UNITED STATES DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION

IN THE MATTER OF:	:	
Schedules of Controlled Substances: Placement of 2,5-dimethoxy-4-iodoamphetamine (DOI) and 2,5-dimethoxy-4-chloroamphetamine (DOC) in Schedule I	:	Docket No. 24-24

Tuesday,
November 12, 2024

700 Army Navy Drive
Arlington, Virginia

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

BEFORE:

THE HONORABLE PAUL E. SOEFFING,
Administrative Law Judge

APPEARANCES:

On Behalf of the Government:

FRANK W. MANN, ESQ.
KAYLA L. KREINHEDER, ESQ.
ALEXIS B. ATTANASIO, ESQ.
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On Behalf of the Science Policy Counsel, Students for Sensible Drug Policy:

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On Behalf of Dr. Raul A. Ramos:

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ALSO PRESENT:

THERESA M. CARBONARO, Government's Expert
T.J. GLEASON, Law Clerk
ALAINA M. JASTER, Petitioner's Expert

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

9:02 a.m.

JUDGE SOEFFING: All right, we are on the record In the matter of Schedules of Controlled Substances: Placement of 2,5-dimethoxy-4-iodoamphetamine, (DOI) and 2,5-dimethoxy-4-chloroamphetamine (DOC) in Schedule I, Docket No. 24-24.

Today's date is November 12th, 2024, and I am Judge Paul E. Soeffing.

The court reporter is instructed to record everything said that is on the record and have it transcribed. This includes testimony, objections by counsel, argument of counsel, rulings by the judge, and discussions between counsel and the judge, except purely housekeeping matters, such as requesting or announcing breaks, et cetera.

These are formal administrative proceedings being conducted pursuant to the Controlled Substances Act and the Administrative Procedure Act.

This hearing is being conducted in a hybrid in-person and video-teleconference, or VTC, technology format from the DEA Hearing

Facility in Arlington, Virginia, pursuant to a Notice of Proposed Rulemaking, or NPRM, published in The Federal Register on December 13, 2023, and pursuant to three hearing requests filed with the Drug Enforcement Administration.

The first request for a hearing was filed by Panacea Plant Sciences on January 8, 2024. I may refer to Panacea Plant Sciences throughout these proceedings as simply Panacea or PPS.

The second hearing request was filed by the Science Policy Council, Students for Sensible Drug Policy, on January 23rd, 2024. I may refer to the Science Policy Council, Students for Sensible Drug Policy, throughout these proceedings as SSDP.

The third request for hearing was filed by Dr. Raul A. Ramos on January 23rd, 2024.

Throughout these proceedings I will also refer to the parties who filed hearing requests as the Petitioners.

Additionally, subsequent to their hearing requests, SSDP and Dr. Ramos have filed joint proceedings and they will, likewise, jointly present their case at this hearing.

The issue in this case is whether 2,5-dimethoxy-4-iodoamphetamine, which I will refer to throughout these proceedings as DOI, should be listed in Schedule I of the Controlled Substances Act, pursuant to 21 USC Sections 811 and 812(b)(1), and, whether 2,5-dimethoxy-4-chloroamphetamine, which I will refer to throughout these proceedings as DOC, should be listed in Schedule I of the Controlled Substances Act, pursuant to 21 USC Sections 811 and 812(b)(1).

Representatives for the parties are present. Participating in person here at the DEA Hearing Facility in Arlington, Virginia, are Government counsel and the Agency representative, the counsel and representatives for SSDP, and Dr. Ramos and his counsel.

Witnesses who are not attending the hearing in person will be permitted to testify via VTC, in accordance with the tribunal's previous orders.

Let me get appearances with office addresses, please.

Government?

MR. MANN: Your Honor, Frank Mann,

M-A-N-N, on behalf of the Government. The address is 8701 Morrissette Drive, M-O-R-R-I-S-S-E-T-T-E, Drive, Springfield, Virginia 22152.

MS. ATTANASIO: Good morning, Your Honor. Alexis Attanasio for the Government. Address: 870 -- 8701 Morrissette Drive, Springfield, Virginia 22152.

