as -- in the recommendation that was transmitted. He's reflected he performed the analysis consistent with that and that the analysis that he did could have gone under the five part test. And some portion partway through, maybe two months before, he was told to use the two part test.

So whether or not he's an expert, sir, but as someone who has applied the test and was reviewing the data consistent with either the five part test or the two part test, he can talk about that. And the question as to what he's authorized to talk about, clearly covers the bases for his opinions, as well as the standards that he applied. That's inherent in this.

The standards, in other words, that -- that he -- this test would not have passed a different standard that he's applied before and that he's familiar with and that he was -- could have applied, and was in the process of applying

in this case, is well within the bounds of what he's authorized to say.

MS. MAN: Your Honor, may I be heard?

JUDGE JULIUS: Go ahead, Counsel.

MS. MAN: And that is an opinion that would need an expert witness. That is not the witness before the Court today. There has been no testimony that the five part analysis was ever complete, and I think that is where we're running into some difficulty where counsel would like Dr. Chiapperino to testify about the results of a test that was never complete. And since that analysis was never completed, he cannot testify to the results of something that was never complete.

JUDGE JULIUS: And then I'll let you have the final word.

MR. McNICHOLS: He didn't write it up. He didn't write that up, and I don't think she's right that the analysis was never complete. They reviewed the data, and the form they put it in in this letter took one form, which was the two part test. But the fact -- but as he has testified earlier today, there's some distinction between the analysis that they

did and what actually made it into the letter. And we should be allowed to explore, in other words, did he get to that point where he got -- where he could reach that conclusion or not before he got directed?

JUDGE JULIUS: Okay. Let me ask a clarifying question that may --

MR. McNICHOLS: Yes, sir.

JUDGE JULIUS: -- set us down one way or another.

Sir, did FDA ever complete a five factor analysis of marijuana in this evaluation?

THE WITNESS: No.

MR. McNICHOLS: Can I follow up on that?

JUDGE JULIUS: Go ahead.

MR. McNICHOLS: Thanks.

BY MR. McNICHOLS:

Q When you say you didn't complete it, sir, I understand at least one thing you mean is you didn't write it up, correct?

A We did not complete it. We did not have ideas formed about each of the five elements in a draft stage at any point.

Q Hold on a second, sir. I believe you

testified yesterday that part 2 of the currently accepted medical use test resembles the five factor test. Was that your testimony?

A Yes, but only in the sense of --

Q "Yes" is good enough, sir. Let me ask you this next question.

MR. McNICHOLS: Court's indulgence.

JUDGE JULIUS: Of course, Counsel.

BY MR. McNICHOLS:

Q In the course of performing your analysis of marijuana in this case --

A Mm hmm.

Q -- did you look at whether the marijuana's chemistry was known and reproducible? Did you consider that?

A The description under factor 3 for chemistry describes marijuana as a variable substance. So, yes, we did consider it.

Q Okay. And in the course of your analysis of marijuana in 2023, did you consider whether there were safety studies of marijuana?

A Yes.

Q And in the course of your analysis of marijuana in 2023, did you discover -- did you consider whether there were efficacy studies of

marijuana?

A Yes.

Q And in the course of your analysis of marijuana in 2023, did you consider whether marijuana was accepted by qualified experts for any particular indication?

A Yes.

Q And did you consider whether scientific evidence on marijuana was widely available?

A Yes.

MR. McNICHOLS: Each one of those questions that -- that, Your Honor, I'm sorry, I'm directing my comment to you, is that every one of those questions that I just asked Dr. Chiapperino about is a factor under the five factor test.

Now, I accept his testimony, and Your Honor's analysis, that the five factor test did not get written up in the recommendation letter that was transmitted to the DEA. He has considered all the things that one needs to consider. He can answer the question.

MS. MAN: Your Honor, the Government objects because it is outside the scope of Touhy. These five factors were -- it was

information that went into the two part test. However, just because somebody considered the information doesn't mean conclusions were drawn. And so to say that he considered it, that doesn't answer the question to the full extent of how it was considered, who considered it, and what conclusions were drawn based on that data.

And so, yes, Dr. Chiapperino considered a large pool of data, but he made conclusions -- he and his team made conclusions only to the two part test. To say that -- I think this mischaracterizes his testimony about he considered this information but did not draw conclusions with the five part test.

I also think it assumes facts not in evidence that they reached a conclusion and it didn't get written up, and it's some secret ~~squirrel~~ thing that, like, they just are not going to talk about. Dr. Chiapperino answered the Tribunal's questions: Did you complete the analysis for the five part test? His answer was "no".

MR. McNICHOLS: Let me follow up on that, Your Honor. I think this will help flesh this out.

BY MR. McNICHOLS:

Q Dr. Chiapperino, back to you, sir. When I asked you previously about analyzing whether marijuana's chemistry was known and reproducible, I think you said your conclusion was that it was not, correct?

A Correct. It's a variable substance.

Q Right. And in the course of discussing whether there were safety studies on marijuana, you concluded that, if I have your testimony correctly from yesterday, that the safety of the drug was reasonable, correct?

A It's a different standard.

Q Okay. But that's what you concluded, correct?

A Yes, under the two part test.

Q Okay.

A We did not object to the therapeutic indications on the grounds that there was a concerning enough safety signal that patients would have adverse outcomes instead of better outcomes.

Q And in the course of preparing your analysis on marijuana in 2023, sir, you reached conclusions about the efficacy of the drug for

certain indications. Did you not, sir?

A We made findings under a threshold of credible scientific support. We did not make findings of efficacy.

Q Okay. But one of the things --

A Effectiveness to a degree.

Q Okay.

A Yeah.

Q But the word you used in your report when discussing the findings was whether or not marijuana was effective --

A Mm hmm.

Q -- to treat a condition, correct?

A Yes. We considered positive results in clinical studies --

Q Right.

A -- to that effect.

Q Okay. And you also -- as you testified earlier when Mr. Kenneally was asking you questions, you also considered whether the drug was accepted by qualified experts and came to the conclusion that it was not, correct?

A There's two parts to that. You'd have to allow me to discuss both.

Q Did you come to a conclusion as to

whether the drug was accepted by qualified experts?

A Yes.

Q And did you come to a conclusion as to whether scientific evidence on marijuana was widely available?

A Yes.

MR. McNICHOLS: Okay. Now he has established, Your Honor, that he came to conclusions about every one of the tests or the standards that goes into the five part test as part of his analysis. At this point, the record is clear. The witness can testify about this.

MS. MAN: And, Your Honor, that is still outside the bounds of his Touhy letter about testifying to his team's conclusions about the five part test. The team did not draw any conclusions when it came to the five part test.

MR. McNICHOLS: He --

MS. MAN: The team drew their conclusions for recommendations for the two part -- from the two part test, and that is what Dr. Chiapperino is here to testify about. Asking him what he and his team would have found for the five part test when putting it all together

is outside the bounds of his Touhy.

MR. McNICHOLS: If he's testified, Your Honor, as to -- as to having applied, considered, and reached conclusions as to every one of the standards under a previous test that he's applied before and since, and that he's applied 120 times in his career, he can answer that. That was part of the process that he performed.

MS. MAN: Your Honor, may I be heard briefly?

JUDGE JULIUS: Briefly.

MS. MAN: There has also been some questions about efficacy, which I think has been lost in translation. The standard for safety and efficacy is different from the CAMU for purposes of drug rescheduling. And I believe a bunch of questions that counsel just asked were about safety and efficacy, which is a different standard, and I think that's gotten lost in this line of questioning.

MR. McNICHOLS: And --

MS. MAN: They've been mixed up.

MR. McNICHOLS: And in that vein, Your Honor, as someone familiar with those standards,

if he, in his analysis, was that the drug would not pass the safety and efficacy standards the FDA ordinarily applies, he can testify to that.

MS. MAN: But that's outside the bounds of his Touhy. He's not here to testify about the safety and efficacy of marijuana. He's not permitted to do so.

MR. McNICHOLS: We've already been over this, Your Honor.

JUDGE JULIUS: I mean, Counsel, I guess -- this is directed to opposing states counsel. So I'm looking at number 2 of the Touhy authorization, and it talks specifically about FDA's part 2 CAMU evaluation.

MR. McNICHOLS: Well, hold on a second, Your Honor. Let me get with you.

JUDGE JULIUS: Sure.

MR. McNICHOLS: Please proceed, sir.

JUDGE JULIUS: Sure. This is number 2 of the things that are -- he's authorized to talk about. So it talks about scientific and medical determinations underlying analysis performed and conclusions drawn by FDA in its August 28, 2023, report, Considerations for whether marijuana has a currently accepted

medical use in the United States for purposes of Section 202B of the Controlled Substances Act, also known as FDA's part 2 CAMU evaluation.

MR. McNICHOLS: Shall I ground -- let me ground my answer in language you just read, sir.

JUDGE JULIUS: Sure.

MR. McNICHOLS: Scientific and medical determinations underlying the analysis performed. That's the first phrase that appears in number 2 under this Touhy authorization. Scientific and medical determinations underlying the analysis performed would include conclusions that he reached, analyses that he did, applications that he considered, whether or not written up in the formal letter that was transmitted to DEA, sir.

JUDGE JULIUS: And the question, again, that you want to ask him is whether it would have passed the five factor test, which is not reflected in this. Am I --

MR. McNICHOLS: The question I want to ask him is: Sir, you can say, can you not, that marijuana would not have passed the five factor test? That's my question.

JUDGE JULIUS: I'll allow him -- I'll allow you to ask the question, and he can answer if he knows.

MR. McNICHOLS: Thank you, sir.

BY MR. McNICHOLS:

Q All right. Sir, as someone who has applied the five factor test 127 times in your career, and who supervised the data that went in -- on marijuana that went into the HHS recommendation in 2023 --

A Mm hmm.

Q -- it's true, sir, is it not, that marijuana would not have passed the five factor test that you've applied in other instances?

A And you would like me to answer that. That's -- in my opinion, the clinical studies that were considered for these indications, I do think they were not large enough to pass an FDA approval as an adequate, well controlled study on the basis of their design as more of pilot study size.

I think they would have had difficulty passing that part, and I would agree that the two tests are very different with regard to part -- the two part, the part -- sorry. The two

part test considers marijuana categorically, what is available in dispensaries that people are using. We don't -- we did not make judgment as to whether that's a good idea or a bad idea. It is just what is going on.

In terms of the five point test, there is still a standard of a particular substance used in an indication being well defined. So on the basis of the first element alone, without even consideration of the other two, I do believe that it would have been difficult for marijuana to pass the five part test.

Q Would not have passed, correct?

A Would not have passed. Sure. May I ask a question?

Q There's no question pending, sir.

THE WITNESS: Can you take a timeout for one second from his time? I have a question about process, and I don't know if there's a mechanism, because I'm not very familiar with court proceedings, to ask the judge a question about process that covers the scope of my testimony.

MR. McNICHOLS: Go ahead, sir.

THE WITNESS: Is that permitted?

JUDGE JULIUS: I'll allow that.

THE WITNESS: Do I do it so everybody could hear or?

MR. McNICHOLS: We'd prefer it be on the record, Your Honor.

JUDGE JULIUS: Go ahead and ask.

THE WITNESS: I think the line of questioning is to get at the decision making between applying the two part test and applying the five point test. And I want the record to reflect that the agencies involved, in terms of HHS and component agencies, including the Office of the Assistant Secretary for Health and FDA, that this request to do the two part test didn't land on our desk in July of 2023 without awareness among component agencies that there was thinking going on within the Department as to an appropriate way to be able to consider a broader scope of information for drugs under -- under what ended up being the two part test.

So FDA, including me and the Controlled Substance Staff team, did not create the two part test and say, "Let's use this instead." We are aware of departmental activities going on to consider development of a test that would be

different to address substances that might have authorized state uses.

So I think this line of questioning is really trying to get at why did we use the two part test and not the five part test. I'm saying that we already had awareness that there was an interest to do a different kind of test.

We are working on the scientific and medical review. We are not part of creating either of the tests, not DEA's test, not the two part test. But we had the information for both. We knew both were under consideration. The fact that there's formalized letters in July -- obviously, we can't put together hundreds of pages of analysis that are geared toward a two part test in a month.

So I do understand your line of questioning, and I'm trying to be -- I'm trying to make the people understand how this situation could be reflected in the -- by what we see in the record.

So we did not ever make conclusions under the five part test. We knew that there was interest to apply a different kind of test. We got the details and the parameters of that

test, and we put the information together. We had the information to apply both. We put it in the form of the two part test. That is what we were asked to use.

BY MR. McNICHOLS:

Q I thought --

MS. MAN: Your Honor, the Government would like to --

BY MR. McNICHOLS:

Q -- part of your question was going to the judge --

A Yeah.

Q -- Dr. Chiapperino. Was there a question directed to the judge in that?

A Well, that is my fault. I probably should have started slower and asked a question as to how far I could go with what I just said. I hope --

Q I thought it was very helpful, sir.

A -- that it's not in -- I hope it is not in violation of my Touhy letter because I could get in a lot of trouble for that. But I think it goes to the question of how the two part test became the documents that we gave to DEA. And I wanted people to understand that this was a

reasonable process between the agencies that make decisions about how to assess currently accepted medical use.

Q And you wanted him to understand that it was not all your fault, correct?

MS. MAN: Your Honor, at this juncture, the Government would like to ask for its comfort break.

JUDGE JULIUS: Okay. Well --

MR. McNICHOLS: Can we get an answer to that question please, then?

MS. MAN: Your Honor, that's -- the court reporter can read the question back.

JUDGE JULIUS: I believe the question was, you wanted to say that so that it was not--

MR. McNICHOLS: Just to -- to follow up very brief -- I'll withdraw that question, Your Honor.

BY MR. McNICHOLS:

Q The reason for your colloquy to clarify things, Dr. Chiapperino, is that you wanted the record to reflect that the decision to apply the two part test was not an FDA determination, correct?

A Correct.

MR. McNICHOLS: If this is the right time for the comfort break, the States have no objection.

JUDGE JULIUS: Okay. Yeah. That's a good idea. Let's take 15 minutes. Let's come back at 10:48, if my math is correct.

We'll be in recess for 15 minutes. Thank you, everyone.

(Whereupon, the above-entitled matter went off the record at 10:33 a.m. and resumed at 10:49 a.m.)

JUDGE JULIUS: Thank you, everyone. Please be seated. Just a few procedural issues before we resume. I just wanted to note for the record, when we were discussing the Touhy letter, it is marked as ALJ Exhibit 44, just so everyone has awareness.

The government has represented a number of times that the OLC opinion is binding on this court. I would ask if there's any authority for why -- why it's binding on this tribunal versus just the federal government, so an issue to potentially address. I'm not going to ask for an answer right now, but something to potentially look out for and see, just put the

issue out there. I don't know that it's 100 percent settled that OLC opinions or -- or orders are binding on this tribunal. It's something we will also look into, but I -- I just wanted to note that may be an open issue.

MS. MAN: Your Honor, would the Court prefer me to address that later on in a briefing? How would the Court like the government to respond?

JUDGE JULIUS: However you would like to do that. I just put the issue out there just to let people know what issues we foresee.

MS. MAN: All right. Thank you. I just wanted to make sure we didn’t need to do something.

JUDGE JULIUS: Yeah. I'm not ordering you to produce anything by end of day or anything. Just however you see best to address that, feel free to do that.

MS. MAN: Thank you very much.

JUDGE JULIUS: Sure. Counsel?

MR. McNICHOLS: We're prepared to proceed, sir.

JUDGE JULIUS: Whenever you're ready, sir.

MR. McNICHOLS: Thank you.

JUDGE JULIUS: Oh, yes. Please retake the stand. Yes.

CROSS-EXAMINATION

MR. McNICHOLS: Dr. Chiapperino, I want to resume by asking you some questions about part one of the two-part test that you used to determine whether marijuana had a currently accepted medical use. Tell me if I have this right, that the test assessed whether there was widespread current experience with medical use by licensed healthcare practitioners under state-authorized programs where medical use is recognized by entities that regulate medicine. Is that a fair statement of the part one test?

THE WITNESS: Yes.

BY MR. McNICHOLS:

Q And am I right, sir, that in the division of labor that went into the eight factor analysis, it was HHS and the Office of the Assistant Secretary for Health and not FDA that did that part of the test?

A Correct.

Q And they wrote up their findings in a separate document that you then incorporated

into the recommendation of 2023?

A We provided that document with our own as a supporting document. It was not considered an FDA document. It was just a relevant document to transmit with the rest of them --

Q Understood.

A To DEA.

Q It ultimately, though, made it into the recommendation letter that went from HHS over to DEA, correct?

A Yes, I think so.

Q Okay. I know that HHS performed it rather than FDA, but tell me if I have this right, that it involved HHS looking into the various state-administered medical marijuana programs around the U.S. Is that fair?

A Yes.

Q Okay. This rescheduling here from 2023 was not the first time that FDA or HHS had been encouraged to look into state-level medical marijuana programs, correct?

A I don't have knowledge of other instances.

Q Well, in the 2015 rescheduling and the recommendation that HHS provided to DEA in

connection with that, HHS actually commented on the state-level medical marijuana programs and the fact that it was not considering them, correct?

MS. MAN: Objection. Dr. Chiapperino was not involved in the 2015 process. He became -- that's assuming facts not in evidence, that he was involved in the 2015 assessment and made recommendations or drew considerations one way or the -- or considered factors one way or the other.

JUDGE JULIUS: Do you want to try to lay a foundation or --?

(Simultaneous speaking.)

MR. McNICHOLS: Dr. Chiapperino, you were with –

JUDGE JULIUS: So is this like --

MR. McNICHOLS: -- with the controlled substances staff in 2015, correct?

THE WITNESS: Yes.

BY MR. McNICHOLS:

Q Okay. And you've been with the Center for Drug ~~and~~ Evaluation and Research for some longer time before that, 20 years?

A Yes.

Q Okay. And in the course of preparing your 2023 analysis of marijuana, did you consider the analysis that HHS or FDA prepared in 2015?

A I have certainly read the 2015 document in the past. We did not work from it for the 2022. It was a new review, a new team, yeah.

Q But you certainly commented on the 2015 recommendation in the analysis that you did in 2023, correct?

A We included it in the background as a statement of the record, yeah.

Q Okay. You mention it on page 1.

A Right.

Q You mention it on page 2.

A Yes.

Q Okay. And you're generally familiar with the document because you reviewed it in the course of your career, correct?

A I am familiar with it in broad strokes, yes.

Q Okay. It's true, is it not, sir, that in the recommendation that HHS prepared in 2015 that HHS considered looking at the state-level medical marijuana programs and declined to do

so?

A That I don't know.

Q Okay. Can you turn in the binder that you have, sir, to tab 4?

A Mm-hmm.

Q And that's in the Court's binder as well and also in the binder that we've handed to the government.

JUDGE JULIUS: Thank you.

MR. McNICHOLS: And for the record, tab 4 is the Exhibit No. 11 of Smart Approaches to Marijuana. With that, let me ask, Dr. Chiapperino, do you recognize the document at tab 4 in the binder? Take a moment to review it if you need to, sir.

THE WITNESS: Yes. I will look. Yes -- yes.

BY MR. McNICHOLS:

Q Is the document at tab 4 marked as Smart Approaches to Marijuana, Exhibit No. 11 -- is that the 2015 recommendation that the Department of Health and Services -- Health and Human Services prepared for the DEA on the issue of rescheduling marijuana?

A Yes.

Q Okay.

MR. McNICHOLS: At this point, Your Honor, we move this exhibit into evidence.

(Whereupon, the document referred to was marked as SAM~~+State~~ Exhibit No. 11 for identification.)

JUDGE JULIUS: Any objection?

MS. MAN: No.

JUDGE JULIUS: Okay. Admitted.

(Whereupon, the above-referred to document marked as SAM~~+State~~ Exhibit No. 11 was received into evidence.)

MR. McNICHOLS: Thank you. Can you turn to page 27 of this document, sir? Just to get back to my question, how we got on this subject of state-level medical marijuana programs, if you go to the last full paragraph on this page, are you there at 27, sir?

THE WITNESS: Yes.

BY MR. McNICHOLS:

Q Okay, the last sentence of this paragraph states, “Furthermore, based on the above definition of a qualified expert, who is an individual qualified by scientific training and experience, to evaluate the safety and

effectiveness of a drug, state-level medical marijuana laws do not provide evidence of a consensus among qualified experts that marijuana is safe and effective for use in treating a specific recognized disorder." Do you see that, sir?

A I'm sorry. I was -- you were in -- you said the fourth full paragraph, or --

MR. McNICHOLS: May I approach, Your Honor?

JUDGE JULIUS: Yes, please.

THE WITNESS: I was scrolling while you were speaking, and I wasn't finding the text about what -- where you were speaking.

JUDGE JULIUS: Court was also having difficulty.

MR. McNICHOLS: That is entirely my fault.

THE WITNESS: Okay. Okay. Okay.

BY MR. McNICHOLS:

Q I should have directed --

(Simultaneous speaking.)

A So you started, I think, in the middle of the paragraph, maybe. That's why. I'm not sure. But yes, I --

Q Are you at the word furthermore, sir?
A Yes. Now I am.
MR. McNICHOLS: And Your Honor, are you there as well?
JUDGE JULIUS: We're on page 27, right?
MR. McNICHOLS: Yes, sir.
JUDGE JULIUS: Okay. Furthermore. In -- you said fourth?
MR. McNICHOLS: One of my colleagues will show you what we're talking about, Your Honor.
JUDGE JULIUS: Yeah. Could you clarify when you say page 27 -- in case there are different Bates stamps? Thank you very much.
THE REPORTER: Excuse me.
MR. McNICHOLS: We're looking at the --
THE REPORTER: Page 27.
MR. McNICHOLS: Page number of the document, not the Bates stamp number, just for the record.
MR. McNICHOLS: Okay.
JUDGE JULIUS: Thank you for the clarification, Counsel.
MR. McNICHOLS: Yes. Apologies to the re -- the Reporter and the Court and everyone, I

guess that went the wrong way. Are you ready, sir?

THE WITNESS: Yes.