MS. KREINHEDER: Good morning, Your Honor. Kayla Kreinheder for the Government. Our address is 8701 Morrissette Drive, Springfield, Virginia 22152.

JUDGE SOEFFING: Okay. Mr. Mann, are you serving as lead counsel throughout these proceedings?

MR. MANN: Yes, I am, Your Honor.

JUDGE SOEFFING: Okay. And who else is with you at counsel table?

MR. MANN: Dr. Theresa Carbonaro, our expert witness.

JUDGE SOEFFING: Okay. Is she also serving as an Agency representative for the proceeding?

MR. MANN: Yes.

JUDGE SOEFFING: Okay. Thank you, Mr.

Mann.

Counsel for SSDP?

MR. PHELPS: Yes, good morning, Your Honor. Brett Phelps, on behalf of SSDP. Would you like my office address or SSDP's address, Your Honor?

JUDGE SOEFFING: Your office address.

MR. PHELPS: Oh, yes, that's going to be 1917 Hot Springs Boulevard, Las Vegas, New Mexico 87701.

JUDGE SOEFFING: Okay. And who is here at counsel table with you representing SSDP?

MR. PHELPS: This is Dr. Alaina Jaster, one of our party signatories.

JUDGE SOEFFING: Okay. Very good.

Mr. Rush?

MR. RUSH: Robert Rush, representing Dr. Raul Ramos. My office address is 600 17th Street, Suite 2600 South, Denver, Colorado.

JUDGE SOEFFING: Okay. And is Dr. Ramos here?

MR. RUSH: Yes, he is.

JUDGE SOEFFING: Okay. Very good.

Welcome, Dr. Ramos.

Okay. This morning the tribunal

received a filing from Panacea Plant Sciences stating that its representative, Mr. David Heldreth, is unable to attend this hearing.

Government, did you receive a copy of Panacea's filing?

MR. MANN: We received an email last night, Your Honor.

JUDGE SOEFFING: Okay. You don't have a copy of the motion that was filed?

MR. MANN: We have it on the computer, yes.

JUDGE SOEFFING: You do? Okay, very good.

Mr. Phelps and Mr. Rush, did you receive a copy of Panacea's filing?

MR. PHELPS: We did, Your Honor.

JUDGE SOEFFING: Okay.

MR. RUSH: Yes, Your Honor.

JUDGE SOEFFING: All right. In its filing, Panacea asked to be allowed to present an opening statement, testimony, and a closing statement in writing. I will be asking for the Government's position and SSDP/Ramos' position on Panacea's motion after the Government has concluded its case-in-chief.

I require that cell phones and all other electronic devices be turned off during these proceedings.

Additionally, as noted in the Notice of Hearing issued on November 4, 2024, the tribunal and Court Security staff reserve the right to remove any individual who does not comply with the direction of the tribunal. The Notice of Hearing provides standards of conduct and expectations for parties, counsel, witnesses, and members of the public in attendance at these proceedings.

I also order that no person photograph, electronically record, televise, or broadcast these proceedings. This rule shall not apply to electronic recordings by an official court reporter or other authorized court personnel.

We will commence proceedings every day at 9:00 a.m. Eastern Time and we will continue all day until approximately 5:00 p.m. Eastern Time. There will be an hour recess each day for lunch and shorter convenience breaks as needed. I plan to break for lunch as close to 12:30 as possible.

At the outset of the hearing, each party will have the opportunity to present an opening statement to outline what evidence they intend to present.

The Government, which has the burden of proof here, will put its case on first. When the Government rests its case, SSDP and Dr. Ramos will jointly present their case. After the Petitioners present their case, the Government may put on additional evidence in rebuttal and, if so, the Petitioners will be permitted to answer that evidence with a surrebuttal.

At the end of the hearing, the parties will have the opportunity for closing arguments.

I will then give dates for the parties to receive the transcript, offer corrections to the transcript, and file post-hearing briefs.

I will then carefully consider all of the evidence and issue a recommended decision. The parties will get a chance to submit any exceptions to my recommended decision before I send it to the Administrator, who is the ultimate decisionmaker for the Agency.