BY MR. McNICHOLS:

Q Okay, yeah. The sentence I was directing your attention to states, "Furthermore, based on the above definition of a qualified expert, who is an individual qualified by scientific training and experience, to evaluate the safety and effectiveness of a drug, state-level medical marijuana laws do not provide evidence of a consensus among qualified experts that marijuana is safe and effective for use in treating a specific recognized disorder." Did I read that correctly?

A Yes.

Q And to return to my question then, it at least appears from this that in 2015, the Health and Human Services Department considered state-level medical marijuana programs when applying the eight factor analysis to marijuana at that time, correct?

A Just give me one minute. It seems that the paragraph is about medical practitioners not being qualified. Are we talking about medical

practitioners still, or are we talking about expert groups? Which are you asking about?

Q Well, I think the question is, is that it appears from my reading of the language --

A Yeah.

Q That at that time, HHS decided that the practitioners in the medical marijuana space were not experts in the use of the drug, and therefore their use of it would not be considered by HHS in the recommendation that it provided to DEA. That's my question.

A The healthcare practitioners were not considered then, and we did not consider them experts for determining which medical uses are eligible under the part 1 memo. That was not the role of evaluating healthcare practitioners there, you know, in terms of making a decision about what conditions they could use marijuana with their patient.

Q If I understand you correctly, the healthcare practitioners decisions about conditions they would recommend marijuana for did not factor into your part 1 analysis. Is that right?

A It did factor in, in the sense that

there was an assessment of which states provided training for practitioners that would be eligible to participate in their state programs. That was, I think, a little variable across states, what level of training in order to be a practitioner that can recommend use of marijuana.

Q I think you saw where I was going with this, sir, and you can reference the part 1 analysis if you need to. We provided it at tab 2 of the binder that you have in front of you.

A Yeah.

Q But I'm correct, am I not, sir, that at least according to the part 1 analysis, most states that have medical marijuana programs do not require any kind of review before a medical board before approving a particular condition to be treated by medical marijuana, correct?

A I think the number was 17 did, yeah.

Q Out of 43, correct?

A 38.

Q Not including Guam.

A Okay, yeah.

Q Fair enough.

A Yeah.

Q Right? Okay. And 43, which includes the District of Columbia and the other territories, that's the figure that appears in the part 1 document, correct?

A I think so, yes.

Q All right. We can use 38 if you'd rather stick with the states, but in all events, you agree with me that most states that have medical marijuana programs do not require that any board of doctors approve treatment for a particular condition before authorizing treatment for that condition using marijuana, correct?

A Yes.

Q Okay. In fact, only 10 states that have medical marijuana programs actually require healthcare practitioners to have training in marijuana before they're allowed to recommend it, correct?

A Yes, I think that's what's reported.

Q Okay. And only two states actually require that healthcare practitioners pass a test in marijuana before they're allowed to recommend it, correct?

A Yes, I think so.

Q Okay. And healthcare practitioners in this context do not equate to physicians, correct, sir?

A That is correct, I think there are different professional qualifications eligible to recommend.

Q Right. I think this came up some yesterday in Mr. Evans' cross-examination, but among the professionals who can recommend marijuana at the state level are nurses, correct?

A I don't know that off the top of my head. I think so. Certainly nurse practitioners.

Q Physician assistants as well, correct?

A I believe so, yes.

Q Psychologists, correct?

A I'm not sure about psychologists.

Q Counselors?

A That's broad, I don't know.

Q Social workers?

A Broad, I don't know.

Q Okay. And am I right, sir, that at least according to the part 1 analysis, only 20 states that have medical marijuana programs keep

track of adverse events of people who are using marijuana?

A Is that reported in the documents? Do you want to bring my focus somewhere? I don't recall.

Q I think if you look over here at table 2B, which --

A Is that --

Q Appears at the very back of the document. Let me know when you're there, sir.

MS. MAN: I'm sorry, Counsel. Where are we looking at?

MR. McNICHOLS: Oh, you need the number?

MS. MAN: Yeah. I just need a tab.

MR. McNICHOLS: Yeah, tab 2.

MS. MAN: Thank you.

JUDGE JULIUS: So just for the record, this is the July 17th, 2023 part 1 analysis?

MR. McNICHOLS: I apologize, Your Honor. Let's do that first. Dr. Chiapperino, can I get you to take a look at the document behind tab 2 before you turn to the page I was directing you? Can you verify for me, sir, that the document behind tab 2 is the part 1 analysis

prepared by the Department of Health and Human Services that later fed into the FDA's analysis for the recommendation as to marijuana?

THE WITNESS: Yes.

BY MR. McNICHOLS:

Q Okay. What I was directing you to in terms of documents there on the question of tracking adverse events is table 2B, which appears toward the end of the document at pages 8 and 9 of the tables. Let me know when you're there.

A I'm there.

Q Okay. The middle column there has ASA grade for dispensary operations. Do you see that, sir?

A Yes.

Q Okay. And then in the legend at the very bottom, when it talks about Americans for Safe Access, let me know when you're there.

A Yes.

Q Are you there, sir?

A Yes, I am.

(Simultaneous speaking.)

Q I didn’t hear what you said. Okay. And one of the things it says it tracks is whether

or not -- whether states are tracking, whether dispensaries are reporting adverse events. Let me know when you find that in the paragraph at the legend under A.

A I see that section, yes.

Q Okay. And if you look at the center column, which keeps track of ASA grade for dispensary operations, you see various yeses and nos next to the states listed there, correct?

A Yes.

Q Now, take your time if you need to, sir, but I think if you count up the yeses in that column, you'll see that there are 20 states that by the ASA standard, keep track of adverse events. Take your time. Count it out for me, please.

A Okay, yes.

Q Okay. So, 18 of the states that have medical marijuana programs, at least according to this, do not track adverse events, correct?

A I'm just reading the footnote again to make sure it clarifies what the negative means. It doesn't actually explicitly say what a yes and what a no means in this table. I don't know what standard they applied in giving a yes

response or a no response. I don't know if it's just that there is no formal system for reporting adverse events or if it's a confirmation that they do not collect adverse events. Is that the significance of a no? I don't know.

Q Okay. But at least, as to the standard that HHS put into this document in other words, the ASA grade for dispensary operations, there's no evidence that any states beyond 20 actually collect -- or collect information on adverse events, correct?

A I'd agree with that. Yeah.

Q Okay. Now, right there in table 3 of this document, the part 1 analysis, it lists the medical conditions that pass the part 1 test according to HHS, correct?

A Yes.

Q Okay. And there are 15 conditions here ranging from amyotrophic lateral sclerosis in alphabetical order down to spasticity at the bottom, correct?

A Yes.

Q Right. And then over in the right-hand column, it lists the number of jurisdictions

that recognize that medical condition as one that can be treated by marijuana, correct?

A Yes.

Q Okay. Now, not every one of those states listed is one where the authorization to use marijuana is recognized by entities that regulate the practice of medicine, correct?

A It does seem so, yes.

Q Right. And I think as you testified earlier, sir, there are 17 of our 38 states or 43 jurisdictions that actually have some kind of board that's involved in the process for authorizing a treatment for a particular condition, correct?

A Yes.

Q So, for most of the figures listed here, there are states, for example, that may have authorized treatment by a ballot initiative, correct?

A Yes.

Q Okay. And you agree with me, sir, that authorizing treatment by ballot initiative is not reflective of medical science?

A Well, I'm not sure. The details of a ballot initiative would be whether or not the

voters favor establishing medical marijuana. You know, the implementation of it through a regulatory program of some sort, I think you'd have to look at what reviews states did and what scientific information they considered before listing the eligible conditions. I don't know of ballot initiatives that establish the specific therapeutic indications.

I assume the implementation of a program would use some level of evidence in order to put a substance on the list. In the 17 states that do have a board, I think it's to consider adding new conditions. So I don't -- I can't speak to what standard they use in establishing the program that first listed an indication.

Q But you would agree with me, sir, that if a state authorizes marijuana for a particular condition by ballot initiative rather than by a review board, that that is not relevant to the question of currently accepted medical use. You agree with that?

A Not entirely. I think the ballot initiative leads to an activity in the state to initiate a medical marijuana program. The fact

that the program is set up, whether by legislation or by ballot initiative, it is still the Departments of Health in most cases that have a role in setting up the individual marijuana program. I'm sure that may vary from state to state, which agency has jurisdiction to regulate the system, but I think there are further steps beyond the ballot initiative to establish the particulars of the program.

Q Am I right, sir, that the conditions listed at table 3 of part 1 are the 15 conditions that HHS determined to pass the part 1 analysis?

A Yes, that was our assumption when we received this memo.

Q Okay. And these are the only conditions that passed the part 1 analysis, correct? Withdrawn. These are the only conditions that passed HHS's Part 1 analysis, correct?

A Yes.

Q Okay. And in your analysis that you did under Part 2, you evaluated seven, correct?

A Yes.

Q Okay. And you determined that of that

seven, three had some level of scientific support and thus passed the Part 2 test, correct?

A Correct.

Q Okay. And those three, I know you covered earlier, were pain, nausea, and anorexia, correct?

A Yes.

Q Okay. And I know we've covered this before, but just for clarity here, the Part 2 test of some scientific support is below the level required to obtain FDA approval, correct?

A Yes.

Q The three that you analyzed that did not pass the level of some scientific support were PTSD, anxiety, epilepsy, and then inflammatory bowel disease, or IBD?

A Correct.

Q Okay. And of the seven that you chose to evaluate -- and those were, in your view, sir, the ones that were most likely to pass the Part 2 test. Is that correct?

A Well, not quite. In terms of the most potential for reviewable data, so I think we've tried to focus on where studies were available

and what is the extent of use in those indications. Some of them more than others, but certainly pain is usually by far the most -- the indication for which most people are using marijuana, although also for depression and anxiety.

Q I think the phrase that you used in the main memo that you wrote was that they were the ones that were likely to have the most robust evidence available for review. Does that sound correct?

A Yeah. Yeah.

Q Okay. Now, of the nine that you chose, or the nine that passed the Part 1 analysis that you chose not to evaluate, right? We should not assume that there would be evidence that would allow them to pass the Part 2 test were you to look for it, correct?

A I'm sorry. We should not assume -- say it again.

Q The ones that you chose were the ones that were likely to have evidence one way or the other that would support -- that you could analyze to assess --

A Yeah.

Q Their suitability, correct?
A Yes.
Q Okay. So the ones that you didn't choose, nobody on the outside should assume that there would've been evidence that would show that they would pass the Part 2 analysis if you didn't include them, correct?
A Correct.
Q Okay. Now, the three conditions that you determined would pass the Part 2 analysis, those are not the only three conditions for which marijuana is used for treatment in the United States, correct?
A Correct.
Q Great, right, and the 15 conditions that passed the Part 1 analysis, those are not the only conditions for which marijuana is used to treat in the United States as well, correct?
A Correct.
Q In fact, there are dozens, if not more than 100, conditions around the United States being treated in medical marijuana programs that have never passed the Part 1 test, never passed the Part 2 test, and never obtained FDA approval, correct?

A Correct.
Q And in fact, some of those conditions that have been authorized in state marijuana programs have actually been recommended against, correct?
A Yes.
Q Some of them are even contraindicated, correct?
A I'm not sure about contraindications.
Q Okay. Well, sir, you agree with me that based on the review of the data that PTSD, or post-traumatic stress disorder, is a condition for which people are taking medical marijuana under state medical marijuana programs, correct?
A Yes.
Q And you reviewed that as part of your Part 2 analysis, did you not?
A We did.
Q And you concluded that the risks of adverse events from taking medical marijuana, according to the science, outweighed the benefits of taking it, correct?
A Yes. That was our finding, I think.
Q Right. Now, I want to talk to you

about how you ended up with seven conditions. Am I right that of the seven conditions that you put into the Part 2 analysis, one of them was not one that passed HHS's Part 1 analysis, correct?

A Correct.

Q It never passed the test of a program for which there was widespread experience under a state program where medical use is recognized by entities that regulate the practice of medical programs, correct?

A Correct.

Q Okay. That's one that FDA backfilled after getting the list from HHS, correct?

A Correct.

Q And was it part of the plan all along that you would be able to add in different conditions that did not pass the Part 1 test of HHS when you were conducting your Part 2 test?

A Let me think about that, the condition you're talking about is anxiety?

Q Correct, sir.

A And I think anxiety is sort of coincident with some of the indications that are on the list. There are a lot of conditions here

where that patient population would also suffer from anxiety. So I agree with you that anxiety is not explicitly listed here, but given what we found in the landscape analysis as to the widespread use among patients for anxiety, whether it was part of the program or not, it is certainly often associated with many of these other therapeutic indications.

I think FDA was interested in knowing what is the state of evidence for something that people are using. Seventy percent of users admit to sometimes using marijuana for anxiety -- if they're using it for a medical purpose, it's something like 70 percent of the time for anxiety. That was very significant to us, and it's related to other conditions, so we chose to look at it. Now, if that had been the only indication where we ended up finding credible scientific support, I could certainly understand making a case that it didn't pass part 1, why are you even looking at it in part 2? It should be invalid. It turns out being that we did not find credible scientific support and it really is irrelevant to the three conditions that we did.

Q Let's go back on that for a second, sir. In choosing to analyze anxiety under the Part 2 analysis, you picked a condition that was not listed among those that HHS had selected, correct?

A It was not in the table, yes.

Q Okay. In fact, you picked it even though, as HHS had concluded, it was illegal in some jurisdictions to recommend marijuana to treat anxiety, correct?

A That I don't know.

Q Well, let's –

(Simultaneous speaking.)

A I don't know where it is listed that it is illegal.

Q All right. Well, let --

A It may be. I just don't have that knowledge myself.

Q Well, let's take a look at this here if you go back to tab 2. Can you go to -- let me know when you're there.

A 2A?

Q 2A.

A Oh, I'm sorry. Well, we're in tab 2. What table or what section?

Q Yeah. It's tab 2, Table 2A.
A Yeah.
Q And let me know when you're there.
A Yes.
Q Okay, if you go to page 4, which has Delaware at the top -- let me know when you're there.
A Yeah.
Q Okay, and in the far right column, it lists anxiety as one of the medical conditions that is denied in Delaware, correct?
A Okay. Yes.
Q Okay. And if you go to the next page, where we have New Hampshire in the far right column, according to Table 2A, anxiety is denied in New Hampshire as an authorized medical condition that you can treat with marijuana, correct?
A Correct.
Q But you included it in your Part 2 analysis anyway, correct?
A Yes.
Q Okay. Now, in your discussion with Ms. Man yesterday, you talked about the Part 2 analysis in terms of five buckets. Do you

recall that, sir?

A Yes.

Q Let me see if I can go through those with you. The first of them was, I think, what you'd call the national surveys. Is that right?

A Yes.

Q And among those were ICPS, correct?

A Yes.

Q And what's that stand for?

A International Cannabis Policy Survey.

Q And a few of the others were the National Survey ~~of~~ on Drug Use and Health, correct?

A Yes.

Q I don't have -- Monitoring the Future, or MTF, is another one?

A Yes.

Q And then the other one was BRFSS, correct?

A Correct.

Q Okay. The second bucket, I think, was the systematic literature review conducted by the University of Florida, correct?

A Yes. Correct.

Q Okay. And then the third was the review by FDA's own medical officer team,

correct?

A Correct.

Q The fourth were the state surveys in Maryland and Minnesota, correct?

A Yes.

Q And then the fifth one was your analysis of drugs that FDA had approved that have some relation to marijuana, correct?

A Yes. Correct.

Q Okay. Those are the five buckets. Now, this came up a little bit earlier in your testimony, I think, when Mr. Kenneally was asking you questions, but there was actually a sixth bucket listed in your report, correct?

A I'm not sure which one, maybe you can just say what was listed?

Q Yeah. Your report -- now, this didn't come up yesterday in your analysis, but you would agree with me, sir, that you also conditioned the statements from major medical organizations under the classification of expert opinions, correct?

A Oh, yes, we did.

Q Okay.

A Yeah.

Q And this is covered, I think, at 4.17 of your Part 2 analysis, which is provided to you at tab 3.

A Okay.

Q Or actually, it's 4.7, sir. I'm just looking at the table of contents. But can you verify for me that the label you gave to this was Summary of Expert Opinions and Position Statements, correct?

A Yes.

Q And what you were collecting there and analyzing in this portion of your report, beginning at page 89, were the statements ~~on~~ of major medical organizations about the appropriateness of using marijuana as a form of treatment, correct?

A Yes.

Q Okay. The particular organizations that you listed there were the ones that had expertise that was relevant to the conditions under discussion, correct?

A Yes. I am still trying -- you said page 89. Can you use the number in the bottom right corner? Was that page 89? Is it that page 89 or by the document?

Q By the document, sir. I'm going to send someone to help you with this, though.

A Yeah.

JUDGE JULIUS: Yeah. The Court is also having difficulty finding where you're talking.

MR. McNICHOLS: That's our fault, Your Honor. We'll address that swiftly.

JUDGE JULIUS: Thank you.

MR. PHILLIPS: What is the page number here so that the judge can try and get it?

MR. McNICHOLS: I'm trying to -- let me get to part 3.

MR. PHILLIPS: It's going to be beyond the survey section, after that.

THE WITNESS: Yep. So it was section 417 or?

MR. McNICHOLS: I said 417 initially, sir -- I think it's just 4.7.

THE WITNESS: Oh, 4.7. Okay. Let's see, 4.2, 4.5, yes, toward the end of this. Okay. So –

JUDGE JULIUS: It looks like it's page 198.

THE WITNESS: 198.

JUDGE JULIUS: Item 252 on the Bates

stamp.

THE WITNESS: Correct, I'm there, too.

MR. McNICHOLS: Thank you, sir.

THE WITNESS: I'm there, too.

BY MR. McNICHOLS:

Q Are you there?

A Yes.

Q And these are the organizations that you listed for their expertise in the particular conditions that were under analysis in the part 2 test, correct?

A Correct.

Q And what you've listed --

JUDGE JULIUS: Sir, I will stop you right there, just to let you know the time for your opposing states has expired. You also are representing SAM, so if you'd like to continue with your time, that will start the clock on your SAM time.

MR. McNICHOLS: That's. And is -- it's 11:30 right now.

JUDGE JULIUS: It is.

MR. McNICHOLS: Is it the Court's preference to go to noon?

JUDGE JULIUS: That would be my

preference. I also know the difficulties that can come from bifurcating examinations, so if you want to find a good place to stop, we can pause then, and we can adjust our lunch hour accordingly.

MR. McNICHOLS: With that in mind, why don't I, I guess, round out or finish my examination on this particular topic, and then we can break if that's suitable to the Court and the witness?

JUDGE JULIUS: Sounds like a plan.

MR. McNICHOLS: All right, great.

JUDGE JULIUS: Thank you.

MR. McNICHOLS: Thank you. Now --

MS. MAN: So just -- I'm sorry. Just for clarification, so now we're starting the SAM clock time?

MR. McNICHOLS: Now this is SAM time, correct.

MS. MAN: Okay, I just wanted to make sure.

MR. McNICHOLS: Correct.

MS. MAN: Okay. I just wanted to make sure. Thank you, Counsel.

MR. McNICHOLS: Yes.

JUDGE JULIUS: So the one hour starts now.

MR. McNICHOLS: Now here in 4.7, under Summary of Expert Opinions and Physician Statements, you've listed the professional organizations that you thought had expertise that was relevant to the conditions under analysis in part 2, correct?

THE WITNESS: Correct.

BY MR. McNICHOLS:

Q And as you described it in your report, the vast majority of these professional organizations did not recommend the use of marijuana in their respective specialty, correct?

A Correct.

Q And in fact, the American Psychiatric Association actually specifically recommended against it, correct?

A Yes, that's correct.

Q Right. On the idea that it actually has been known to worsen psychiatric conditions, taking marijuana, that is, correct?

A Correct.

Q Okay. And in the same, one of the

associations -- or the organizations that you listed here as to pain was the International Association for the Study of Pain. You listed that as well, correct, sir?

A Yes.

Q Okay. And they do not endorse the use of marijuana or recommend the use of marijuana for the treatment of pain, correct?

A Yes. They say specifically that the evidence base regarding efficacy and safety fails to reach the threshold at which IASP can endorse their general use for pain control. As you know, in our findings, we focused more on neuropathic pain specifically as providing evidence of some benefit with credible scientific support.

Q We'll come back and talk about that, sir, when we get into the rest of your report. Those are my questions, Your Honor, as to the sixth bucket, as I call it. If this is a suitable time to break in the middle, we can go to lunch now.

JUDGE JULIUS: That sounds like a good plan. We'll still take just the hour, so instead of from 12:00 to 1:00, we'll go from

11:30 to 12:30. So we'll still do the hour lunch. I'll see everyone back here at 12:30. Please be safe out there. It is very warm. Stay cool, get water, hydrate, all that good stuff. We'll be in recess until 12:30. Thank you.

MR. McNICHOLS: Thank you.

THE LAW CLERK ~~BAILIFF~~: All rise.

(Whereupon, the above-entitled matter went off the record at 11:31 a.m. and resumed at 12:31 p.m.)

JUDGE JULIUS: A good lunch, and we are ready to resume with SAM cross-examination. Sir, if you would please retake the witness stand.

And, Counsel, whenever you're ready.

CROSS-EXAMINATION

BY MR. McNICHOLS:

Q Sir, have you had any discussion with anyone about your testimony during the lunch break?

A No.

Q Before we took off for lunch, we were talking about the five buckets that fed into your Part 2 analysis for currently accepted

medical use.

And, I think you agreed earlier that the first one consisted of the national surveys, groups like ICPS, NSDUH, MTF, and then another one. Is that familiar?

A The RFSS, yeah.

Q Right. Okay. And, the national surveys will give you information on patterns of use, correct?

A Yes.

Q Okay. And, you agree with me that surveys are not studies?

A They're a form of studies. They're --

Q Right. Well, they're not double-blinded, right?

A No.

Q They're not placebo-controlled?

A I'm trying to think. Sometimes there are observational st -- no.

Q Okay. Right. And, for that reason, you did not look to that group of studies for proof of the efficacy or the effectiveness of marijuana, correct?

A No. I mean, correct, yeah.