Both sides have been provided with copies of the ALJ exhibits in this case, which,

in accordance with 21 CFR Section 1316.59(f), I'm including in the record as ALJ Exhibits 1 through 71.

(Whereupon, the documents were marked as ALJ Exhibit Nos. 1 through 71 for identification.)

JUDGE SOEFFING: I am in possession of proposed Government Exhibits 1 through 9 for identification.

(Whereupon, the documents were marked as Government Exhibit Nos. 1 through 7, 7A, and 8 through 9 for identification.)

I am also in possession of SSDP and Dr. Ramos' proposed Exhibits 1 through 5, 8 through 13, 16 through 22, 24 through 26, 28, 32, 33, 35 through 42, 46, 49 through 55, 57, 61 through 71, and 73 through 87 for identification.

(Whereupon, the documents were marked as Petitioners' Exhibit Nos. 1 through 5, 8 through 13, 16 through 22, 24 through 26, 28, 32, 33, 35 through 42, 46, 49 through 55, 57, 61 through 71, and 73 through 87 for identification.)

JUDGE SOEFFING: At the conclusion of these proceedings, any proposed exhibits which

are not offered will not be forwarded to the Administrator.

Proposed exhibits which are offered, but not admitted, will be retained with the record of proceedings for review by the Administrator.

If any party seeks to introduce an exhibit that has not already been noticed and provided, that party will need to seek permission and demonstrate good cause for late notice, except for rebuttal evidence.

I do not permit piecemeal objections. Pose all of your objections to an offer of proof when the question is asked or the evidence is offered.

There will be no colloquy or sidebar between the parties during the hearing.

Also, except for any closing arguments, there will be no argument presented during the proceedings.

Does any party have any questions about the process or procedures for the hearing?

Mr. Mann?

MR. MANN: A couple of issues.

First of all, you mentioned a number

of Government exhibits. We have a motion to substitute 7A for 7. I just wanted to --

JUDGE SOEFFING: I'll be turning to that in a moment.

MR. MANN: Also, I've noticed -- is there anyone participating in this hearing at this moment who is on the screen and there virtually?

JUDGE SOEFFING: No.

MR. MANN: All right. So --

JUDGE SOEFFING: We will only be using the screen for individual VTC witnesses.

MR. MANN: In light of that, Your Honor, Panacea Plant Sciences has, essentially, not appeared here today.

JUDGE SOEFFING: I will -- okay. Right.

MR. MANN: Do you want me to address that now?

JUDGE SOEFFING: Let me just see --

MR. MANN: Okay.

JUDGE SOEFFING: -- questions on procedure first --

MR. MANN: Okay.

JUDGE SOEFFING: -- and then, I'll

turn to a couple more things. I'll give you an opportunity to talk about Panacea.

Any questions about process or procedures? Mr. Phelps?

MR. PHELPS: Just one minor matter regarding if there's going to be any restrictions on any journalistic postings. So, Dr. Jaster is also a medical journalist and is interested in doing daily recaps, but just of what's been said, just restating the facts, no arguments, that kind of thing. I just wanted to get the Court's position on that and be able to let her know, so she's not violating any of the Court orders.

JUDGE SOEFFING: I mean, these are public proceedings. So, whatever is said here can go out and be talked about, yes.

MR. PHELPS: Okay. Thank you.

JUDGE SOEFFING: Okay. Mr. Rush, any questions about process or procedures?

MR. RUSH: No, Your Honor.

JUDGE SOEFFING: Okay. All right. Before turning to opening statements -- and, Mr. Mann, your other issue -- at the second prehearing conference held on October 30th, 2024, the tribunal discussed with the parties whether

sequestration of witnesses is necessary for this case.

The tribunal notes that witnesses testifying via VTC will be on the VTC only to provide their testimony. Thus, sequestration is not an issue for these witnesses.

Further, at the second prehearing conference, counsel for SSDP and Ramos agreed to sequester in-person witness Dr. Harrison Elder, who is not a party representative.