Q Okay. Now, the state surveys from

Maryland and Minnesota, similarly, those are not double-blinded studies, correct?

A Correct.

Q They're not placebo-controlled, correct?

A Correct.

Q Right. And, in the same vein, you did not look to them for proof of efficacy of medical marijuana, correct?

A Correct.

Q Okay. And, you also mentioned as one of the buckets, the FDA-approved products that contained THC or some other cannabinoid, is that right?

A It was dronabinol, which is one of the stereoisomers of Delta-9 THC.

Q Right. And, the particular drugs that you looked at I think were Marinol, Syndros, Cesamet, and then Epidiolex. Is that right?

A Epidiolex, Cesamet, I think, and yes, the other two, Marinol and Syndros.

Q Okay. Now, you agree with me, sir, this may be obvious, but none of those substances are actually marijuana, correct?

A Yes. Agreed.

Q They're not within the definition of marijuana that you used, correct?

A Dronabinol is a compound in marijuana. Marijuana's definition says all compounds, all preparations, derivatives. Dronabinol as a chemical entity, is chemically identical to compounds in marijuana.

And, also would contribute to the 0.3 percent standard that makes marijuana, marijuana.

Q The products that we're talking about, sir, by your analysis in the Part 2 memo that you prepared, do not fall under the definition of marijuana, correct?

A Correct.

Q And, you agree with me that there are limits on the conclusions you can draw about whether they work when they are refined substances, rather than marijuana itself, correct?

A It is a scientific question to investigate, yes.

Q Okay. And, none of those drugs, FDA-approved drugs, are approved for the pain indication, correct?

A Correct.
Q Okay. And, of those drugs, I think, is it called Cesamet?
A I believe so, yeah.
Q I was mispronouncing it earlier.
A You know, I might be the one mispronouncing it.
Q Either way, sir. We'll --
A Either way, either way we choose.
Q Okay. All right. But, Marinol, Syndros, and Cesamet are all drugs that use THC, correct?
A No. Actually, Cesamet uses a keto analog of THC. It has a double bond to oxygen in place of a methylene CH2 group.
Q Okay. And, does that limit the kind of conclusions you can draw from Cesamet because it does not have THC?
A Yes. Yeah.
Q Makes it less analogous to marijuana, correct?
A Yes.
Q Okay. But, for Marinol, Syndros, and Cesamet, those drugs -- oh, wait a minute.
A You know, while you're looking, I'm

also going to turn to the page where we discuss that, if you don't mind. Just give me a minute.

Q I do not, sir. I'm looking there as well. Yeah. It's in Tab Three of the report.

A Um-hum.

Q And, I think the page number at the bottom, well, hold on, let me help you out. Section 4.6., my colleague is going to make sure we get on the right page.

A Okay.

JUDGE JULIUS: And, just to be clear for the record, we're looking at which document?

MR. McNICHOLS: This is Part 2 of Dr. Chiapperino's analysis. It is included within ALJ Exhibit 1, and part of Government's Exhibit 3.

But, I broke it out into three just so it would be easier to find stuff.

JUDGE JULIUS: Thank you, Counsel.

MR. McNICHOLS: Yes, sir.

THE WITNESS: This is 4.2 only. Now I'm at 5.6 here.

MR. HARRINGTON: You guys don't have those numbers for us?

MR. McNICHOLS: John does.

MR. HARRINGTON: Okay.
THE WITNESS: Tab 3?
MR. McNICHOLS: Tab 3.
MR. HARRINGTON: 4.6.
JUDGE JULIUS: I think it's page 197 of 252 on the Bates.
MR. McNICHOLS: Yeah.
THE WITNESS: Thank you. Okay. Thank you.
BY MR. McNICHOLS:
Q Okay. My question to you concerns the scheduling of these analogs that you've listed here in section 4.6.
Now, I think you said that Marinol is a substance that contains a synthetic version of THC, correct?
A Correct.
Q And then, Syndros also contains a synthetic version of THC?
A Synthetically derived, yes.
Q Okay. And then, Cesamet is the one that is a synthetic analog of THC, correct?
A Correct.
Q Okay. Now, Syndros and Cesamet are both controlled under FDA Schedule II, correct?

A Syndros is controlled in Schedule II, and Cesamet, yes.

Q Right. And, drugs in Schedule II are those that have a high risk of abuse, correct?

A Correct.

Q Right. In fact, the only difference between Schedule I and Schedule II, is that drugs in Schedule II have a currently accepted medical use, correct?

A Correct.

Q So, two of the three drugs that you have here as analogs to marijuana that contain either THC or an analog, are deemed by the FDA to have a high risk of abuse, correct?

A Yes. They were controlled at their respective times in those Schedules, which are now eight years ago, or seven years ago for one and many years ago for the other.

Q And, as of today, though, my question is that's still correct, correct?

A Yes. The Schedule II status is still correct.

Q Right. And, as of today, they're still deemed by the FDA, therefore, to have a high risk of abuse, correct?

A There's been no reevaluation of the drugs by FDA. They are deemed by DEA to still be controlled in Schedule II, yes.

Q Which means, sir, to my question, they have a high risk of abuse by FDA standards?

A By FDA standards, that's a different question, yes.

Q And, in light of the limitations of the surveys and the drugs themselves, am I right, sir, that in your analysis of the efficacy of marijuana for these particular indications, that you were primarily relying on the literature review conducted by the University of Florida, and the literature review conducted by the medical officer team at FDA?

A Yes. I think those are the two more significant contributions to the review.

Q Right. And, those were buckets two and three in the list that we talked about before --

A Yes.

Q Correct?

A Yes.

Q Okay. Now, as between those two literature reviews, sir, am I right in understanding that the University of Florida did

a deeper dive into the literature than the medical officer team at FDA?

A No. I don't -- I can't say yes or no to that question. I think they both did independent systematic reviews.

I can't qualify one as being more comprehensive than the other. I think they were similar efforts.

Q Well, you described this yesterday as bringing in the University of Florida as something of a resourcing issue. You recall that testimony?

A Yes, I do.

Q Okay. And, the University of Florida team was from the Epidemiology Department. You recall that?

A I believe that most of them were in the Department of Epidemiology.

Q Okay. And, how many people did they have working there?

A Um --

Q Let's get -- withdrawn. How many people did they have working on this particular project?

A I cannot say. I was only in

discussions that had representatives of the group. And, the Office of Surveillance and Epidemiology served more as a primary contact from FDA.

Q Okay. Well, can you tell me how many people in the FDA's medical officer group were involved in reviewing literature as part of this review?

A Two within my team and a person and their team leader in the Office of Surveillance and Epidemiology medical use team, not non-medical use team that did the epidemiological data analyses on harms.

Q Sounds like three people.

A Four, yeah.

Q Four. Do you know whether the group at the University of Florida was bigger or smaller than four?

A It might have been four, because there were only two that I remember by -- from the meetings that we had in the beginning of the process.

Q The reason for my initial question about the deeper dive, sir, was that in your description, in your report --

A Yeah.

Q It appeared you stated that the medical officer team did a review of meta-analyses. Is this ringing a bell?

A Yes.

Q Okay. And, what is a meta-analysis?

A A meta-analysis is when you bring in some number of studies that have a similar enough design to be considered comparable to each other, where you might pool the data to see the results of that meta-analysis.

Q Right. And, the meta-analysis is the pooling of the data from other individual studies, correct?

A Yes.

Q Great. Right. And, the University of Florida, though, actually went and reviewed study by study, correct?

A Yes.

Q Great. And, in fact, the studies that they reviewed were worked out with you beforehand.

You agreed on search terms, and date ranges, and databases, and things like that, correct?

A Correct. But, they also looked for the opportunity for meta-analyses.

Q Right. But, where I'm going with this though, is that the FDA's review team looked only at the meta-analyses, not at the individual studies, correct?

A I think that the medical officer looked at a systematic literature review. And, I think, he did look at the references in that to see what studies were included in it.

Q Okay.

A I can't speak to the details right now as to what he did. But, I think, it involved looking at individual studies, even if it was a systematic literature review.

Q Okay. And, when you say even if it was a systematic literature review, you mean he would have reviewed it at one level ~~of~~ removed in a pooled data, rather than at the individual level, correct?

A I'm saying he may have done both.

Q You don't know.

A I don't know at this moment, no.

Q Okay. Great. Now, when did your team, or excuse me, when did the FDA's team start

doing the literature review that fed into your analysis here, sir?

A Probably by March.

Q Okay.

A Yeah.

Q And, when did the University of Florida team finish its review?

A I think we got their report in July.

Q Okay. So, in other words, both teams were --

A Maybe, I think actually, I'm sorry, not to interrupt you, but, I think there were actually two reports, one on non-medical use, one on medical use.

I think we received them a few weeks apart. And, I don't recall in the moment which one we received first.

Q All right. But, it sounds like the two teams that were involved in the literature review were working in parallel. Is that correct?

A Correct. Yeah.

Q All right. Now, as to the pain indication, I think yesterday you said that the FDA's medical officer team and the University of

Florida's team that did the literature review, shared the same view of what the data showed.

Is that fair?

A I think I said that, yes.

Q Okay. Well, you see, that's at odds, at least how I read the report, which seemed to suggest that University of Florida's team thought, as to the pain indication, that the data was inconclusive or mixed.

You recall writing that in your report?

A I recall reading that, yes. I didn't write that section, yes.

Q Okay. Well, did the FDA's medical officer team that did the literature review, share the view of the University of Florida team that the data was inconclusive or mixed as to the pain indication?

A So, the University of Florida team is providing a work product. The medical officer team and CSS is both doing their own review separately.

And, they're also responsible for writing the CAMU Part 2 document. So, they also had the responsibility of summarizing results of the University of Florida report.

So, in bringing in the University of Florida report summary as Section 4 point something UF, that was written by the medical officer reading the University of Florida report, documenting their findings, and then writing about his own findings.

Q Right. But, my question to you is not that, sir.

A Yeah.

Q My question to you is where, whether as to the pain indication, the FDA team agreed with or disagreed with the words written in the report --

A Yeah.

Q That the Florida team thought the results were inconclusive and --

A Yes.

Q Mixed on the pain indication. Did they agree with that?

A Yeah. I think they disagreed with the UF team and concluded themselves from a broader look at the data that there was support.

Q Okay. That's where I'm going with this.

A Yeah.

Q So, as between the two reads of the data and the one that ultimately ended up in the eight-factor analysis here --

A Um-hum.

Q Or, excuse me, the currently accepted medical use analysis, you went with the review of the FDA team, not the view of the Florida team, correct?

A Yes. The review of the FDA team focused also on neuropathic pain individually as a special category of pain, which is common in drug approvals to have specific painful conditions with their own approval.

Not everything could be, could meet approval for a broad pain indication. Some things have to look at a specific disease condition in order to find a patient population that benefits.

So, as we testified earlier, you only need one currently accepted medical use. The medical officer thought about that through the lens of many potential specific pain indications, and his findings is based more in the finding for neuropathic pain as showing better efficacy.

I shouldn't use the word efficacy, more effectiveness that meets the credible scientific support standard.

Q Okay. But, the University of Florida and the team that you hired to review the literature, they reviewed the same studies, correct?

A Correct.

Q Okay.

A I believe they were the same.

Q And, they thought on the neuropathic pain condition that the literature on that point was inconclusive or mixed, correct?

A I would have to look at their section that we summarized here, on whether it's specific to neuropathic pain. I don't know offhand how it was summarized.

Q Okay. Now, you mentioned earlier that one of the professional organizations that you reviewed in considering the pain indication was the International Association for the Study of Pain. Is that correct?

A Yes, correct.

Q Okay. And, one of the libraries that you had the University of Florida team look in

for their literature review was called Cochrane, correct?

A I believe so, yes.

Q Yeah. And, that is, for everybody, that's a database of medical literature, correct?

A Yes.

Q Okay. So, and they would have looked or been instructed by your office to look for things that bore on neuropathic pain, correct?

A I do not know if the directive to them was that specific when we discussed the indications that we wanted them to review.

There were also meetings that happened that did not have me present. So, because this was a task that was allocated to the medical officer team, that I was monitoring progress, et cetera.

So, I don't know how specific the directive was to look at or no, don't bother looking at subcategories of pain.

Q Okay. Well, let me ask you this, sir. Is it fair to say, based on your understanding, that it was the neuropathic pain indication that tipped the balance for pain in favor of a

currently accepted medical use?

Am I understanding your testimony correctly?

A I think that the broad pool of pain studies, when pooled, showed a treatment benefit. I think the treatment benefit that it showed was small, and we noted adverse events.

I don't know if without the neuropathic pain specialty we would have considered those mixed results and that small margin meeting our credible scientific support. I don't know, because that wasn't the conversation.

We knew that we could conclude on the basis of neuropathic pain that the standard was met.

Q Okay. I think I understand what you're saying, is that without the neuropathic pain data, you don't know whether or not you would have been able to make a finding that pain was a currently accepted medical use for marijuana. Is that correct?

A I think that's fair, yes.

MR. McNICHOLS: Okay. All right. Okay. Okay. I'm handing you a document, sir, that's not been marked as an Exhibit yet. But,

we're going to ask to have it marked as SAM Exhibit 45.

(Whereupon, the above-referred to document was marked as SAM Exhibit No. 45 for identification.)

MR. McNICHOLS: And, I want you to take a look at it. And, it says on the front, Cannabis-Based Medicines for Chronic Neuropathic Pain in Adults.

And, it appears to be found within the Cochrane Library. You see that, sir?

THE WITNESS: Yes, I do.

BY MR. McNICHOLS:

Q Okay. And, the authors of this are someone named Mucke, Phillips, Radbruch, Petzke, and Hauser. You see that, sir?

A Yes.

Q Okay. And, this document, at least at the bottom, suggests a copyright of 2018, for the Cochrane Collaboration.

You see that, sir?

A Yes.

Q Right. So, this would have been a document in existence at the time you were doing your review, correct?

A Yes.

Q Okay. And, if you go to page two on this document, which is actually the fourth page in, there's something called the plain language summary.

And, let me know when you're there.

A I'm there.

MS. MAN: Your Honor, the --

MR. McNICHOLS: And, what it says on this is, bottom line --

JUDGE JULIUS: Is there an objection or something?

MS. MAN: There is. I think we're missing a few questions about whether or not this was considered in his review. Because, if he considered it in his review, I think it's fair game.

But, if he didn't consider this in his review, then I would ask that the Court find that the Touhy letter does not allow him to opine on something outside of what he considered for his review.

JUDGE JULIUS: Well, I think, so far he's just been asking him to verify what the document says on its face.

MS. MAN: Sure. But, the next question is going to be an opinion. And, I'll have an objection there.

But, I think we're missing a couple ground laying, some foundational questions.

JUDGE JULIUS: I'm going to overrule the objection for now. I think, he's just asking him to verify what the document says at this point.

If we get to something that's objectionable, I will hear further objections.

MS. MAN: That's fair.

JUDGE JULIUS: But, at this point I'm going to overrule the objection, and you can continue your questions.

MR. McNICHOLS: Thank you. And, if you turn with me, let me know when you're on page two, sir.

THE WITNESS: Yeah, I'm on it.

BY MR. McNICHOLS:

Q And, what it says under plain-language summary, under the phrase bottom line, is there is a lack of good evidence that any cannabis-derived product works for any chronic neuropathic pain.

Do you see that, sir?

A I see it.

MR. McNICHOLS: Okay. Can we move this into evidence now, Your Honor?

JUDGE JULIUS: Any objection?

MS. MAN: No objection.

JUDGE JULIUS: All right. SAM Exhibit 45 will be admitted.

(Whereupon, the above-referred to document was received into evidence as SAM Exhibit No. 45.)

MR. McNICHOLS: Thank you, sir.

Now, another indication for one of the ones that passed the Part 2, part of your analysis was that of anorexia, correct?

THE WITNESS: Yes.

BY MR. McNICHOLS:

Q And, I believe you testified yesterday that the University of Florida team and the FDA team shared the view as to the current medical use, currently accepted medical use of anorexia. Is that correct?

A Yes.

Q Okay. Well, as I was reviewing your report, I actually had a different take on it.

There it looked like the FDA's review of the meta-analysis showed mixed results.

Is that consistent with your recollection?

A I would have to look. But, I won't argue the point now. Yeah.

Q Well, I have some time left in the cross-examination, sir.

A Okay.

Q Let's go to page 26 --

A Sure.

Q Of Tab 1, which is the main report, the final one and the recommendation that went over to DEA.

A Yeah.

Q Thank you.

A Yes.

MS. MAN: I'm sorry Counsel, Tab 1?

JUDGE JULIUS: I'm sorry Counsel, could you repeat where you're looking?

MR. McNICHOLS: Yeah. We're going to square this away right now. Before any questions though, sir.

MS. MAN: Could you do me a favor, Counsel --

MR. McNICHOLS: Page 27.
MS. MAN: Which tab is that, gentlemen?
MR. McNICHOLS: Tab 1.
MR. HARRINGTON: On the Government's Bates stamp, it's page 27.
MS. MAN: Tab 1?
JUDGE JULIUS: This is at Government's Exhibit 3. Is that right?
MR. HARRINGTON: Yes, Government's Exhibit 3.
JUDGE JULIUS: Is that August 29, 2023? Okay. I just wanted the record to be clear about what document we're looking at. Thank you, Counsel.
MR. McNICHOLS: Yeah. Now, just to my point, you can read it on here if you need to, sir, but my question ultimately was that the FDA's view of the literature on the anorexia indication was that it showed mixed results, correct?
THE WITNESS: Which paragraph on that page are you looking at?
MR. McNICHOLS: Well, actually, may I approach the witness?
JUDGE JULIUS: Yes, you may.

MR. McNICHOLS: It's this, sir. This is the one I would look at.

THE WITNESS: Okay. Yeah, I see anorexia there. Okay.

BY MR. McNICHOLS:

Q Thank you. Can you verify for me there, sir, that as the FDA's findings are described in that paragraph, the results of the literature review were mixed as for the anorexia indication, correct?

A Well, the sentence before it lists three indications, anorexia, nausea and vomiting, and PTSD. Then there is a however statement about FDA, and we only speak about PTSD, so.

Q Actually, I disagree, sir. Let's drill down on that. Let's be very careful. I see the sentence you're talking about.

UF, which means University of Florida, correct?

A Yes, yes.

Q Found that there is low to moderate quality evidence supporting the use of marijuana as a medical treatment for outcomes in anorexia, nausea and vomiting, and PTSD. Do you see that?

A Yes.

Q Okay. And, after that, however, FDA review of systematic review showed mixed results for these indications.

And, I thought indications there referred to the same ones that were mentioned in the prior sentence. Do you see that, sir?

A Yes.

Q Okay. In other words, that sentence verifies that according to FDA's literature review, the results for the anorexia indication were mixed, correct?

A I see that that is a -- yeah, it could be that meaning.

Q Okay. So, as to the anorexia indication, in concluding that a currently accepted medical use had been established for that indication, you went with the views of the University of Florida rather than the views of the FDA based on reviews of the literature, correct?

A I agree that there is a problem with the way that sentence is written. If I may, I think that, to be clear, the low to moderate quality of evidence, and I think you know this

as well, means that with a moderate quality of evidence, the actual result is probably similar to the observed result.

So, that was considered meeting the credible scientific support standard. So, UF is saying that the standard is met for those three indications.

We do have a sentence after that that suggests that all three of those findings are sort of questionable, and that is problematic wording. However, I don't think there was ever disagreement between FDA and UF in all three of those indications.

Q But, isn't --

A I know that we took issue what --

Q Go ahead, sorry. Finish your sentence.

A Okay. I'll let you go.

JUDGE JULIUS: Were you done with your answer, sir?

THE WITNESS: Well, I was just going to say the only indication that we wanted to reverse in these findings was PTSD. Had the medical officer intended to reverse views on the others, they would have chosen to.

But, the conclusion was that the only

one that we reversed our findings versus UF was PTSD. In that sentence, I should say.

MR. McNICHOLS: Yeah. Well, actually, the FDA's view of the anorexia indication, I think, is covered at 4.4.1.7 of Tab 3 of your report.

JUDGE JULIUS: I'm sorry, Counsel, could you repeat that section?

MR. McNICHOLS: 4.4.1.7, sir.

JUDGE JULIUS: Thank you.

THE WITNESS: Okay, getting there almost.

JUDGE JULIUS: And, just for the record, this is Government's Exhibit 3, page 80. It's also an ALJ Exhibit.

Just keeping track for the record of what document we're actually looking at in real time.

MR. McNICHOLS: Yes, sir. Thank you.

JUDGE JULIUS: Okay, thank you.

MR. McNICHOLS: And, are you there at section 4.4.1.7 entitled Anorexia Related to Medical Conditions, sir?

THE WITNESS: Yes.

BY MR. McNICHOLS:

Q And, does that section there summarize the FDA medical officer's write-up of the literature as it pertains to the anorexia condition?

A I'm going to read more of it. Hold on one minute. Okay. I've, I think, digested those paragraphs.

Q My question to you, sir, are those paragraphs under 4.4.1.7 entitled Anorexia Related to Medical Conditions, do those summarize the FDA medical officer's conclusions as to the literature review for the anorexia indication?

A I think this was a summation of all available data on the indication. Is 4.4 at the beginning entitled, what is the heading 4.4 in the --

Q I think that says FDA Review of the Literature, sir.

A Okay.

Q On that 4.4. See what I'm saying?

A Okay.

Q And, my next question then, is the bottom line, the concluding sentences of this were, In summary, it appears the majority of

systematic reviews covered synthetic forms of THC with limited information supporting marijuana's benefit related to this review.

You see that, sir?

A I do.

Q Okay. Now, is it fair to say, sir, that for each of the three indications that passed your Part 2 analysis, that there were competing interpretations of the data?

A I think there were some different views, yes.

Q Okay. There was no consensus view as to whether marijuana offered a benefit to helping with these conditions, correct?

A Between the UF and FDA, there were differences.

Q And, as to each of those three indications, in coming to the conclusion of a currently accepted medical use, you went with the interpretation that favored the currently accepted medical use, correct?

A I think I would want to read a little bit from Section 5, Overall Conclusions, because each of these subcategories draws conclusions in a certain category.

It was in Section 5 that, I think, we pulled together the views of these.

Q I have a limited amount of time, sir.

A All right.

Q I just want, as you're sitting here --

A Okay.

Q Do you know the answer to my question? As to each of these three indications, did you resolve the doubts in favor of an interpretation that favored a finding of currently accepted medical use?

A We favored the finding listed as the conclusion from the medical officer reviewing these. Yeah.

Q Which in this case was, there is a currently accepted medical use?

A Yes.

Q Now, I want to shift gears for just a moment and talk about the safety of marijuana as to these indications, because that was also part of your analysis under Part 2, correct?

A Yes.

Q Okay. And, in your discussion yesterday with Ms. Man, it appeared as though you gave significant weight to the state surveys

from Maryland and Minnesota. Is that right?

A We gave weight to them. I mean, significant, you know, it depends where we had data to weigh.

Sometimes data was limited in the clinical studies, so, yeah.

Q Okay. Right. But, you recall testifying yesterday on direct examination, for example, that as to the Maryland and Minnesota surveys that there were not a significant number of adverse events reported?

A Serious adverse events, yes.

Q And, not a significant number of serious adverse events. Okay.

A Yes.

Q All right. And, it just sounded as though that played a part in your conclusion that there was a currently accepted medical use for these indications, correct?

A Yes. Had we saw an unfavorable imbalance of benefit versus serious adverse events, we would not have made a finding of credible scientific support, as was the case with PTSD.

Q Okay. Now, we talked about this a

little bit before, sir, but I think you agreed with me that a survey is not the same thing as a double-blinded study, correct?

A Correct.

Q Okay. And, in fact, the studies that you relied on here from Maryland and Minnesota are ones based on voluntary participation, correct?

A Correct.

Q Okay.

A Well, no. Well, for Minnesota, if they're going to acquire medical marijuana, they must fill out a patient questionnaire.

Q Okay.

A So, that's different.

Q Right. Right. But, it's -- I'm right though, am I not, that neither of these state surveys that you relied on actually included information from patients who stopped taking marijuana?

A Yes, I agree.

Q Okay. Which could, as I think you acknowledge in your report, skew the safety results in a positive direction, correct?

A I think it skews more whether the

patient thought that it was working for their condition. I think, well, we did also note that a negative experience could be the reason that they don't come back. That's speculative.

Q Right. But, you took that into account when you were writing your report, correct?

A Yes. Yes.

Q Right. And, that's a limitation of the study, correct?

A Yes, it is.

Q Okay. And, the effects that were documented in these studies, can they be defined as events?

A Say that one more time, please.

Q Let me try a little bit better question, sir.

A Yeah.

Q That was not. That some of the adverse effects that I saw captured in the Maryland and Minnesota studies were things like panic attacks, and anxiety attacks, shortness of breath, correct?

A I think so, yes.

Q You know, and I'm describing those as discrete events. Do you understand what I'm

saying?

A Yes.

Q Okay. Now, what they, these studies did not assess, though, neither the Maryland study nor the Minnesota one, was any long-term degeneration as a result of chronic marijuana use, correct?

A Correct.

Q Right. And, that is a concern when you're talking about marijuana, correct?

A Correct.

Q Right. And, yesterday when you were describing some of the conditions that you saw people taking marijuana for, I think it was in the Minnesota study, one of them was anxiety, correct?

A Correct.

Q Depression?

A Yes.

Q You say yes?

A Yes.

Q PTSD?

A Yes.

Q And, bipolar disorder, correct?

A Yes. To a lesser extent, yes.

Q Okay. But, all of those, right, are mental health conditions, correct?

A Correct.

Q Okay. And, at least as to mental health conditions, we saw earlier that the American Psychiatric Association ~~indication~~ has said that marijuana use is known to worsen those conditions, correct?

A Yes.

Q Okay. And, as to PTSD, your own review of the literature suggested that the risks of adverse events outweigh the benefits, correct?

A Yes.

Q Okay. And, those were all indications that appeared in one of the surveys that you're relying on for safety, correct?

A That survey reveals that many of the survey respondents were using it for that indication, yes.

Q And, you --

A We don't connect, in that survey, we were not able to connect reported adverse events by indication, I don't think.

Q But, you were relying on that survey, sir, in your conclusion that the safety of

medical marijuana --

A Yeah.

Q Was adequate, correct?

A Actually, those surveys served a different purpose. There was a landscape analysis where we looked at that data early on to support which findings, which indications we were going to use.

So, even though maybe it has been discussed, it could be confused as a bucket of support. It, well, has some bucket of support.

The safety-reported adverse events are important. But, the study of indications and other details about medical use patterns were actually helpful in making determinations as to which indications to focus on.

Q Are you saying, sir, that you did not rely on the state surveys from Maryland and Minnesota in arriving at your conclusion that marijuana was safe as to the three indications that passed Part 2?

A No, we did weigh safety data.

Q That's my only question.

A Okay.

Q And, the surveys are safety data,

correct?

A I'm sorry. Say that again.

Q The surveys are safety data?

A They provided safety data.

Q All right. Now, I want to shift gears briefly and talk about the other components of your eight-factor analysis.

One of which, which sort of filters down to various factors, is a drug's potential for abuse, correct?

A Yes.

Q And, under the eight-factor analysis, there are several of the factors which actually bear on this to one degree or another. Do you agree?

A Yes.

Q Okay. Factor 1, for example, is potential abuse. Factor 4, history and pattern of abuse. And then, we can go on from there.

But, there's more than one factor that touches on the abuse issue, correct?

A Yes.

Q All right. And, do you agree, I think this has been established already, but do you agree, sir, that by your analysis, as set forth

in your recommendation, marijuana is the most frequently abused illicit drug in the United States?

A Yes.

Q Okay.

A I want to remind you, though, that in Factor 1A, it is the evidence that an individual is using a substance in amounts sufficient to create a hazard to himself.

So, it's, Factor 1 was not only about potential for abuse, it's also about outcomes. Yeah.

Q I understand. But, the other factors, though, are not so limited, correct?

A Limited how?

Q Well, you said that Factor 1 is limited because it's principally concerned with things that'll affect someone's health.

A I don't think I said, did I say limited, or was that your word?

I said that Factor 1A is about more than just prevalence of use, is what I intended to emphasize.

Q Okay. Now, you also agree that based on your analysis as set forth in your report,

most use of marijuana in the United States is non-medical?

A Yes, that's true.

Q And, non-medical use is abuse, correct?

A Some would argue in the case of that use of a substance as marijuana is currently being used, often the user is using it consistent with their state laws.

So, use and abuse, we use the term non-medical use too often to not suggest that every use of a drug, even if it is a drug of abuse, is not necessarily abuse.

Q One of the things that you consider when considering abuse under Factor 1 is whether an individual is taking the drug of their own initiative --

A Yes.

Q And not based on medical advice, correct?

A Correct.

Q So, taking the drug of your own initiative and not based on medical advice means abuse, correct?

A It's one of the considerations. It doesn't say that it means abuse.

Q Right.

A It's a factor. They could be taking a drug for a medical purpose but not under someone's medical advice.

Q Okay.

A I mean, you have to consider the range of possibilities for each of the A, B, C, D.

Q Okay. But, you at least agree, sir, that under the Factors as you've outlined them under your report, that taking marijuana or any drug, not because a doctor tells you to, but because you want to, counsels in favor of a finding of abuse, correct?

A I think that abuse is excessive use.

Q Is that defined as such anywhere in the document that you submitted to DEA?

A Not that phrase, no. I think that 1A captures that users of a substance are, we weigh whether they are using the substance in a way to cause harm to themself or others.

Q I think you said a minute ago, sir, that if someone is taking medical marijuana obtained through some legal program that, tell me if I get this right, that you would not consider that abuse, correct?

A I'm sorry. Say that again.
Q Yeah. If someone is taking marijuana where it's legal under state law, you don't consider that abuse?
A No. I'm saying that there are use patterns, and there's a substance that some people feel that they are using in a lawful way.
So, for people to label all such use as abuse is, I think, unique for marijuana, that it is unusual because it is not an illicit substance in those states.
If you asked me a general question about does abuse always mean, or does use of a substance non-medically always mean abuse, I would say that we have treated all non-medical use as abuse.
Q Okay.
A And, I'm trying to be more nuanced here, because we are dealing with a large population that has access to recreational use of marijuana. And, it seems unusual to characterize all use of marijuana as drug abuse.
So, we're trying to weigh the harms related to non-medical use. And, of course, if it's used excessively, we would call that abuse.

Q Okay. Now, am I right, sir, that under the diversion analysis in your report, right, you focused only on legitimate use or sources of marijuana, correct?

A Yes.

Q And, by the analysis --

A Under federal --

Q And your use of the word --

A Under federal law.

Q Hold on a second.

A Sorry.

Q By your use of the word legitimate in your report, you do not include marijuana obtained through state medical marijuana programs, correct?

A Correct.

Q Right. That is not, under the terminology of your report, a legitimate source, correct?

A It's a source that we did not weigh for the question of diversion from a legitimate, diversion from a legitimate source. We only talked about federal acceptable uses of marijuana.

Q It's not a legitimate source, correct?

A Not under federal law.
Q And, not under the analysis that you provided to the DEA, correct?
A I think that's right.
Q Now, in terms of abuse and the effects of abuse, I think you'll agree, sir, that more Americans are addicted to marijuana than any other illegal drug, correct?
MS. MAN: Objection.
JUDGE JULIUS: Basis?
MS. MAN: Dr. Chiapperino's Touhy letter does not ask him to opine about the addiction rate of marijuana as compared to anything else.
If it didn't go into his, excuse me, if it didn't factor into his analysis, he can't testify to that.
MR. McNICHOLS: This is directly in his report, which compares addiction rates of marijuana to other substances.
MS. MAN: Well, then I --
MR. McNICHOLS: I want to know whether it's true that there are more Americans addicted to marijuana than any other illegal drug according to the analysis that you did in 2023,

sir?

JUDGE JULIUS: Hold on. We have an objection. I haven't ruled on it yet.

Can you point the Court to where you're referring, where he does this?

MR. McNICHOLS: Well, I'd rather see, Your Honor, if the witness can answer the question first before I have to direct him to the document.

THE WITNESS: I would --

JUDGE JULIUS: Hold on.

THE WITNESS: Sorry.

JUDGE JULIUS: I understand your point, Counsel. If it's in the report, then it's fair game for question.

So, I'll overrule the objection with the understanding that it is included in here. And then, hopefully, we can get a direction once we get some answers.

Okay, Counsel?

MR. McNICHOLS: Yes, sir.

Is it your understanding, sir, that more Americans are addicted to marijuana than any other illegal drug?

THE WITNESS: You're using a term, and

that's not the way we discuss substance use disorder in the document.

BY MR. McNICHOLS:

Q Then let me withdraw my term then, alter the question, I mean.

A Yeah.

Q Is it true, sir, that of all illegal substances, substance use disorder is more prevalent for marijuana than for any other illegal substance?

And by more prevalent, I mean --

A Yes. Yes, it is. Because, I think, the only other one is alcohol, yes.

MR. McNICHOLS: That's what I thought. Okay. And, that's page 40 in case there were concerns about that.

JUDGE JULIUS: Thank you, Counsel.

MR. McNICHOLS: And, the section entitled National Survey on Drug Use and Health, in case there's confusion about the page.

All right. Now, you mention alcohol having more, but you agree with me, sir, that alcohol is not a controlled substance?

THE WITNESS: Yes.

BY MR. McNICHOLS:

Q Okay. And, I think yesterday in your analysis, and when you were testifying when Ms. Man was asking you questions, you agreed that you don't normally use unscheduled substances in your eight-factor analysis. Is that correct?

A That is correct.

Q Have you ever, on any other previous, any other occasion, used alcohol as part of the eight-factor analysis?

A No.

Q Only for marijuana?

A Correct.

Q And, in terms of it, the effects of using marijuana, am I right, sir, that marijuana has been linked to mental health disorders?

A Yes. There's an association.

Q It's been linked to psychosis?

A Yes.

Q Schizophrenia?

A That is a psychosis, yes.

Q Bipolar disorder?

A Yes.

Q And, even suicide risk, correct?

A Yes.

Q All right. And, all of those things

are relevant to the abuse potential of this substance, correct?

A Yes.

Q Okay. And, I think you testified earlier, sir, that you try to be consistent in the content that you put into each drug evaluation, correct?

A Correct.

Q Okay. Now, in the eight-factor analysis that FDA prepared for marijuana in 2015 --

A Um-hum.

Q There was actually a specific section in there that mentioned marijuana and its effect on mental health. You recall that?

A Yes.

Q Okay. Now, I did not, in your report, see an analogous section that similarly outlined the effects of marijuana on mental health, at least not in the main report that you prepared. Do you agree with that?

A Yes. We focused -- yes, I agree with that.

Q Okay. And, what you did focus on, I think you were about to say, in your discussion

of the abuse potential were the severest outcomes of using illicit substances, correct?

A Yes.

Q Let me withdraw the question, sir. Oh, sorry. Did you say yes?

A Severe, I think I used the term acute also.

Q Acute.

A Yes.

Q And, those were things like overdoses, correct?

A Correct.

Q Emergency room visits?

A Emergency room visits, yes.

Q Right. And, hospitalizations?

A Um-hum.

Q You said yes?

A Yes.

Q Poison center calls, correct?

A Yes.

Q And, even deaths, correct?

A Yes.

Q Okay. But, I think you agreed earlier when my colleague, Mr. Kenneally, was asking you questions, that harms below a fatal level are

still relevant to the question of the abuse and public health impacts of a drug, correct?

A Say that one more time. Sorry.

Q That was probably a bad question, sir. A drug does not to cause, did not have to cause fatalities at any particular level in order for it to potentially be a concern of abuse. Correct?

A I would agree, yeah.

Q Right. Okay. And, what you talked about yesterday in your discussion with Ms. Man concerned the risk ratio and utilization rates of harms for particular substances.

A Yes.

Q You recall that?

A Yes.

Q Okay. And, I think what you said was that as too severe harms, things like overdoses, ER visits, things like that, that on a utilization-adjusted basis, marijuana has less severe outcomes than certain other drugs in Schedule I and Schedule II. Correct?

A Yes.

Q And, the drugs that you used for comparison purposes were cocaine?

A I believe so.
Q Heroin?
A Yes.
Q Oxycodone?
A Yes.
Q Fentanyl?
A Yes.
Q Okay. Ketamine?
A That's Schedule III. Okay.
Q Right.
A And Hydrocodone, in Schedule II, yeah.
Q Okay. And, on a per user basis, those things are more likely to kill you than marijuana, correct?
A Yes.
Q Okay. But, where a drug falls on the Schedule between I and V often does not align with where it ranks in the severity of harms. Do you agree with that?
A Yes, I think -- or yes. I'll just say yes to keep it simple.
Q Okay. And, in fact, there are several other Schedule I drugs that do not have a high risk of overdose, correct?
A Yes.

Q LSD is one.
A Oh, yes.
Q Peyote is one.
A Yes.
Q Psilocybin is one.
A Yes.
Q Okay. And, one called DMT or dimethyltryptamine as well.
A Dimethyltryptamine, yes.
Q Right. And, all of those drugs, in other words, are in Schedule I, even though they have a relatively low risk of overdose, correct?
A They do not have a currently accepted medical use, yes.
Q Right. But, they're also, they don't have a huge risk of --
A True.
Q Of hospitalization.
A True.
Q Okay. And, this rescheduling in 2023, was not the first time that someone had suggested using things like cocaine and oxycodone as comparators to marijuana, correct?
A I'm sorry. Say that again.
Q Yeah. This rescheduling in 2023, the

one that you --

A Yeah.

Q Assembled a report for, --

A Yeah.

Q That was not the first time that someone had suggested to the FDA that you use things like cocaine and oxycodone as comparator substances, correct?

A When you say the first time for a marijuana review? I'm not sure what you're --

Q That is a legitimate point.

A Yeah.

Q So, let me harken back. In the 2015 --

A Yeah.

Q Review, or excuse me.

A Let me save your time. I don't know what comparators were used in 2015. If you want to state them, that would make this faster.

Q Let me ask you this. In 2015, the FDA stated that it would be inappropriate to use cocaine and oxycodone as comparators to marijuana, correct?

A I don't know. If you've read that in the review, I will take your word for it.

Q Okay. Let me ask you this. Am I

right, sir, that when you're assessing the abuse potential of a drug, that selecting appropriate comparators is very important?

A Yes.

Q And, that when you're looking for appropriate comparators, ideally, you look to drugs in the same pharmacological class, correct?

A Yes.

Q Okay. Which, in the case of marijuana, is hallucinogens, correct?

A It is controlled under the CSA paragraph for hallucinogens, yes.

Q Right. Right. And, as we talked about a minute ago, there are plenty of other hallucinogens that are Schedule I, correct?

A Yes. They work by a different pharmacological mechanism. They definitely have different properties than marijuana.

Hallucinogens would be a broad term to capture them in the same category.

Q But, there are other hallucinogens in Schedule I, and they also have a low rate of overdose risk, correct?

A Yes.

MR. McNICHOLS: Those are my questions, Your Honor.

JUDGE JULIUS: Thank you very much, Counsel. Our schedule has Phillip Drum, PharmD, as the next one to have opportunity.

He's not physically present. I don't believe anyone is here representing him. I believe he remains pro se. Is that the case?

If anyone is representing Phillip Drum, identify yourself.

MR. HARRINGTON: That is the case, Your Honor. He is pro se.

JUDGE JULIUS: Thank you very much. And, as I indicated yesterday, if someone did not attend on a day when they had an opportunity to cross-exam, that would be a waiver of that opportunity.

So, we'll move onto the next phase, which would, I believe, be a redirect. I believe we've finished cross-examination from all other interested persons?

MR. McNICHOLS: I think that's right, Your Honor.

JUDGE JULIUS: Thank you. Ms. Man, if you're ready?

MS. MAN: Your Honor, based on the questions that were posed to Dr. Chiapperino, the government has no redirect.

JUDGE JULIUS: All right. So, that concludes your testimony. Thank you very much, Doctor.

THE WITNESS: Thank you. Can you advise on my, I am done as far as talking to friends, things like that?

JUDGE JULIUS: I don't know if there's any possibility that you'll be recalled in any rebuttal context. I would advise to not, I don't know. Government, do you plan to recall him or is it an open question?

MS. MAN: I thought the Court's order said there were no rebuttal witnesses.

JUDGE JULIUS: We did not schedule rebuttal time. We said we would take it as the issue arose.

MS. MAN: Very well. I will leave that question open then --

JUDGE JULIUS: Okay.

MS. MAN: On the possibility. So, I would advise you not to speak to anybody.

THE WITNESS: Thank you.

MS. MAN: On the possibility that we will call you for rebuttal, I don't want to exclude myself from that possibility.

JUDGE JULIUS: Thank you for clarifying. And so, I would --

THE WITNESS: Okay.

JUDGE JULIUS: Please refrain from discussing your testimony with anyone until it's determined whether or not you'll be called as a rebuttal witness.

THE WITNESS: Thank you.

JUDGE JULIUS: Thank you very much for your testimony. I know it's --

THE WITNESS: Sure. Thank you.

JUDGE JULIUS: You have had a lot of questions. Thank you, sir.

THE WITNESS: It is my job. Thank you.

JUDGE JULIUS: Absolutely. And, Ms. Man, will you be handling, I'm so sorry, I didn't mean that. Who will be handling the next witness?

MS. RACE: I will be, Your Honor.

JUDGE JULIUS: Okay. And, if you could identify yourself for the record, please?

MS. RACE: Sure. My name is Stacy

Race.

JUDGE JULIUS: Thank you, Ms. Race. And, do you want to call your next witness?

MS. RACE: I will. The Government now calls Dr. Corey Burchman. And, he is here. If the Court will just give us a few minutes to bring him in

JUDGE JULIUS: Absolutely.

MS. RACE: Thank you.

JUDGE JULIUS: Welcome, sir. Good afternoon.

DR. BURCHMAN: Thank you. Appreciate it.

COREY ANDREW BURCHMAN, having been first duly sworn, testified as follows:

JUDGE JULIUS: Before you have a seat, if I could ask you to please raise your right hand. Do you swear or affirm that everything you say in these proceedings will be the truth, the whole truth, and nothing but the truth?

DR. BURCHMAN: I do.

JUDGE JULIUS: Thank you so much. You are officially sworn in. You may be seated. Ms. Race, whenever you're ready to begin your direct examination.

MS. RACE: Thank you, Your Honor.

JUDGE JULIUS: Thanks.

DIRECT EXAMINATION

MS. RACE: Dr. Burchman, can you please provide your full name for the record?

THE WITNESS: Corey Andrew Burchman.

BY MS. RACE:

Q Sir, where do you reside, city and state?

A Hanover, New Hampshire.

Q Are you --

JUDGE JULIUS: Please be sure to let her ask the full question before you --

THE WITNESS: Oh, so sorry.

JUDGE JULIUS: No, no worries. When she finishes her question, just pause for a beat to see if there's any objection. If you hear the word objection, please pause until I have an opportunity to rule on it, okay?

THE WITNESS: Yes, sir.

JUDGE JULIUS: And if you ever do not understand a question, please just say that you don't understand the question before you try to answer it, okay?

THE WITNESS: Yes, sir.

JUDGE JULIUS: Thank you. Please continue.

MS. RACE: Thank you, Your Honor. Dr. Burchman, are you a physician?

THE WITNESS: Yes.

BY MS. RACE:

Q Do you currently hold a medical license?

A Yes.

Q In which state do you hold a medical license?

A The state of New Hampshire.

Q Dr. Burchman, do you currently provide direct patient care?

A No.

Q Did you ever provide direct patient care?

A Yes.

Q Okay. When did you stop?

A 2019.

Q And I should have asked you this earlier, when did you become a physician, sir?

A 1983.

Q So is it fair to say that between 1983 or so and 2019, you were providing direct

patient care?

A Correct.

Q After you stopped providing direct patient care, Doctor, did you continue to provide additional medical services perhaps to other professionals?

A Yes.

Q Can you explain that a little bit more to the Court?

A When I retired in 2019, I was engaged in multiple advisory and consultation roles.

Q And these would be consultation roles with whom?

A Let me list them for you. I was a member of the New Hampshire State Therapeutic Cannabis -- Medical Cannabis Oversight Board. I sat on the board of a medical marijuana dispensary in the state of New Hampshire. I still maintain my Dartmouth Medical School faculty appointment. I mentor medical students, and I receive questions from physicians with respect to New Hampshire around the state on medical issues, particularly concerning the safety, administration, and science behind marijuana.

Q About how many a month -- how many consultations with other physicians and prescribers do you receive a month regarding marijuana use?

A I would say between 15 and 20. Again, let me parse that a little bit. They're not formal consultations. They might just call me or email me because I'm a known domain expert in the state.

Q Are you currently employed, sir?

A Yes.

Q By whom?

A I have an advisory role at a marijuana dispensary in Vermont called The Tea House.

Q Can you also explain to the Court what the Pavilion Group is?

A Certainly. The Pavilion Group is an LLC I formed shortly after I retired from clinical medicine, and it is ostensibly to be a vehicle with which I can give advice primarily to minorities and marginalized people to perhaps assist them in pursuing opportunities in the marijuana space.

Q Sir, do you receive a salary from that organization?

A No.

Q You referenced a few minutes ago, your continued involvement with Dartmouth. Are there any other medical schools that you currently work with?

A Yes, I am a mentor to students as well at the University of Vermont School of Medicine.

Q And also you commented on some of the organizations that you currently have a role in. Can you also tell the Court about Hemp for Victory?

A Certainly. As a U.S. Navy veteran, I have an interest in veterans affairs, and Hemp for Victory is a nonprofit out of Texas that approached me and wanted my opinion on aspects of medical marijuana with respect to veterans affairs.

Q How about Veterans Cannabis Project?

A That is also a Texas-born organization allied with Hemp for Victory, and I play a similar role, although of a much lesser degree.

Q Are you familiar with the organization or the group referred to as Therapeutic Medical Cannabis Oversight Board for New Hampshire?

A Yes.

Q Sir, Doctor, can you please explain to the Court what that is?

A Certainly. That is an organization. It's a division of the Department of Health and Human Services of the State of New Hampshire, and it serves an advisory and education role in setting marijuana policy and advising on marijuana policy to the legislature of the State of New Hampshire and as well clinicians, healthcare providers, and patients throughout the state.

Q How did you find yourself on this board?

A I believe my colleague in medicine was the chair of the board, and he knew I was retiring from clinical medicine and he asked if I would sit on it. It required an appointment by then Governor John Sununu, which I received, and I think I've been on that board since 2018.

Q Are you still on that board currently?

A Yes.

MS. RACE: Your Honor, at this point, I would like to present to the witness what the government has marked Exhibit 6 for identification purposes.

(Whereupon, the document referred to was marked as Government's Exhibit No. 6, for identification.)

JUDGE JULIUS: Okay.

THE WITNESS: Thanks.

MS. RACE: Dr. Burchman, after you've had a moment to look at this, if you'll just look up, and I'll ask you. Okay, well, there you go. Dr. Burchman, do you recognize this document?

THE WITNESS: Yes.

BY MS. RACE:

Q What do you recognize it as?

A It's my curriculum vitae.

Q Do you have any changes to this CV, sir?

A Let me look at it briefly. Yeah, a few minor changes, maybe typographical errors.

Q Please, if you'll just explain those changes to the Court.

A On the third page, under Professional Society Memberships, the New England Pain Society is actually a misnomer. It used to be the New England Pain Association and it morphed into something called the Eastern Pain

Association. It says 2002 to present. I don't know when that lapsed. I'm not a present member of that. Further, the American Pain Society on page 4, 2002 to present, that society folded in 2019, and so I'm no longer a member of that. Finally, on page three, under Major Committee Assignments, the Legislative Committee of the New Hampshire Medical Society, I was on that for maybe two years, so that's not a present position as well.

Q Is the rest of this CV accurate related to the times that you were on and off certain organization boards and committees?

A Yes.

Q Okay. Outside of those changes, are there any other changes that we need to discuss related to the CV?

A No.

Q Okay. So with those changes taken into consideration, is this a fair and accurate representation of your current CV with the changes noted?

A Yes.

Q And does this fairly depict your education and your studies, Dr. Burchman?

A Yes.

MS. RACE: At this point, the government moves to introduce Exhibit 6 into evidence.

JUDGE JULIUS: Any objection?

MR. HARRINGTON: No objection.

JUDGE JULIUS: Any objection from anybody?

MR. EVANS: None.

MR. HARRINGTON: No, Your Honor.

JUDGE JULIUS: Okay. Admitted. Thank you, Counsel.

(Whereupon, the above-referred to document marked as Government's Exhibit No. 6 was received into evidence.)

MS. RACE: Thank you. All right, Dr. Burchman, let's now talk a little bit more about your medical training and experience. Sir, do you know the phrase board certified?

THE WITNESS: Yes.

BY MS. RACE:

Q Can you please explain to the Court what that means?

A Board certification is a designation by the American Board of Medical Specialties and it

demonstrates a higher degree of proficiency in a surgical or medical subspecialty, and it's usually conferred following a residency of medical education.

Q Is there a separate test associated with board certifications?

A Yes, there are several. There is a part 1, part 2, and part 3. They have to do with basic science and then the understanding and appreciation of the breadth of whatever the residency training is, and then finally with the anesthesia side of things, there was an oral examination.

Q And that brings me to my next question, Doctor. Have you ever been board certified in a particular specialty?

A Yes.

Q Okay. Can you explain those, please? Identify them for the record.

A Board certified in anesthesiology as well board certified in pain medicine.

Q Can you explain the difference between anesthesiology and pain management, please?

A Yes. Anesthesiology is the practice of rendering patients insensate to surgical

procedures, and pain medicine is the study of pain management where we evaluate and manage patients with acute and chronic pain.

Q Are you currently board certified in both anesthesiology and pain management?

A No.

Q Are you currently board certified in anesthesiology?

A I am.

Q Okay. But not in pain management?

A That's correct.

Q Okay. When did that lapse?

A That's a 10-year designation. I took my pain boards in 2005, and it lasted 10 years.

Q If we can move into your undergrad now, sir. Can you talk to us? Where did you go to undergrad? What degree did you get? And then we'll move up to present day.

A I attended Cornell University. I graduated with a degree, a BA -- a BS I should say, in Neurobiology and Behavior.

Q And then what did you do?

A Then I went to medical school at George Washington University School of Health Sciences and Medicine.

Q Were you in the Navy when you went to medical school, sir?

A Yeah, I couldn't afford medical school and I received a health profession scholarship and was commissioned as a naval officer, and they paid my way through medical school. I owed an obligation to service with the Navy following graduation of medical school.

Q So after medical school, what did you do?

A I attended an internship with the Navy at Oakland Naval Hospital in Oakland, California.

Q What was the internship in?

A It was a unique internship designated a rotating internship, which meant I rotated on all of the medical specialties; pediatrics, obstetrics, emergency medicine, intensive care, surgery, drug and rehabilitation and I did that to gain a breadth of an understanding of the practice of medicine.

Q At some point, Doctor, did you move on to a residency?

A I did.

Q Okay. Can you talk to the Court about

that?

A Yes. My residency was delayed approximately two years because following internship I needed to be deployed, so I was a general medical officer on a ship. Following the discharge from that position, I obtained a residency at Massachusetts General Hospital in Boston.

Q Can you explain, please, the difference between an internship and a residency?

A An internship is a medical experiential education, clinical, dealing with patient care and that's conferred almost universally following graduation from medical school. Residency training deals with a specialty of the choice of, you know, myself, for example, and so I chose a residency in anesthesiology.

Q Why did you choose anesthesiology?

A For a long period of time, I was interested in how drugs act on the brain and as well the anatomy of the central nervous system, and there was a natural inclination to pursue a degree in anesthesiology, a pursuit of residency in anesthesiology, because that combined my interest in drugs, pharmacology, and the nervous

system.

Q Did you go on to other residencies and fellowships?

A Yes. Following the anesthesiology residency, I pursued a -- first of all, I wanted to have a pain fellowship, but Harvard did not offer one at that time. There were no pain fellowships when I was training. I took a fellowship in neurosurgical anesthesia, which further consolidated my interest in the central nervous system. Additionally, because I was interested in pain, I did an advanced pain management track during that residency and to go on, I pursued a fellowship in obstetrical anesthesia, which sort of highlighted pain management in a specific type of patient. I further did a fellowship in ambulatory surgical anesthesia, which at the time was a new specialty.

Q In these residencies and fellowships that you've just discussed, did you treat patients with acute pain?

A Yes.

Q Did you also treat patients with chronic pain?

A Yes.

Q Did you use opioids in the treatment of your patients during these residencies?

A Yes.

Q Did you return to the Navy at any point?

A Yes. Following my fellowships, I actually stayed on at Mass General and Harvard for a few months as clinical instructor until the Navy picked me up again for active duty since I owed them years from their subsidizing my medical education.

Q What did you then do for the Navy?

A I was an anesthesiologist stationed at a base in Puerto Rico.

Q Were you ever the chair of a Department of Anesthesiology for the Navy?

A Yes. At the hospital in Roosevelt Roads, Puerto Rico, I was the chair of the department.

Q Did you treat patients -- personally treat patients with acute pain while you were working at that hospital for the Navy?

A Yes.

Q Did you also treat patients who

suffered from chronic pain?

A Yes, I did.

Q And did you use opioids in the treatment of those patients?

A Absolutely.

Q Where do you go next?

A Following my stint in Puerto Rico, I was discharged from the Navy, and I took a job with the University of Maryland Medical System in Baltimore.

Q What title did you get in that position?

A I was the chief of anesthesia at one of their affiliate hospitals, James Lawrence Kernan Hospital.

Q Did you also have a title in the pain service?

A Yeah, I practiced pain management at James Lawrence Kernan.

Q Did you use opioids in the treatment of your patients at the James Lawrence Hospital?

A Yes.

Q Were you treating patients with chronic pain at that point?

A Yes, I was.

Q Where'd you go next?
A I then left the University of Maryland, where I had a faculty position, and took a job in private practice in York, Pennsylvania.
Q What was your role in that practice?
A I was an attending clinical anesthesiologist, and as well I started a pain management center.
Q Did you see patients while you were practicing in York, Pennsylvania?
A Yes.
Q And did the patients that you treated, did they suffer from acute pain?
A Yes.
Q Did you also treat patients that suffered from chronic pain?
A Yes.
Q Did you use opioids in the treatment of patients who suffered from chronic pain?
A Yes.
Q During your time at York, did you ever prescribe synthetic THC products for the treatment of your pain patients?
A Yes.
Q Can you talk to us about that, please?

A Certainly. It was very clear to me, particularly in the late ‘90s, that the opioid epidemic was beginning and new data was coming out describing chronic opioid management for chronic pain patients as not really being a sustainable medical therapy. As such, pain management docs across the country, but particularly with myself as well, were interested in non-opioid analgesics for these patients. It became obvious that the endocannabinoid system was starting to become well-described in medical literature, and me being kind of a neurochemistry geek, I was very fascinated by it because I'd really never heard anything about it in medical school. The FDA had recently approved a synthetic THC, which was, at least in the literature, demonstrated to have potential analgesic effects. Sorry for the long-winded answer, but we were using dronabinol in some of our patients, which is synthetic THC.

Q I think we're going to get to this a little bit more in depth later, but if we can just for the chronology, I'm going to move you now into your next stop, which is Dartmouth. Can you please talk to us about what you did for

Dartmouth?

A I was a clinical anesthesiologist and as well I was the division director of the neurosurgical anesthesia program. I also directed the post-anesthesia care unit, the same-day surgical unit. There was another title I was the director of surgical innovation.

Q Did you perform any work with the acute pain service?

A Yes. I, in fact, I ran the acute pain service for a few years, and, as well, I was actively involved in the chronic pain management center there.

Q Were you on rotation at the pain clinic while you were at Dartmouth?

A Yes.

Q How many times a week or month, however you want to quantify it, were you on rotation at the pain clinic?

A It was variable, but generally one to three times a week, depending on the surgical schedule and their needs.

Q Did you treat chronic pain patients while you were at the pain clinic?

A Yes.

Q Can you please –
A -- well, exclusively, I should say.
Q Okay. I've jumped into this, but I didn't ask you to define. Can you please define for us acute pain versus chronic pain?
A Acute pain is generally self-limited. It most reasonably can be described as what one would have if they were having a surgical procedure or if you had an acute trauma. Chronic pain is described as any moderate-to-severe pain lasting three months despite medical management.
Q And in your treatment of your chronic pain patients while you were at Dartmouth, did you use opioids?
A Yes.
Q In your treatment of chronic pain patients while you were at Dartmouth, did you use FDA-approved THC synthetics?
A Yes, we did.
Q And in your treatment of chronic pain patients while you were at Dartmouth, did you treat those patients also with botanical marijuana?
A Not at that time, but once botanical

marijuana was available to patients as a medical therapeutic, which I believe was 2016, we did.

Q Do you recall when you left Dartmouth?

A 2019.

Q Okay. So between 2016 and 2019, were you using marijuana in the treatment of chronic pain patients while you were at Dartmouth?

A Yes.

Q We're going to jump back to teaching appointments just quickly and finish this off, sir. Can you talk to us quickly about your teaching appointments? Say we'll start first with Dartmouth. What did you teach?

A I taught anesthesiology to medical students and residents, as well as fellows, as principles of surgical operative care for anesthetized patients, as well as pain management.

MR. EVANS: Your Honor, if I may make just a brief objection.

JUDGE JULIUS: Just be sure to speak into the microphone so we can hear you.

MR. EVANS: Okay, I'm sorry. You know, this is about marijuana, and counsel is calling Marinol marijuana. It is not marijuana. It is

a synthetic THC. So it would be inappropriate to call that marijuana medicine. I just want to get that on the record and help clarify with everybody so we know what we're talking about. Synthetic is not marijuana. Thank you.

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

MS. RACE: I refer to it as FDA-approved synthetic marijuana. It was clear that the witness understood what that meant. I'm happy for this note to be on the record. I don't think that should delay the testimony further.

MR. EVANS: It's a synthetic THC, and I would like the record to accurately reflect what it means. It's not marijuana. He understood it as medical marijuana, but it's not.

JUDGE JULIUS: Okay. Thank you, sir. I think it's noted for the record, and Ms. Race, just please be --

MS. RACE: We have no objections.

JUDGE JULIUS: Specific and accurate in our characterizations of everything going forward just for everyone, but please proceed.

MS. RACE: Thank you, Your Honor.

JUDGE JULIUS: Thank you, Mr. Evans.

MS. RACE: If we can go back to your teaching appointments, you've previously talked to us about your teaching appointment for pain management at Dartmouth. Can you also talk to us about your teaching appointment for the University of Maryland?

THE WITNESS: Yes, as the chief of the department within the University of Maryland Medical System, I taught University of Maryland medical students as well as Johns Hopkins students that rotated through.

BY MS. RACE:

Q Did you teach them pain management courses?

A Yes.

Q How about for Harvard Medical School? Did you teach for them?

A Yes. I taught Harvard medical students, as well as BU medical students at Massachusetts General and the Brigham and Women's Hospital.

Q What was the course title or topic that you taught them?

A Well, I was an attending

anesthesiologist and pain management doc, and it would be lectures on the topic of chronic pain management and acute pain management as well.

Q Going back to your time at Dartmouth, were you involved in any international conferences?

A Yes.

Q On what topic?

A Cannabinoid therapeutics. Marijuana contains molecules called cannabinoids. That's derived from the word cannabis, and those are the psychoactive agents that are actually the molecules that confer clinical effects.

Q Were you involved in the planning of the production of these conferences at all at Dartmouth?

A Yes.

Q Okay. What was your position?

A I was the co-director.

Q Doctor, in your roles, both in your practice as well currently as we sit here today, do you review the scientific literature on the use of marijuana for pain patients?

A Yes.

Q Do you use that information, or did you

use that information in your treatment of patients?

A Yes.

Q And do you currently use that information in your consultations with other medical providers?

A Yes.

Q Have you ever been designated as an expert in a trial before?

A Yes.

Q How many times?

A Between 6 and 10.

Q And what was your expert designation? Was it as a medical expert?

A Medical expert.

Q In any specialty?

A Anesthesiology and pain management.

Q What types of courts were you so designated?

A I don't understand the question.

Q Was it a state court or federal court or --

A State courts.

Q As we sit here today, about how many pain patients have you treated with opioids?

A Thousands, well over 10,000.
Q As we sit here today, how many pain patients have you treated with synthetic THC?
A I would say several hundred.
Q As we sit here today, how many pain patients have you treated with botanical marijuana?
A Between 2 and 400. It really depends. You know, when I was at Dartmouth and we were utilizing medical marijuana, that is marijuana that was allowed in the state for patient use, it was kind of a team effort, so it was myself as well as medical students and fellows and residents, as well as nurse practitioners I worked with or worked under me. So, when I state I used it and prescribed it, I want to put it in the context of myself as the supervising physician or the attending physician, and they were using it under my guidance.
Q And would that be also with your direction and approval?
A Yes.
MS. RACE: Okay. At this point, Your Honor, the government would like to offer Dr. Burchman as a medical expert in pain management,

including the use of opioids and marijuana for the treatment of pain. We recognize, because of the preliminary order, that this would be likely an introduction of this witness as an expert witness provisionally for argument to be taken later.

JUDGE JULIUS: Understood.

MR. EVANS: No objection.

JUDGE JULIUS: Okay. Thank you. We'll proceed with the provisional and then as to be argued in the closing statements if there's any challenge to the expertise. If you could just reiterate the expertise that he's being proffered for.

MS. RACE: Yes, Your Honor. The government would like to introduce Dr. Burchman and have him admitted as an expert witness in pain management, specifically including the use of opioids and marijuana for the treatment of pain.

JUDGE JULIUS: Understood. Provisionally admitted.

MR. EVANS: Your Honor, I would like to, if I may, ask the doctor one question that may help that –

JUDGE JULIUS: You'll have an opportunity to do that on your cross-examination, Mr. Evans.

MR. EVANS: Okay, fine. I --

JUDGE JULIUS: Thank you.

MR. EVANS: So I'm objecting to having him qualify as an expert until I can ask that question.

JUDGE JULIUS: Understood. It's provisionally accepted subject to cross and arguments in the closing arguments or closing statements. Thank you. Ms. Race, please continue.

MS. RACE: Thank you, Your Honor. Dr. Burchman, I'd like to talk to you about brain science for a moment, please. How does marijuana work in the brain for the treatment of pain?

THE WITNESS: There exists within the body a system called the endocannabinoid system, and that is how marijuana works. The endocannabinoid system is a very diffuse system within the central nervous system and the peripheral nervous system. It's mediated by the presence of what are called cannabinoid

receptors. A receptor in a cell is kind of like an inbox or a lock into which a key fits, and the molecules that circulate in the bloodstream go into the lock and open it, and therefore, a channel exists in a cell, and that's how drugs and molecules get into cells.

The endocannabinoid receptors, the cannabinoid 1 and cannabinoid 2 receptors in the brain, are part of a family of receptors in the central nervous system that number in the hundreds of billions. They belong to a family called the G protein coupled receptor and that receptor is very important. That's the receptor that's on all of the cells in the body, and it allows activities to occur like glucose can enter the cell and epinephrine and dopamine and hormones. The endocannabinoid receptor, which is the receptor that -- I should say the cannabinoid receptor, is the one that allows marijuana-like particles that are produced by the body -- the body produces two different compounds: 2-arachidonoylglycerol and anandamide. Those are special compounds which are pretty much like compounds that the marijuana plant produces. The important, interesting thing is

it turns out the cannabinoid receptor is the most prevalent receptor in the central nervous system and nobody knew this 30 or 40 years ago.

MR. EVANS: Judge, I would object at this time to relevance as well as narrative.

JUDGE JULIUS: Ms. Race, response to the objection?

MS. RACE: I asked Dr. Burchman to explain the science behind marijuana in the treatment of pain, and I think he's still working on that?

THE WITNESS: Right.

JUDGE JULIUS: I'll overrule the objection for now. It may be helpful, as we go through, to ask directed questions as he goes.

MS. RACE: Thank you, Your Honor.

JUDGE JULIUS: Just to make sure that we're getting directed testimony, but continue with your answer, and then we'll --

THE WITNESS: It turns out that the cannabinoid receptor, being so important, is located in areas of the cerebral cortex as well as the spinal cord that relate to pain control and modulation, and therefore, when marijuana-like molecules -- the molecules, the

cannabinoids in marijuana -- latch onto these cannabinoid receptors, pain is affected -- I should say the sensation of pain, and pain control can occur.

MS. RACE: Dr. Burchman, if I can bring us back to your time at York Hospital, at that point, at your time at York, were you talking to patients or were your patients communicating with you during your treatment, during your patient care, about the use of marijuana for pain?

MR. McNICHOLS: Judge, I would object to hearsay as well as relevance. I don't see how that question goes to the eight-part test. I don't see how that question or any conceivable answer goes to whether or not there's an abuse, whether or not there's a CAMU, or whether or not there's dependability. His own personal experiences with patients is irrelevant to all of those things, Your Honor.

MR. EVANS: I'd also like to join in. Judge, I don't think he testified that he worked in York Hospital. He said he worked at York, and it could have been in a private practice, not in the hospital.

JUDGE JULIUS: Thank you. Response to the objections?

MS. RACE: Yes, Your Honor. There is a specific exemption to hearsay when we're talking about patient and physician treatment because there's an inference of reliability there, that's actually 803.4 under the Federal Rules of Evidence, so I think there's no hearsay concern here. The government's argument would be that there's no hearsay concern here. We did, in the last witness, hear about the CAMU and certainly the government's position that there's a medical use. We now are presenting a witness who's going to talk about that medical use, and that's the purpose of this testimony.

JUDGE JULIUS: Did you have something to add?

MR. McNICHOLS: I would like to, Your Honor.

JUDGE JULIUS: Go ahead.

MR. McNICHOLS: Thank you. Judge, under the CAMU test, the question is whether or not there's credible literature that supports the use of cannabis as medicine, and then whether or not, based on the literature, there's

overriding health concerns. That is not what this goes to. We would object to relevance at this time.

MR. EVANS: Your Honor, I'm concerned about York Hospital because I own a nursing home right next to York Hospital and if he's speaking as a physician at York Hospital about cannabis and so forth, it implies that York Hospital was in favor of it at the time or whatever. Our nursing home will not use cannabis, and I just want to get it clear, who is he working for?

JUDGE JULIUS: Understood, Mr. Evans. I will remind those in the gallery to maintain decorum. Although the Federal Rules of Evidence do not strictly apply here, they are a good guideline for what we do. I will say that there is a hearsay objection. Tailor the questions to be as relevant as possible. I will allow the questions. And also, as a follow up on Mr. Evans' point, if we could get clarity on what he means when he says he worked at York. So overruled, and please just get clarity at some point.

MS. RACE: Yes, Your Honor.

JUDGE JULIUS: Thank you.

MS. RACE: Can you please provide the Court information on where you worked in York?

THE WITNESS: I was an attending physician at York Hospital and, as well, the director of the York Hospital Pain Management Center that I started.

MS. RACE: Thank you. If I may, Your Honor, ask the question about his patient care while he was there?

JUDGE JULIUS: Proceed.

MS. RACE: Thank you.

MR. McNICHOLS: Judge, I would just make one more objection for the record. If this is purportedly supposed to go towards the CAMU, on page 25 of the HHS opinion, it discusses what factors are relevant with respect to the CAMU, and it's one: favorable clinical studies. His treating the patients is not favorable clinical studies. Number two, it's whether qualified expert organizations have opined in favor of it. His experience treating patients has nothing to do with expert organizations.

Factors that weigh against it is data or information likely to indicate that medical use of substances is associated with an

unacceptably high safety risk. That's not what his testimony is going to. Number two, whether or not there's clinical studies with negative efficacy. His personal experience treating patients has nothing to do with that clinical evidence. And number three, whether or not qualified organizations have weighed in against recommending cannabis for medical purposes. Again, his personal experience in treating patients and what he's seen from them has nothing to do with any of those factors. Based on that, we don't think it's relevant, and we'd object, Your Honor.

JUDGE JULIUS: Do you want to respond to the objection?

MS. RACE: Yes, Your Honor, I would like to. Thank you very much. Part 1 of the CAMU test specifically related to widespread use by healthcare providers and their use of medicinal marijuana in practices, particularly in states, of course, where they have legalized such thing. Dr. Burchman has already testified that he not only is involved or was involved in the practice of pain management using medical marijuana for New Hampshire, but he actually

sits on the oversight board. I think that this clearly goes to part 1. Part 1 is a factor that FDA took into consideration when they were doing the part 2 of the part 2 test, and so I think that it is entirely relevant.

JUDGE JULIUS: Understood. I'll overrule the objection. You can continue, Counsel. Thank you.

MS. RACE: Thank you. Dr. Burchman, let's go back to York, if we can. During your time at York, did you talk to patients during your patient interactions about the use of marijuana to treat their pain?

THE WITNESS: When I was in Pennsylvania, marijuana was not legalized for the use of pain management or any purpose, yet the patients were coming to me and giving me anecdotal stories. I had a patient with prostate cancer who was on high-dose opioids, and he volunteered to me, He was educating me about the fact that, Hey, doc, I don't need as much MS Contin. It wasn't OxyContin at the time; it was morphine sulfate. That prompted me to actually begin what I feel is the arc of my scientific inquiry and investigation into

cannabinoids as an adjunct to analgesia --

MR. McNICHOLS: Judge, I --

THE WITNESS: But it wasn't available for us as yet.

MR. McNICHOLS: Judge, I would just renew the objection for the record. Under part 1 of the CAMU test, what should be considered is whether or not there's widespread current experience with medical use of marijuana in the United States by licensed HCPs. His personal journey with respect to how he came to cannabis is irrelevant to that. His personal experience with respect to him treating patients is irrelevant to the question of whether or not there's widespread use among HCPs.

JUDGE JULIUS: Ms. Race?

MS. RACE: Your Honor, in order for there to be widespread use, there's got to be specific use, just a lot of specific use, and we have an example in the courtroom today who is willing to talk about his experience with that specific use, which then forms, of course, provides some additional benefit and background for the Court when considering the widespread use. This is entirely supportive of the part

one and part two of the CAMU.

JUDGE JULIUS: Go ahead.

MR. McNICHOLS: Judge, she's saying that specific use shows widespread use. That's just a contradiction in terms. The question is whether or not there's widespread use among HCPs. His personal experience treating ~~physicians~~ patients as one doctor, which is what he's testifying to, is entirely irrelevant to that.

JUDGE JULIUS: Ms. Race?

MS. RACE: I think relevancy is a pretty low burden, and the government has clearly met it. To the extent that counsel has some concern about the weight of the evidence, I think that that's a very different argument than excluding it altogether. This is evidence of part 1 CAMU, and this is background. We're moving into some additional pieces. I'm happy to get that on the record.

JUDGE JULIUS: Understood. I do tend to agree with Ms. Race on the issue of exclusion versus weight. I will overrule the objection. If you want to make a standing objection regarding this line of questioning, I would allow for you to do that. Also, you'll all have

an opportunity to argue weight and all these other issues in your closing statements as well.

MR. McNICHOLS: Judge, I would like to take the Court up on the opportunity to make a standing objection, just so there's no further interruption.

JUDGE JULIUS: Understood. Thank you, Counsel. Ms. Race, please continue.

MS. RACE: Thank you. Dr. Burchman, you talked about your experiences at York Hospital. Did that then factor into your later work at Dartmouth?

THE WITNESS: Yes.

BY MS. RACE:

Q Please explain how.

A New England was significantly hit by the opioid crisis, and opioids at the time, the early 2000s, was our primary means of tackling chronic pain. Myself, as well as other physicians within the pain clinic, were looking for alternative analgesic options, and one of them was synthetic THC, which was an FDA-approved drug. Knowing what I know about the endocannabinoid system, it seemed like a reasonable approach in addition to other agents,

and we began to employ, say, from 2006 to 2015, Marinol, dronabinol, as one of the agents to add to our patients' regimens.

Q At some point at Dartmouth, did you start to transition patients from opioids to botanical marijuana?

A Yes.

Q Can you explain to the Court what transition means?

A Transition means to limit and hopefully lower the maintenance doses of opioids in these patients. Some of these patients were on what we call, in the medical community, industrial doses. These are supraphysiologic doses, and there are significant risks associated with that. So, the impetus for safety was to try and limit opioids.

Once medical marijuana, I should say marijuana, was available to medical patients in the state, which I believe was 2016, we would very avidly use that ability to limit opioids.

Q Now, when you're talking opioids, are you talking Schedule II opioids, or is there something else you're referencing?

A No, these are Schedule II, OxyContin,

hydromorphone, which is Dilaudid.

Q Did the pain patients that you were transitioning from opioids to marijuana, were those chronic pain patients?

A Yes.

Q Did you make a determination as to whether or not marijuana assisted or benefitted those chronic pain patients at Dartmouth?

A Yes, we made a determination that it was positive.

Q That it benefitted the patients?

A Yes.

Q So going back to the transition process, is it such that when you're transitioning a patient from opioids to marijuana, you start them on marijuana on Monday, and they no longer need opioids on Tuesday?

MR. EVANS: Objection, leading.

JUDGE JULIUS: I'll sustain that.

MS. RACE: Can you talk about the process, sir?

THE WITNESS: The process varies between patients, but I wish it was as quick as you alluded. The process is generally a slow

one, where we introduce the cannabinoid, marijuana in this case and then discuss with the patient the slow draw down, which can be months until the ultimate goal to be not on opioids at all.

BY MS. RACE:

Q Were there patients that you were unable to transition fully off of opioids?

A Yes.

Q And were there separate other patients that you didn't even attempt to transition off of opioids?

A Yes.

Q Was it a patient-specific analysis?

A Yes.

Q Now, Dr. Burchman, based on your training and experience, do you have an opinion to a reasonable degree of medical certainty whether marijuana provides a therapeutic benefit for pain patients?

A Yes.

Q What is that opinion?

A That marijuana is extremely helpful in chronic pain patients as an effective means of analgesia.

Q Sir, what do you base that opinion on?
A Well, my medical judgment, which is comprised of my training, where I started out with advanced pain management, my knowledge of the endocannabinoid system and how the neurologic system works, and then finally, and perhaps more importantly, my experiential knowledge, where treating thousands of patients with agents such as the ones we described and the results thereof.
Q Sir, are you aware of any literature, scientific literature, in support of your position?
A Yes.
Q Can you provide that information to the Court, please, on the scientific literature?
A Certainly. The scientific literature that describes the endocannabinoid system and the receptors where there's receptor density in the cerebral cortex that correlates with where pain control can occur with cannabinoids. There was a landmark review paper by Dr. Ethan Russo that described why botanical marijuana is superior to an isolate like synthetic THC. That was actually very interesting, and it's because

botanical marijuana contains multiple cannabinoids, not just THC, but there's CBD, which is cannabidiol. There are terpenes, which are specific plant alcohols like limonene and myrcene. These also confer analgesic effects that are lacking in an FDA-approved synthetic THC.

Q Are there any more recent studies that you're aware of and you can discuss related to the benefits of marijuana in the treatment of pain?

A Yes, quite a few, but I would focus on one I wrote with a bunch of colleagues that was published in 2017. It was actually one of the largest studies at the time, and it was a patient study. It was what we call a real-world study where we had patients who, through survey data, demonstrated that if they used marijuana, botanical marijuana, they decreased their utilization of opioids, which confirmed all of the experience we had prior and even more recently -- and let me just add, in my role as ~~the~~ a part of the Therapeutic Cannabis Board in New Hampshire, we're required to continuously review current literature.

As it relates to chronic pain, for example, one of my colleagues from Harvard, Stacy Gruber, recently -- actually, I think it was 2021 -- she kind of replicated our study from New England. But it was a very well-designed, albeit small, study that was pretty conclusive in the effectiveness of marijuana for pain. But if I could just add one more thing, the linchpin in terms of the ability to recognize marijuana a pain component, pain control component --

MR. EVANS: Objection, narrative.

JUDGE JULIUS: I mean, he's still talking about the literature. Are you still talking about the literature?

THE WITNESS: I am.

JUDGE JULIUS: Overruled.

THE WITNESS: The 2017 review publication by the National Academy of Science, Engineering, and Medicine, it's a 440-page document. I can cite you the chapter and verse on page 90. It says with extreme confidence that marijuana is an effective pain control agent.

MS. RACE: Thank you, Doctor. If I can

just pivot us to some patient care -- your patient care. In talking to you about your opinion, you expressed a basis for it in the science, thank you, and also in your patient interactions. Now, let's pivot to the patient interactions, please. Can you please provide this Court some of the common patient interactions you had at Dartmouth while you were transitioning patients from opioids to marijuana?

MR. KENNEALLY: Judge, I would renew my objection. This is entirely irrelevant to the eight-factor test. This is entirely irrelevant to the first factor of abuse, as well as CAMU, as well as dependability. His personal experience and the hearsay statements of specific individuals, patients who we don't know, who we can't identify, who we weren't even told of in terms of their disclosure, not only is it irrelevant, it's also a process violation at this point because we received two paragraphs with respect to what the doctor was testifying to, and nowhere do they tell us that he's going to be testifying with respect to specific patients, who these patients are, so that we

have the opportunity to test that.

JUDGE JULIUS: Ms. Race, response to the objection.

MS. RACE: Your Honor, this does appear to be a very similar objection that was lodged earlier, and there's a standing objection on the record. I asked Dr. Burchman whether there's a common patient type, whether he could provide some examples of common patient types in his patient treatment. This goes directly to the use of marijuana for the treatment of pain, which is, of course, a CAMU-supported condition. As a result, all of this continues to be relevant. We're not going to give specific patient names during the course of this public setting, but the doctor's engagement with his patients and common patient examples, I think, is certainly well within the part 1 and part 2 analysis.

JUDGE JULIUS: I will overrule the objection, and of course, all counsel have opportunity to cross-examine and elicit any information you want on cross. So overruled. Please continue, Ms. Race.

MS. RACE: Yes, Your Honor. Thank you.

Dr. Burchman, if you can provide us some common patient examples from your interactions with those patients during your time at Dartmouth that you transitioned off of opioids to marijuana.

THE WITNESS: Sure. I had a young woman in her mid-thirties metastatic breast cancer to her spine. She had adjuvant cancer chemotherapy as well as radiation. She had a mastectomy. She developed horrible radiation-induced pain to her chest wall as well as the lytic lesions in her bone. She was on large doses of round-the-clock opioids, I believe it was OxyContin, and she went from a cycle of obtundation, which means heavy sedation, nausea, vomiting. She would wake up in pain, take further drugs. That's pretty cyclic and common for these kinds of patients on high-dose opioids. We transitioned her, I believe, to a tincture. A tincture is kind of an essence of the marijuana product, a couple of drops under the tongue. It's absorbed very quickly. She was miserable, it was a horrible situation. I would say over 8 to 12 weeks, we were able to get her to minimal opioids. She was able to

function with her activities of daily living. She drove a car. All she wanted to do was see her kids play soccer, and that made us very happy.

Q And, Doctor --

MR. KENNEALLY: Judge, I --

MS. RACE: -- do you have a number of--

MR. KENNEALLY: Judge, I would object, and I don't mean to belabor the point. But I just, for the record, would like a ruling with respect to the process objection that I've lodged on behalf of DUID Voices as well as Mr. Finn. So if you look at the attachment that was provided by the government to all the participants in this case on June 24th of 2026, it sets forth what Dr. Burchman is going to testify to, and it's on page 4 through 10. The first paragraph talks about he's going to testify as a fact witness. He's also going to testify with respect to his medical expertise in pain management. He's also going to testify that he routinely reviews the literature. He's also going to testify about safety measures utilized in the industry.

Nowhere in this disclosure does the

government provide us with any information or indication that Dr. Burchman to establish widespread use by healthcare professionals, is going to talk about his personal interactions with patients. We think that's a due process violation at this point, Your Honor, and we would object.

JUDGE JULIUS: What I read is Dr. Burchman will testify that he provided direct patient care for pain patients as an anesthesiologist and pain management physician following his residency and fellowship training in 1986 until 2019. That is going to inform his opinion as to the expertise that he's been proffered for on and we've accepted on a provisional basis. So, I find that this was sufficient to cover what he's discussing in this testimony, so I will overrule the objection and Ms. Race may continue. Thank you.

MS. RACE: Thank you, Your Honor. Now, Dr. Burchman, you just gave us one example. Did you have many examples? We don't have to go through all of them, but just for the purpose of the testimony today, did you have many examples with patients who you identified had benefitted

from the transition from opioids to marijuana?

THE WITNESS: Yes.

MR. EVANS: Objection. Leading question. The use of the word many.

MS. RACE: Your Honor, I believe that's the question and he answered yes.

MR. EVANS: Well, many is a definite. It implies that there's a large group. I think a proper way of asking the question: Can you give me a number of how many people you did, or how would you qualify it? It's a leading question. If he says yes, his testimony is many. We don't know what many means.

JUDGE JULIUS: I'll sustain that objection.

MR. EVANS: I'd like to have that struck down.

MS. RACE: Do you have other examples, other patient examples, that followed a similar benefit or presented a similar benefit to you when you were treating them at Dartmouth?

THE WITNESS: Yes, I do, quite a few.

BY MS. RACE:

Q Thank you. Can you define quite a few for the record?

A I could probably expound on dozens, if not hundreds, of individual stories.

Q Thank you. Now, during your interactions, your patient interactions with those hundreds of patients that you just referenced at Dartmouth, did you come to an opinion about whether or not it was beneficial to them to transition them from opioids, those chronic patients, from opioids to marijuana?

A Yes, I did.

Q Okay. How did you determine that -- excuse me, what was that opinion?

A That marijuana is a viable and useful tool in the pain practitioner's toolbox, particularly to transition patients from opioids.

Q And how did you come to that determination relative to your patient population at Dartmouth?

A Well, just the experience of seeing patients in whom we could successfully titrate opioids downward.

Q Now, in your pain practice, sir, did you make a determination as to whether or not marijuana was specifically beneficial to any one

type of pain over another?

A For chronic pain, yes.

Q If you can, sir, I'd like to get you to compare the benefits and risks in your practice between opioids and marijuana.

A Well, in terms of benefits, opioids stand alone as being a superior analgesic agent, and opioids have been in use for thousands of years. It doesn't come without a price, and that price is what we in the business call habituation, which means that you require increasing doses to get the same effect of pain control. Yet, there are downsides to habituation, and one is that as you start to reach really high doses of opioids, you run the risks because opioids have significant risks to the patient such as addiction, serious constipation, stupor, sedation, and ultimately death, which is our most serious concern with respect to opioid use.

Q Now, sir, did you also see habituation with marijuana users?

A Yes.

Q Can you explain the difference, if there is one?

A Well, I won't go into the neurochemical details of how habituation occurs, but there is what we call drug tolerance both in opioids as well as marijuana. The difference is safety. High-dose opioids it does not turn out well. In terms of marijuana, if one becomes addicted or habituated, about 30 percent of patients maybe develop cannabis use disorder, which is a true entity of concern, but the addiction, the dependence, the drug craving is far less with marijuana, as are the consequences of high dose or overdose.

Q If I can turn your attention, please, to your time as an anesthesiologist. This is your personal experience as an anesthesiologist. Did you ever see the habituation present in a patient at an emergency room?

A Yes.

Q Can you explain that?

A It was unfortunately not infrequent that we were called to the emergency room in Dartmouth, as well as other hospitals I was attending physician at, in terms of a respiratory arrest secondary to opioid overdoses. Whether it was fentanyl, commonly

used as a recreational abused drug.

Q About how many times did you present in your anesthesiology practice to an emergency room to care for a patient who had overdosed on opioids?

A Hundreds.

Q About how many of those patients survived?

A It depends on how quickly they got to the hospital, but I would say it was a more -- if they were lucky enough to get into the EMS system and be brought to a hospital and reversed with naloxone, there was probably a 60 to 70 percent resuscitation rate, so 30 percent would die.

Q Do you have a number here that you can provide the Court as to how many overdose-causing death cases you've dealt with related to opioids?

A Can you repeat the question?

Q Yes, Doctor. Can you please provide a number or a range on how many overdose-causing death cases you've been involved with related to opioids?

A Certainly over 2 to 500.

Q Can you also provide us a number, please, on how many overdose-causing death cases you've been involved with involving marijuana?

A None. Because the lethality of marijuana is so rare, it would be a reportable incident.

Q What does reportable incident mean?

A That means we would know about it. It would probably be published by the Morbidity and Mortality Weekly Report by the CDC.

Q If I can bring you back to the habituation or tolerance, your habituation and tolerance testimony from a few minutes ago. Did the habituation -- did, excuse me -- did patients present to you in the hospital with a higher level of opioid tolerance?

A I don't understand the question. I'm sorry.

Q Okay. We'll move on. Dr. Burchman, can you please provide a comparison, if you can, between the withdrawal symptoms that you saw in your patients, the comparison being withdrawal symptoms for opioids and withdrawal symptoms for marijuana?

A Withdrawal from opioids is a horrific

experience. It's accompanied by extreme pain. There is what's called autonomic hyperreflexia, which basically means the patient has very high blood pressure, sweating, tachycardia. If the patient unfortunately has any associated coronary artery disease, there's a significant risk of cardiac arrest and death secondary to that. And it's a protracted syndrome, usually lasting anywhere from 6 to 12 days. And if you've seen one, you'll never forget it, actually.

Q How about the withdrawal symptoms from marijuana to the extent you've experienced that in your patient population?

A Well, I haven't really seen it a lot. I mean, these patients generally don't end up in the hospital, and certainly, you know, anesthesiology wouldn't be called to intubate them because that really doesn't occur. While I won't say it's mild because withdrawal from any drug, even caffeine or nicotine, is particularly bad, but in comparison to opioids, it's fairly mild. When I teach my residents, I say withdrawal from opioids is like a dumpster fire and withdrawal from marijuana, cannabis use

disorder, is more like, you know, the dying glowing ember of a campfire. I can't quantify it, but it's subjectively and qualifyingly significantly less. There's sleeplessness, there's irritability. Sometimes there's anxiety. There can be muscle aches. These are generally not clinical symptoms that would bring somebody to a hospital.

MS. RACE: Thank you very much, Dr. Burchman. If I can ask for a time check.

JUDGE JULIUS: Yes.

MS. RACE: We're not done, but we're almost done, and I want to make sure that we're okay.

JUDGE JULIUS: I was also just going to bring up that we're due for a break sometime soon. I don't know, depending on how much longer you have, if you just want to finish and then we can take our break. We are actually running ahead of schedule.

MS. RACE: Perfect. I wouldn't mind if we could take a break right now, just for a few minutes.

~~MS. RACE~~ JUDGE JULIUS: That's totally fine. We're due for a 15-minute break. I think we were set

for 2:30 anyway.

~~MR. McNICHOLS~~ MR. EVANS: Your Honor, if I can ask, I'm scheduled to do cross tomorrow at 9:00.

JUDGE JULIUS: Yeah. I was going to suggest. If you're going to be ready to go when Ms. Race is finished, I'm happy to hear you this afternoon or if during the break you'd like to discuss with other --

~~MR. McNICHOLS~~ MR. EVANS: I've got some incoming emails from some pain specialists that I haven't had a chance to read yet, and I'd like a chance to look at those before I do the cross. So if we can leave early, that'd be great.

JUDGE JULIUS: Well, what I would prefer is maybe during the break discuss with some of the other interested parties to see if anybody is able to do their cross this afternoon. I'd like to make the most of court time while we have it.

~~MR. McNICHOLS~~ MR. EVANS: I see.

JUDGE JULIUS: In the event that we get behind in the future, I'd like to make up a little bit more. If no one's ready, I'll hear that. But to the extent that any of the interested parties are going to be ready to

cross-examine this afternoon, just feel free to have that conversation and let me know. Okay? Thank you, everyone. Please, Doctor, during the break, don't discuss your testimony with anyone. We'll take a 15-minute break. Let's come back at 2:55. Thank you, everyone.

MS. RACE: Thank you, Your Honor.

JUDGE JULIUS: We'll be in recess till then.

(Whereupon, the above-entitled matter went off the record at 2:40 p.m. and resumed at 2:56 p.m.)

JUDGE JULIUS: Before we resume --

MS. RACE: Yes, Your Honor.

JUDGE JULIUS: -- direct, I just wanted to double-check with the other parties.

Did anyone --

MR. EVANS: Your Honor, Counsel, nobody is prepared, so I can start.

I could do a half an hour now, half an hour in the morning, but I really would like to consult.

Like I said, I've had several emails from people that I think it'd just benefit the whole discussion to get that additional

information.

JUDGE JULIUS: I understand.

I mean, if you -- if you are willing and able to do half an hour just to get us to -- to move the momentum, since we are running ahead of schedule, I want to take advantage of that.

If you're willing to do that, I'm happy to do that.

MR. EVANS: I think I can do it.

JUDGE JULIUS: All right.

MR. EVANS: I think I can do it.

And I'll -- I -- I'm looking forward to, you know, getting to know the Doctor more.

Turns out we have some connection to York Hospital. My uncle was there and -- and so forth.

So --

JUDGE JULIUS: All right.

MR. EVANS: He was stationed at James Lawrence, my brother was a Navy doc, and his name is James Lawrence Evans.

JUDGE JULIUS: Oh, my, it's a small world.

MR. EVANS: So --

JUDGE JULIUS: Well, thank you --

MR. EVANS: He seemed a very compassionate man, I think.

JUDGE JULIUS: Yes.

MR. EVANS: I'm going to enjoy meeting him.

JUDGE JULIUS: Thank you so much, Mr. Evans, I appreciate your flexibility and your willingness to at least start.

MR. EVANS: Sure.

JUDGE JULIUS: And we'll -- we'll just do bifurcation, and we'll -- we'll get another 30-minute start on tomorrow.

So, I very much appreciate that, thank you.

Ms. Race, whenever you're ready, please resume.

MS. RACE: And, Your Honor, if the Government can just be heard on one thing relative to the schedule as well.

JUDGE JULIUS: Sure.

MS. RACE: Dr. Burchman, we have him until the end of Thursday, which is well within the kind of the suggested time line for the Court.

But I just want to note that, you know,

as we're talking through the timing of when cross examination may or may not begin, that's what we have him for, and then, we lose him to a, I think, a sail boat somewhere in a very big body of water.

So --

JUDGE JULIUS: Fair enough.

MS. RACE: And with your indulgence please, Your Honor, I'll be happy to start.

JUDGE JULIUS: Whenever you're ready, Counsel.

MS. RACE: Okay.

JUDGE JULIUS: Thank you.

MS. RACE: Thank you.

DIRECT EXAMINATION

BY MS. RACE:

Q Dr. Burchman, just going back to some of the overdose-causing death discussions that we had or testimony that you provided right before break, can you please talk to the Court about what receptors opioids latch onto in the brain?

A Yes. Primarily the mu receptors, and they are located throughout the central nervous system as well as the spinal cord, and there's a

high density of mu receptors.

That is -- that's the -- that's the structure on the cell that grabs the opioid and then acts.

There is a large concentration of mu receptors in the brainstem, which happens to be the seat of respiratory drive as well as cardiac drive.

But -- but when high-dose opioids affect the mu receptors in the brainstem, it turns off the ability to breathe, basically, and patients die of respiratory arrest.

Q Can you please compare that to marijuana related to the locations of any receptors in the body for marijuana?

A Sure.

The -- the cannabinoid receptors which are, actually, outnumber the mu receptors significantly, are devoid of any presence in the brainstem, which kind of is the intrinsic safety factor.

You could give a patient a huge dose of THC and -- and marijuana, and you won't affect the system of breathing or -- or cardiac function.

Q Sir -- Doctor, if I can now move us to talk about the difference, if there is one, between botanical marijuana and the FDA-approved synthetic THC, please?

A Sure.

I'll talk about it from a kind of a neurochemical standpoint and then a -- a pharmacologic standpoint.

Neurochemically, as I said, botanical marijuana contains over 100 different compounds that are known as cannabinoids, pharmacologically active, the most common ones known as THC and CBD.

So, those are the -- what we call the major cannabinoids, as well as terpenes and esters and other -- other drugs actually that can modulate pain.

Whereas, Dronabinol or Marinol, synthetic THC, is a single isolated, synthesized molecule, devoid of any of the other components I mentioned in the biomass portion.

Q Sir, when you were prescribing -- just to reorient -- reorient ourselves here on the testimony, at some point, you were -- you prescribed synthetic THC to your pain patients?

A That's correct.
Q Is that right? Okay.
Did you come to a determination as to how they responded to that pain treatment?
A Yes.
It -- it was pretty obvious and evident early on, even being informed of it when I was using it in Pennsylvania on patients.
It lacks a lot of the desirable properties we -- we are looking for in terms of analgesia.
Patients didn't like it, it was intoxicating, they would get stoned or fatigued, and they had a extremely dry mouth.
And it was also really expensive, and a lot of them couldn't afford it.
The -- the other issue is one that we call drug titration.
When we give a drug, we're looking for an effect, and while dosage is important, we start low, and we, you know, like we do with antibiotics or with antihypertensive drugs, we -- we give a little until we see the effect.
And then, as a physician or a provider, we know how much to give, because every patient

is different in terms of their requirement.

The fixed doses of Marinol, I think it's two and a half and five milligrams per capsule, you can't really titrate that, you would just give it to the patient.

Whereas, botanical marijuana, which is either inhaled or can be administered orally, we can ch -- we can alter the dose.

We can either cut a gummy, which has THC and other agents, or a tincture, you can put instead of seven drops under the tongue, you could put two drops under the tongue.

And so, in anesthesia, we titrate all the time. We give drugs to patients until they fall asleep, and some might require 300 milligrams of a drug, where some might require 30.

So, this ability to titrate to effect, which is basically what we do in anesthesia, we do that in pain all the time.

And -- and -- and botanical marijuana facilitates that.

We can't do that, certainly can't do it with the synthetics.

Q What is full spectrum marijuana?

A Well, a full spectrum really refers to the product that may be manufactured from marijuana.

When you see the plant material, that is full spectrum, and that means it has the cannabinoids, it has terpenes, it has other plant esters. It's -- it's like a smorgasbord.

Manufacturers can take that, they can isolate the different components, and then reassemble it into a gummy or into a tincture.

If a patient were to be inhaling it, if it was in a -- in a -- a vape cartridge, that -- that agent, the -- the liquid in the vape is kind of the essence of marijuana.

And then, certainly, excuse me, the plant material itself is, by definition, full spectrum.

Q Did you come to a decision -- a medical opinion, pardon me, regarding whether or not the FDA-approved synthetic THC was more or less beneficial to your pain patients than botanical marijuana?

A I did.

Q What was that opinion?

A It wasn't particularly useful.

I mean, it was the best thing we had until we had access to botanical marijuana, in terms of alternate agents for analgesia, if we were going to go the cannabinoid route.

Q Thank you.

Now, Doctor, if I can actually turn your attention to some patient safety questions, please, to round out the conclusion of our -- your testimony today.

Focusing on your patient experiences, your patient treatment experiences in New Hampshire, please, can you walk the Court through what happens, typically in your patient treatment experience, when you have made a recommendation as the physician that your patient could benefit from marijuana?

A Okay.

In New Hampshire, as in all states, actually, we don't prescribe marijuana, all we can do is as a -- as a clinician, we can attest to some established condition that a patient has.

Let's pick cancer, for example, which is fairly common, that for us to see in terms of chronic pain patients, and there are forms we

fill out.

The patient actually brings them to us, or we have them in the clinic, and we Xerox them, and -- and -- and the patient can fill them out, and it describes the pain.

All we do is indicate the condition.

Now, in the State of New Hampshire, it's a little different than most states, the -- the condition and the symptom are linked.

For example, if a patient presents with cancer, and th -- there's a symptom associated with that cancer, such as pain, because they're at a pain clinic -- chronic pain or severe pain -- we can sort of check off the box.

We talk to the patient about that qualification, and then, we release the patient to go obtain marijuana at a state-regulated medical dispensary.

Q Now, sir, Doctor, in your practice, would you then call in the prescription or the recommendation for marijuana to a pharmacy for pick up?

A No.

Q Okay.

Would you call in the prescription or

the recommendation for marijuana to a dispensary for pick up?

A No.

Q To your knowledge, based on your experience in New Hampshire treating patients with marijuana, how does a patient obtain marijuana?

A Once the patient has the -- the blessing of the State, they receive a card, and that's a medical marijuana card.

They can go to one of the approved -- in New Hampshire, they're called alternative treatment centers, and it kind of looks like an apothecary.

They go in, they show an ID, they show their card, and then, they discuss with a dispensary technician, who's not a medical provider, although we give lots of medical education and about risks and factors, different forms of -- of -- of marijuana to the dispensary technician as well as the patient.

And then, the patient and the dispensary technician discuss what the patient will get.

Q Earlier, you testified about dose for

marijuana.

In your -- practicing and your experience as a practicing physician recommending marijuana, how would you advise your -- how did you advise your patients about what dose they should have or receive?

A Well, if you recall, we talked about titration.

And if a patient, say, has, for example, severe pain -- I have a patient, for example, lost his arm in Iraq and has severe neuropathic phantom limb pain -- we would instruct him to start very low and titrate himself, he'll -- he'll self-titrate.

And there's large bodies of literature that support this technique of self-titration.

And he would talk to the dispensary technician, say, my doctor suggests a tincture.

This -- the dispensary technicians, and as I said in -- in my Oversight Committee's work as well as my work on the Board of GraniteLeaf, which is one of the dispensaries in New Hampshire, we stress the fact that dispensary technicians cannot discuss medical aspects with a patient.

They're not healthcare providers, they're not trained in it. They're merely there to offer the patient choices and instruct them on the mode of use.

And hopefully, as a physician, I've done my job about telling the patient how he should dose himself or herself.

Q Do you determine in your physician role recommending marijuana to your pa -- chronic pain patients, do you determine the THC concentration that the patient should receive in the marijuana they ultimately get?

A No.

Q Why not?

A Well, as I said, with titration, the potency is not really a factor for us because if a patient is titrating to effect, they will use the drug until they see the desired effect or a -- a side effect that perhaps is unwarranted.

For -- and -- and we do titration all the time.

If -- if I go to CVS and I buy ibuprofen, it can come in 200, 400, 600, and 800 milligrams.

If I -- if I was playing tennis and my

elbow's really sore, I might take 200, but if it's not working, I'll take another -- is -- to make it 400, up to a limit that is the upper limit of a proper dose, which is 800 milligrams.

And so, very simply my patients, I talk to them about titration very ex-ex-explicitly, and they understand they should start low, and I'll -- I'll give a suggested amount, but I leave it to them to determine because pain is -- is an individual phenomenon, it's totally subjective.

Q How about the types of marijuana products available at the dispensary?

Do you guide your patients and tell them which types of products they should use for their pain?

A I -- I do in the sense that some patients -- let's talk about a patient who is marijuana tolerant, in other words, they already use it.

They might use it in a -- in a fashion where they haven't obtained it from a regulated source.

He might -- he -- I'll -- I'll just say he for the sake of argument -- he might be a --

a smoker. He might, you know, inhale it and take the inhalational route.

And so I'll talk to the patient, and the first thing I want to determine is, do you have any experience with marijuana? And if you do, I want to know about it.

And if he says, well, I can't smoke, I have bronchitis, or, you know, my wife won't let me smoke in the house. We are in a rental unit, so what else is there?

And I'll go through the different formulations, because there's oral formulations, there's a topical formulation, there's a formulation under the gum, you know, under the tongue.

And -- and there's a, as I said, there's a purified form that is actually put in a vape pen, similar to the nicotine vapes, but this is different, same -- same kind of situation, though.

Q As a physician, Dr. Burchman, are you concerned that you cannot control the type of in -- ingestion method that your patients use to receive the marijuana?

A Well, I'm concerned about every aspect

of medical therapy that I suggest to a patient.

Q And how do you handle that concern related to the ingestion method?

A I keep close tabs on my patient.

I will -- I will tell that patient to follow up with me either by a phone call or electronic communication.

Or typically, when I was at Dartmouth and I had the luxury of residents, students that would do a lot of that kind of work, I would just say, hey, David, you know, I want you to call Mrs. Baxter on Friday, see what she did, and we would make an entry in the record to that effect.

And if we need to feedback on her, we will.

Q Do you, in your practice when you were pr -- recommending marijuana for pain patients -- did you limit the amount of product that the patients could obtain at the dispensary?

A Well, I -- I didn't, but the State has limits on what a patient can obtain.

Q Were you ever concerned about the quality of the marijuana product that your patients could obtain from the local dispensary?

A Well, yes.

As -- as I said, I'm concerned about every aspect of medical therapy that I dictate to a patient.

MS. RACE: Were you able to -- or did you, I don't know, are you -- strike that, Your Honor.

How did you handle your concerns about quality in your patient engagement on marijuana?

MR. KENNEALLY: Objection, I would object just to relevance.

I don't believe the Doctor's own personal opinions with regard to the quality of cannabis relates to anything related to the eight-part evaluation, CAMU, or any of the three factors that Your Honor has to consider.

So, I would just renew my standing objection for the record.

JUDGE JULIUS: Understood, thank you.

MR. EVANS: Your Honor, I would like to add an objection that we're supposed to be looking at widespread medical use.

JUDGE JULIUS: Can you -- into the microphone? If you need to sit, that's totally fine.

MR. EVANS: Yeah, we're -- we're supposed to be looking -- this whole study that we're doing has to do with widespread medical use, and we're looking at standards for physicians, and who should be able to do this, and so forth.

This is one doctor's experience, and if the DEA wants to say that what's happening here is what's happening in the rest of the country, they can put that on the record. It'd be very easy to -- to refute.

So, I would just object that this does -- has nothing to do with what's going on in the country with the 30,000 physicians that they say.

And I object that this testimony gets to that point or puts any proof to that point.

It's one -- one doctor's experience.

JUDGE JULIUS: Understood.

Ms. Race, would you like to respond to the objections?

MS. RACE: Yes, Your Honor, just quickly.

I mean, these are similar objections that were raised earlier.

They go to the weight, not the admissibility of it.

But I -- I have, I think, four questions left in the direct examination, and I'm happy to pivot off of that one, if it just is of ease for the benefit of the -- of the debate.

JUDGE JULIUS: I fully understand that the objections have been made.

I will overrule them and allow the testimony.

It -- Counsel are free to argue weight that should be afforded any piece of evidence or testimony, as they deem appropriate.

Please continue.

MS. RACE: Thank you, Your Honor.

Dr. Burchman, are you aware of any QR codes that are applied to marijuana at dispensaries in New Hampshire?

THE WITNESS: Yes.

BY MS. RACE:

Q What do those QR codes provide?

A The QR code is a -- an addition to the product label.

The label has verbal instructions.

The QR code, a patient can snap with a smartphone, excuse me, and they will obtain a -- a readout of the Certificate of Analysis.

Q Was this also beneficial to you, as a physician recommending the product?

A Yes.

Q Okay.

Are you familiar with any warnings that are on labels to marijuana in dispensaries in New Hampshire?

A Yes.

Q Can you please explain some of those warnings that are on the labels in New Hampshire to this Court?

A Yes.

It's a standard label that is authored by the State regulators, and it basically says, this is not an approved modality by the FDA.

Keep out of -- I'm not doing it in any order, keep out of the reach of children.

There may be contaminants.

There may be side effects to use.

Do not operate a motor vehicle under its ~~guidance~~ influence.

Those are the basic ones, and then,

says, this may be produced in a facility that has peanuts and eggs, et cetera.

Q Okay.

Dr. Burchman, are you aware of any lab tests that are run on product sold from New Hampshire dispensaries?

A Yes.

As we discussed, the Certificate of -- of Analysis in the State of New Hampshire, the -- the CoA, as we call it, contains information about constituents, primarily concentrations amounts of THC and CBD, generally by percentage.

It talks about evidence of residual solvents, because solvents -- organic solvents are occasionally used to extract cannabinoids from plant material.

It talks about moisture content, because moisture is a function of whether mold will grow.

And pesticides, evidence of pesticides.

MR. KENNEALLY: Judge, I just -- I, just for the record, I want to review -- I want to renew Dr. Ken Finn as well as DUID Voices objection to the process in this case.

At no point were we notified that this

witness was going to be testifying as to potential adulterants or otherwise with respect to cannabis.

JUDGE JULIUS: Understood, Counsel.

Ms. Race, do you have a response to that objection with regard to this line of questioning?

MS. RACE: Yes, Your Honor.

And also, I mean, I've -- I've got one more question, but I'm happy to respond to this line of questioning.

He -- specifically, the last paragraph on page 4 -- it's actually the last paragraph of his section on page 4, which is the first paragraph of page 4.

It says, Dr. Burchman will also testify about patient safety measures utilized by the industry regarding cultivation, processing, and dispensing of medicinal marijuana, including CAPS, which was part of the testimony today.

The QR codes, also part of the testimony today, Certificates of Analysis, and lab testing.

JUDGE JULIUS: Thank you both, Counsel.

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

object, again, that we're trying to look at the national picture here, and he's only talking about, for all those items, just as it refers to New Hampshire.

There's a wide variety across the states on this.

First of all, the type of marijuana that can be used, the potency, the laboratory tests, the safety features vary from State to State.

And unless he's prepared to talk about what happens in the country, I -- I would object to this testimony.

I -- and I'm not aware, for example, that any of these technicians are licensed by anybody.

The common name for them is bud tenders, usually people that are marijuana users.

But -- but anyway, he's not testifying -- we're here to find out what's going on nationally, widespread medical use.

What are the studies?

We've got one experience here.

JUDGE JULIUS: Ms. Race, anything to

say to that objection?

MS. RACE: Same response, generally, Your Honor.

JUDGE JULIUS: Okay.

So, I do find that the disclosure of what he was intending to testify about is sufficient to allow the line of questioning.

I -- I fully appreciate the -- the nature of Mr. Evans' objection, which was similar to the standing objection by Co-counsel.

I will allow the question, overrule the objection.

Counsel are free to, again, argue the weight that should be afforded the testimony based on what they perceive as the limitations, and you will have an opportunity to ask him any questions that you would like about the scope of his experience.

So, overruled, and feel free to continue.

MS. RACE: Thank you, Your Honor.

Dr. Burchman, just to clarify something, in New Hampshire, are you qualifying a patient?

Did you qualify a patient for the use

of marijuana based on their symptoms or based on a condition?

THE WITNESS: In the State of New Hampshire, it -- it's unique in that both components are required to qualify a patient.

You need a condition as well as a symptom, at least from the period of 2016 to 2020, when they changed it, I believe when they changed it -- no, actually, 2025.

But my point is, a qualifying condition, such as cancer, in association with a qualifying symptom, such as pain.

So, a patient needed to fulfill both of those in order to receive the ability to obtain a marijuana card.

MS. RACE: Thank you, Your Honor.

Thank you, Dr. Burchman.

If, Your Honor -- if I could just have one minute to confer with Counsel, I believe that -- that might be it.

JUDGE JULIUS: Of course.

MS. RACE: Thank you.

JUDGE JULIUS: Thank you, Counsel.

MS. RACE: Your Honor, th -- this is all the questions that the Government has for

Dr. Burchman at this time.

JUDGE JULIUS: Thank you very much, Ms. Race.

MS. RACE: Thank you.

JUDGE JULIUS: And Mr. Evans, thank you again for your flexibility.

Just to make sure we keep track, do you want to split your time, 30 minutes -- 30 minutes? How would you like for us to --

MR. EVANS: I'll do 30 minutes, Your Honor.

JUDGE JULIUS: Okay.

MR. EVANS: I'll do 30 minutes, and I --

JUDGE JULIUS: Reserve 30 for tomorrow?

MR. EVANS: I will -- I will try not to be passionate this time.

JUDGE JULIUS: No worries.

Yeah, I -- so, Mr. Phillips is going to give you a five-minute warning.

MR. EVANS: Thanks a lot.

JUDGE JULIUS: Just know that it's for the 30 minutes, you're not going to be cut off totally, you'll have another 30 tomorrow morning.

CROSS EXAMINATION

MR. EVANS: Yeah, Doctor, I -- you -- you certainly sound like a very compassionate person concerned about your patients, I appreciate that.

How -- how would I --

JUDGE JULIUS: I'm sorry, Mr. Evans, I think our Court reporter's having a hard time picking up the recording.

Are you able to angle it closer to you?

MR. EVANS: Yeah, the cord is kind of --

JUDGE JULIUS: I think we also brought in a block to maybe get it up a little bit higher for you.

MR. EVANS: Okay.

JUDGE JULIUS: If you don't mind.

MR. EVANS: No, we'd love it.

Thank you, thank you.

JUDGE JULIUS: Thank you.

MR. EVANS: So, looking at these dispensaries, you -- you started off the patient's journey into, as you referred to it, marijuana space, that they got an approval by the State.

How did they get that?

THE WITNESS: The -- I mean --

BY MR. EVANS:

Q You started talking about how a patient obtained medical marijuana.

The place you started was that they got an okay ~~for~~ from the State.

Did anything happen before that?

A I'm sorry, I don't quite understand the question.

Q Did somebody just walk up to the State and say, I want to get marijuana, and the State says, okay?

A The patient would obtain two forms, one of which the patient would give to a physician or a healthcare provider.

In -- in the State of New Hampshire, they can go to a dentist and other providers, and that -- that healthcare practitioner would attest to a list of qualifying conditions as well as qualifying symptoms.

And if -- if that physician side of the form is completed, then, the patient fills out the rest, basically demographic data, mails it to the Department of Health.

And then, usually within 14 days

receives a card in the mail, and that enables the patient to go to one of the regulated dispensaries, of which there are only four in the State.

MR. EVANS: Okay.

Well, you -- you -- you started at that point, let's just leave off there.

Now when you say --

JUDGE JULIUS: I'm sorry --

MR. EVANS: -- a list of these --

JUDGE JULIUS: I'm sorry, is there an objection?

MS. RACE: There is, because I just want to make sure that -- that Dr. Burchman has the full ability to provide the answer instead of being cut off by Counsel.

MR. EVANS: Well, he did provide the answer, he said it starts when you get approval from the State, and I was asking what happened before that.

So, he's told what happened before that, and then, he was talking about what happened with the State, so, I got the answer to my question.

JUDGE JULIUS: Okay.

Well, let's make sure that he completes his answer before we move on to the next question.

MR. EVANS: Okay.

JUDGE JULIUS: Thank you, everyone.

MR. EVANS: All right.

So, this list of conditions, who created that list?

THE WITNESS: That list is created by the legislature with advice from the Therapeutic Medical Cannabis Oversight Board, of which I sit.

BY MR. EVANS:

Q Mm-hmm.

Is anybody else involved in that?

A The -- the Oversight Board receives feedback from patients, and from time to time, we consider adding conditions as well as subtracting conditions.

Q Okay.

Are any of these conditions for botanical marijuana approved by the FDA for -- for the use of botanical marijuana?

A If I could just get some clarification?

Q Okay.

Well, let's define botanical marijuana, because we haven't done it yet.

How do you define botanical marijuana?

A Marijuana derived from plant material.

Q Okay.

And that could be something that came about ~~of~~ from the plant material being crushed or the oil being processed out of the plant.

Is that one way that it would be still botanical marijuana?

A Yes.

Q Okay.

And isn't that how solvents get into marijuana because they use butane and other substances like that to push the oil out of the marijuana?

A I can't say, because I'm not a processor.

So, I -- I have a rudimentary understanding of how it's actually processed.

Q Okay.

Now, on these -- these -- well -- well, let me ask you a question.

How would you describe your understanding of how the FDA approves a

medicine? Would you say that -- that is also rudimentary?

A Well, it really depends on what time frame we're talking about. If --

Q Well, right now, your current understanding, do you have only a rudimentary understanding of the FDA process approving medicines as being safe and effective, or do you have an -- a -- a greater understanding of it?

A I -- I -- I'm sorry, but I don't really understand the -- the question.

Q Okay.

Did anybody tell you to respond to questions in that manner?

A No.

Q Okay.

Can I ask, other than attorneys, did you talk with anybody in preparation for your testimony today?

A Yes.

Q Who did you talk to?

A I have personal counsel.

Q I -- I said not your lawyer, did you speak to anybody else?

The -- the communication with your

lawyer are confidential.

Did you speak to anybody else?

A Yes.

Q Who did you speak to?

A I spoke to colleagues, and some of my colleagues are in the law field -- the legal field.

Q Okay.

When you say colleagues, you mean other doctors, healthcare providers, people like that?

A Some of them are.

Q Okay.

Did you speak to anybody in the marijuana industry?

And I define marijuana industry as persons involved in the creation, marketing, delivery of -- of botanical marijuana.

A No.

Q Okay.

Now, this -- this Tea House that you're involved with, is that the one that's in White River Junction?

A Yes.

Q Okay.

Now I -- I have looked at their

website, they're both for recreational and medical, so their products could be used either way, is that correct?

A Yes.

Q Okay.

So, what medical condition would you use a Blueberry Lobster for?

A Could you elaborate, please?

Q Is one of their products named Blueberry Lobster?

A I -- I don't know.

Q Are you familiar with any of their products?

A I am familiar with their formulations. That is flower, tincture, a class of orally ingested agents called edibles, gummies, chocolate, and vaporizers.

Q Did you ever go to the Tea House and look at their products?

A Yes.

Q Okay.

Did you ever see Cherry Pie Flower?

A I'm not familiar with the brand names.

Q Okay.

Well, let me give you some more names,

Cream Crusher Flower, Crunch Berries, Dante's Inferno, Dope Dog, and Girl Scout Cookies.

Have any of your patients recommended -- told you that they're taking Girl Scout Cookie marijuana?

A No.

Q Okay.

Have any of your patients brought any packages to you, showing you what they're taking, described to you what they're taking, by using any of these names?

A Well, I don't see patients, and so, I don't have patients, and I -- I certainly don't have patients in Vermont that go to the Tea House.

Q Okay.

And what is your responsibility with the Tea House? What do you do there?

A I assisted the owner in obtaining a license, and I assisted her in aspects of financing.

MR. EVANS: But you never actually looked at the products, how they're formulated, how they're packaged, whether they have any photographs on them, any photographs -- pictures

of animals or things that might be attractive to children?

Did you ever talk to her about that and say, look, we have to have a professional presentation?

I mean, unless this one product is aimed specifically at Girl Scouts, Girl Scout Cookie, it doesn't sound very medical to me.

And yet, this is a -- a place where you're an advisor.

These dispensary technicians --

MS. RACE: Your Honor --

JUDGE JULIUS: Hold on, Mr. Evans --

MR. EVANS: Yeah.

MS. RACE: I just had an objection. Just --

MR. EVANS: The -- the question I have is that --

JUDGE JULIUS: Well, hold -- hold on.

MS. RACE: Thank you, Your Honor.

JUDGE JULIUS: Let me hear the objection.

MS. RACE: Just to the extent that there's a question pending before the witness, that would -- but it seems like there's a lot of

discussion with no question pending.

And so, I just want to make a -- an -- a point for the record.

MR. EVANS: Well, I'm sorry, I'll ask the question.

Did it ever occur to you to find out exactly how these products were packaged, sold, and dispensed?

THE WITNESS: My interest is, first of all, in safety.

I'm interested in the constituency, purity, analysis, and in educating the dispensary staff on the aforementioned risks and side effects that we discussed earlier.

I'm not really up on product names.

BY MR. EVANS:

Q Well, Doctor, you -- you talked about warnings on the packages, have you ever read those warnings?

A Yes.

Q So, you've read some of the packages then?

A Well, I've read the labels on the packages.

Q That's all you read, just the label?

You didn't -- you didn't look at the name Crunch Berries or Dante's Infernos or Dope Dog?

A I have zero interest on the trade names of the products.

Q I believe you.

Now, these dispensary technicians, are they licensed?

A No.

MR. EVANS: Are they trained by the State?

MS. RACE: Objection, just a point of record, Your Honor.

JUDGE JULIUS: Go ahead.

MS. RACE: Which State are we talking about?

MR. EVANS: Well, right now we're focusing on New Hampshire, but --

THE WITNESS: Oh, I didn't know that, I thought we were talking about Vermont. The Tea House is in Vermont.

BY MR. EVANS:

Q Oh, Vermont -- New Hampshire, okay.

But you were talking about dispensary technicians in general.

So, what about New Hampshire? Are they licensed by the State?

A No.

Q What about Vermont? Are they licensed by the State?

A No.

Q Is there any certification board that okays them and says, you're properly trained to tell people the difference between Cream Crushers, Dope Dog, and Dante's Inferno?

A Which State are we referring to, please?

Q You can pick either State, it's fine with me.

Are you aware of any certification process that -- that when these people are involved in this very intimate healthcare, okay, I mean, I was an EMT, I had to go through four months of training to get certified, okay?

These people are dispensing a medication, okay, on their own accord, doesn't it bother you that they -- there's no certification for that?

A I don't quite understand the question because you asked a prior question, and then you

asked a secondary question.

Q All right, let me --

A I'm -- I'm a little confused.

Q Let me -- let me go to another scenario.

You -- have you ever written a prescription for somebody that is dealt with in a pharmacy?

A Are we referring to marijuana? I'm -- I'm very confused.

Q I didn't mention marijuana.

A I'm sorry.

Q I didn't mention marijuana, and you're being very thoughtful in trying to dodge my questions, I get that.

But did you ever write a medical prescription for any drug that was sent to a pharmacy?

A Of course.

Q Okay.

And why did you have that person go to a pharmacy?

A If I write an FDA-approved drug prescription, commonly, in this country, in the United States, that drug is dispensed by a

licensed pharmacy.

Q Have you ever written a prescription for any medicine where you told the pharmacist, you decide the amount?

A No.

Q Okay.

Have you ever made a recommendation that somebody should get Cherry Pie Flower or -- or Cream Crusher, anything like that?

A No.

Q Okay.

Now, when you recommend marijuana to somebody, and -- and I'm -- now, do you recommend -- do you recommend tincture? Do you recommend flower?

A I discuss with the patient, as I previously stated, the history of possible marijuana ingestion and what their preference might be.

Q I'm not talking about their preference.

Do you discuss flower with them as an option?

A Yes.

Q Okay.

Can you define flower, please?

A Flower is the dried component of the marijuana plant flower.

Q Okay.

And when you -- when you titrate people off opiates, do you then titrate them on marijuana?

You know, is titrate being raising or lowering of the amount or the potency?

A Yes.

Q Okay.

Now, how would you titrate the dry leaves of marijuana?

How would you tell a person how much to smoke or did you just tell -- well, answer that question first.

A The inhalational route for flower is through combustion, generally, and there is a component of the cannabinoids that gets vaporized through the mechanism of combustion and inhaled and absorbed in the pulmonary tree.

With each inhalation, there is some dose that is ingested.

As I spoke about titration, self-administered dosing is titration in this instance.

Q Okay.

So, you leave it to the patient to decide how much, is that correct?

A Yes.

Q Okay.

And if the patient comes back and says to you, I've been smoking this marijuana and I feel good, how would you respond to that?

A I would respond by asking further questions.

Q Okay.

Now, because somebody feels good for ingesting marijuana, does that mean that they're getting cured or healed of any disease?

A In the clinical evaluation of a patient who has chronic pain, I would personally, in my opinion, want to elicit more than just the descriptor feels good.

Q Now, you -- you testified earlier that pain is very subjective, I -- I -- I've been a personal injury lawyer, I can testify to that.

But do people sometimes -- are there people that have a different tolerance for pain than others?

A Yes.

Q Do people sometimes, in your experience, lie about having pain in order to gain some financial advantage?

A I can't answer that question, I don't know, I can't read minds.

Q Okay.

But is -- there's no chemical test for pain or a medical test or any test for pain other than just what a person says, is that correct?

A Not entirely.

Q Well, what -- how would you verify that somebody was in pain?

A There are objective measures.

Q And do you do that every time?

A Of course.

Q Okay.

Now, what do you know about these interactions with physicians in the rest of the country?

The -- what do you know are there any states where -- have you heard about Venice, California, for example, where they have, on the beach, they have these little offices you can walk in and get a marijuana certification for

$40 without any exam or nothing? Have you heard about that?

A My pain practice -- pain management practice was restricted to the State of New Hampshire.

Q I asked you what you heard about, what is your knowledge about what's going on nationally?

Because that's what we're talking about here.

Let me give you an example, you let me know if you think this is proper, this is an actual case.

Guy walks into a marijuana doctor in New York, Plattsburgh, New York, says that he has a spinal cord injury and cancer, brings his medical records with him.

And as he's sitting in the office, the doctor walks in and says, how you doing? We're going to get you your medical card today.

And then, he sits down and talks to the person and says, and the person says, well, I've had cancer and spinal cord injury.

And the doctor says, fine, I'll -- I'll get you your card, but I got to write down

something else because of this. I'm going to put down post-traumatic stress disorder.

Patient says, but I don't have post-traumatic stress disorder.

Doctor says, well, I got to put it down anyway, and it's a sworn statement that the doctor fills out.

The guy takes it to the dispensary, okay, and walks into the dispensary and hands the doctor's thing.

And the pat -- the patient then, says, to the dispensary guy, this doctor put down post-traumatic stress disorder, I don't have post-traumatic stress disorder.

And the dispensary said, don't worry, we put that down on everybody's certification.

Does that sound like the proper way to do things?

A I really can't comment on the practice of other physicians, only --

MR. EVANS: I'm just asking you for a process to get medical marijuana.

Was that enough of an evaluation of that patient who had his medical records there, okay?

MS. RACE: Objection, Your Honor --
MR. EVANS: And who denied having a condition.
Do you think that's proper to sign a sworn statement without -- without examining the person, not even looking at them?
JUDGE JULIUS: Hold on, don't answer yet.
MR. EVANS: All right.
JUDGE JULIUS: There's an objection.
MS. RACE: I just have two succinct objections.
The first one being, the first objection I lodged, which is that I would request Counsel please allow the witness to complete the answer.
And the second being that we've got a series of compound questions in the answer, in the question, too.
And so, I just want it -- for the benefit of a clear record for everybody, I just want to make sure that I --
MR. EVANS: Okay.
MS. RACE: -- I referenced that.
MR. EVANS: Do you think it's proper

for a doctor to walk in without saying a word to somebody, and the first thing the doctor says is, I'm going to give you a medical marijuana card? Do you think that's proper?

THE WITNESS: I'm a little confused by your question, because you said a doctor walks in to see a doctor.

BY MR. EVANS:

Q No, a patient, pardon -- pardon me.

Patient's sitting there, doctor walks in, looks at the patient and says, okay, I'm going to get you a medical marijuana card today, not even asking the patient anything.

Do you think that's proper?

A I can only speak for my own practice, and that is not how I would conduct myself.

Q Okay, great.

Would that be legal or illegal in Vermont or New Hampshire for a doctor -- for a doctor to ex -- to give somebody a medical marijuana card without examining them? Would that be proper in either State?

A Again, I don't know the law in that respect, I mean, I just know how to --

Q You know the law about dispensing

medical --

A Excuse me --

JUDGE JULIUS: Hold on, let him finish, please.

MR. EVANS: I'm sorry, I'm sorry, I'm sorry, pardon me.

THE WITNESS: I'm not of the legal mind, I only know how to practice what I consider to be judicious and appropriate medicine.

And all I would respond to that statement and that scenario is that would not be something I would approve of and I would do.

BY MR. EVANS:

Q Okay.

Are you familiar with the laws in Vermont and New Hampshire about a physician requirements in examining a patient before giving them a card? Are you familiar with what those requirements are?

A Well, I don't practice medicine and -- and never have in Vermont, so, I really can't comment on that.

Q But don't you advise a medical marijuana dispensary in Vermont?

Shouldn't you know the -- what the -- what they're supposed to do and not do?

You help them get licensing. They -- they had to understand, agree to certain things that they were going to do.

A If --

Q I've helped a lot of healthcare providers get licensing, and they got to -- they got to give a lot of information.

Well, it's okay if you just say you don't know, that's fine, you can just say you don't know.

A Sorry, I can't talk.

MS. RACE: Objection, Your Honor.

MR. EVANS: Don't look at the attorney, please.

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

MS. RACE: A variety of questions were posed, no time was provided to the witness to answer any of those.

And then, it appears that we're kind of moving into a badgering space as well.

And so, I have objections based on this line of questioning.

Certainly --

MR. EVANS: Well, I --

JUDGE JULIUS: Hold on just a second.

MR. EVANS: I'm sorry.

JUDGE JULIUS: I'll give you an opportunity, sir.

MS. RACE: I understand that Counsel would like to pose questions.

I just request -- the Government requests that Counsel poses those questions one on one so we can appropriately debate whether or not the individual questions were appropriately asked.

MR. EVANS: Okay.

MS. RACE: Thank you.

MR. EVANS: Doctor, are you familiar with the law that guides a doctor in deciding that a person should get a medical marijuana card in New Hampshire?

THE WITNESS: There are guidelines, I don't know if they're called laws.

BY MR. EVANS:

Q Well, okay, it could be a statute, it could be an administrative rule put out by the Department of Health after going through

administrative rule process.

There could be guidelines put out by the Department of Health.

But I happen to know there's specific statutes in New Hampshire and Vermont on these issues, I happen to know that.

And I'm asking you, do you know what you're supposed to do under the law in New Hampshire?

You advise other doctors. You advise a marijuana dispensary, okay?

When a doctor says, I want to do this, and do you know whether or not they can do it or not?

What is your knowledge of the laws?

A As I said, in the State of New Hampshire, a physician needs to examine the patient, attest to the qualifying condition and symptom, and then, the patient fulfills the rest of the process and reports to the State for obtaining a medical card.

Q Okay.

Do you know what the process is in the rest of the country generally?

A It varies, that much I do know, there's

a large variation.

However, the intrinsic process is similar in that there is a patient-healthcare provider interaction whereby a qualifying condition needs to be documented and then, followed.

Q Okay.

A And -- and at such time, the patient can obtain a authorization --

Q When you --

A -- to obtain medical marijuana.

Q When you say an examination, what does that require?

A I can only speak to the State of New Hampshire.

It requires an assessment of the patient's condition.

Now, I can speak generally in terms of other medical qualifying conditions or specifically to pain.

Q Okay.

Now you talked about the CoA, the Certificate of Analysis, and that that provides information on the -- does it provide information on the -- the specific cannabinoids

that are in that product?
A Yes.
Q Okay.
And are there cannabinoids on these CoAs that are reported other than Delta-9 THC? Other forms of THC?
A Well, Delta-9 THC is the main form of THC.
Q That wasn't my question.
Do they report on other types of THC also?
A In the State of New Hampshire, you're referring, sir?
Q Right now we're stuck there.
But what about, do they put in the -- the type of CBD, or CBD there?
A Yes, but I need to emphasize that CBD is a separate -- totally separate molecule to THC.
Q To where?
A You referred to multiple types of THC.
Now, there are isomers of THC, I don't believe that those are generally part of a CoA.
Q Okay.
Let's talk about CBD, do you consider

CBD to be botanical marijuana?

A Cannabidiol, which is known as CBD, is one of the cannabinoids, probably the second most common cannabinoid in most strains of botanical marijuana.

Q Okay.

Is there an FDA-approved medicine that's made of CBD?

A Yes.

Q What is the name of it?

A Epidiolex.

Q Was Epidiolex tested on anybody over the age of 55?

A I am unaware.

Q Are there any risks in somebody ingesting CBD?

A As with any drug, come risks of ingestion.

Q No, I'm asking specific risks with CBD, it's right on the package insert, approved by the FDA.

And I'm surprised that you don't know that because you're supposed to be an expert in botanical marijuana, which would include CBD.

But you don't appear to be an expert in

that particular item, do you, Doctor?

A I certainly know the pharmacology risks and benefits of most cannabinoids, including cannabidiol.

Q Give me three of the risks of cannabidiol, what are they?

A Serotonin syndrome, induction of liver enzymes cytochrome P450 and 480, and occasionally, sedation.

Q Now, you talked about the process with the liver.

Could you be more specific about why that is harmful?

A If I may just ask, are you specifying with respect to cannabidiol?

Q Right now, Epidiolex.

A Okay, CBD?

Q That's published, you should have read it, you should be familiar with it, correct?

A Of course.

Q Okay.

So, it specifically mentions problems with your liver.

You gave a technical answer, time's expired, can you just answer that question?

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

MR. EVANS: Okay.

What is the problem that CBD causes with somebody's liver?

THE WITNESS: CBD can inhibit the enzymes I talked about, these are called cytochrome complexes.

The liver is an organ responsible for metabolism or breakdown of all kinds of molecules, including drugs.

MR. EVANS: May I just ask one more follow-up question? Are you done with that?

JUDGE JULIUS: We can then --

THE WITNESS: No, not really, but --

JUDGE JULIUS: It's okay.

MR. EVANS: Sorry.

JUDGE JULIUS: Yeah, you can ask another question, we'll just count the time.

MR. EVANS: Okay.

JUDGE JULIUS: You may have 28 minutes.

MR. EVANS: Now, you -- you talked about how you monitored --

MS. RACE: Objection -- objection.

THE WITNESS: I didn’t get to answer the

--

JUDGE JULIUS: Hold on.

MR. EVANS: Oh, I'm sorry. I didn't -- I thought you were finished, pardon me.

JUDGE JULIUS: Hold on, objection.

MS. RACE: If that's resolved, I appreciate that, that was going to be my objection because I believe the witness wasn't finished with that question.

JUDGE JULIUS: Okay.

If he's -- if you aren't finished with your answer, please finish your answer.

THE WITNESS: Thank you.

CBD is one of the cannabinoids that can both inhibit and augment certain enzymatic functions of the liver.

The liver is important in detoxification.

If -- if these liver enzymes are affected, it can affect how the liver metabolizes substances.

MR. EVANS: Okay, one more question.

Have you ever recommended CBD or prescribed CBD or Epidiolex to any patient?

THE WITNESS: No.

MR. EVANS: Okay.

We'll see you tomorrow morning.

JUDGE JULIUS: Thank you, Mr. Evans.

Just for the record, I want to make sure, because you are Counsel for a number of parties, I just want to make sure that the 30 minutes that you took this afternoon was for National Drug and Alcohol Screening Association.

MR. EVANS: Correct.

JUDGE JULIUS: Okay.

MR. EVANS: Correct.

JUDGE JULIUS: Very good, thank you, sir.

MR. EVANS: Right, right.

JUDGE JULIUS: And again, appreciate your flexibility this afternoon.

MR. EVANS: Well, for sure.

JUDGE JULIUS: Before we adjourn for the evening, I would thank you for your testimony today.

Again, please don't discuss your testimony with anyone between now and tomorrow.

And looking at the schedules of attendance, it looks like we may pick up a little bit more extra time tomorrow as well.

We did in our preliminary order say that no one's going to be forced to present their case-in-chief earlier than the day scheduled, which I think would mean that, potentially, Government maybe be prepared for any redirect tomorrow, even though it's originally scheduled to be first thing Thursday.

So, just be aware that we may be picking up some time, and I want to be able to -- to --

MS. RACE: We'll be ready.

JUDGE JULIUS: -- capitalize, to the extent possible, on any ahead of schedule processing that we have.

MS. RACE: Thank you.

JUDGE JULIUS: Sure. So, thank you everyone for your flexibility today.

We will be adjourned until tomorrow. Have a great evening, everyone.

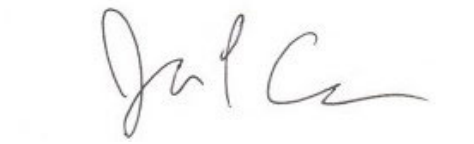
Thank you.

THE LAW CLERK ~~BAILIFF~~: All rise.

(Whereupon, the proceedings went off the record at 3:58 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.



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