Mr. Phelps and Mr. Rush, do you still agree to sequester Dr. Elder?

MR. PHELPS: Your Honor, we actually would, as Dr. Elder is listed as an expert, we do believe that he is entitled by law to be here. The policy reasons behind sequestration are related to fact witnesses and he has technical know-how that can assist counsel. So, we believe that him, that Dr. Elder should be allowed to remain in the courtroom.

We would also request we -- our other expert witnesses, and particularly Dr. Palamar who is our expert in epidemiology, who is going to be testifying via VTC, but we would request that he be allowed to observe the Government's

case, specifically Dr. Carbonaro's testimony. Again, as an expert, we believe that he is entitled under law to be able to do that and to provide his scientific expertise and know-how to do that. So, that would be our request for the Court today.

JUDGE SOEFFING: Okay. Dr. Elder is here in person?

MR. PHELPS: Yes, he's here.

JUDGE SOEFFING: Yes? Okay. All right. Very good.

And then, the other four individuals that were at issue are all party representatives: Tanner Anderson, Joseph Hennessey, Dr. Jaster, and Dr. Ramos, is that correct?

MR. PHELPS: That's correct. Mr. Hennessey and Mr. Anderson will be coming next week. They're not here today, but they will be present next week in person.

JUDGE SOEFFING: Okay.

Okay. Mr. Mann, what's the Government position regarding sequestration of the witnesses?

MR. MANN: Your Honor, the Government has no objection -- first of all, the

Petitioners, I believe, have approximately 15 expert witnesses. The Government is still very unclear as to what opinions they're going to be offering, except for what is in their prehearing statements.

The Government has no objection to these so-called experts watching the Government's case, but I do believe there is good grounds for keeping them out of the hearing while the Petitioners are putting on their case.

I know that we don't follow the federal rules, but there is a -- I have a Second Circuit case here from 1995, the United States Court of Appeals, Second Circuit, United States v. Jackson.

The cite is 60 F.3d 128, and I'm looking at the headnote No. 4, which says, even though sequestration is up to the discretion of the court, if the witnesses all have the same agenda, which they do, and there's the possibility of bias, and the possibility that the witnesses will watch each other to stay in conformity to each other's opinions, then I think that the Court should exercise its discretion to sequester them at least for their own case, or at

least for that part of the case.

Again, we don't have a problem with them watching the Government's case, but I don't see -- I see a lot of potential bias here for one witness, one expert listening to the other and making sure that he or she is completely consistent with the testimony that came before them. They may have differing opinions and we would like to explore that possibility.

And also, I don't see how their presence is essential in terms of listening to their own other witnesses.

JUDGE SOEFFING: Okay. Thank you, Mr. Mann.

Mr. Phelps, do you have a response?

MR. PHELPS: Your Honor, again, we would maintain the position that, at the very least, the party Petitioners are all able to be present during the testimony.

Additionally, we would just note they've referred to them as our so-called experts, but they've lodged no challenges challenging their expertise. So, at this point, they are recognized as experts without any filing to challenge that.

In regards to, you know, I think the -- I don't think we're going to have a bunch of people on VTC that are going to be watching our own case. So, we'll leave that to the Court's discretion. But we would ask that any of the party people be here.

And I do still think that, they can -- again, they can help us understand the technical expertise; that that's exactly what this case is about. It's deep in the science. And they -- each of them, as noted, are experts in particular areas, and that particular understanding can only potentially be offered by that witness. So, we do think that it is a critical component of our case and we would request that, if desired, they be able to watch and participate.

JUDGE SOEFFING: All right. Thank you, Mr. Phelps.

Mr. Mann, there's no issue with sequestration of any of the witnesses while the Government is presenting its case?

MR. MANN: I think to the extent that they have all been identified as experts, and they may very well be qualified as experts in particular areas -- as you know, their expertise

is very discrete here. I mean, I think one is an expert in auditory neuroscience. I can't remember the other categories, but they're very different.

So, I think that there's no issue with them listening to the Government's case, but I'm very concerned about them listening to each other.

JUDGE SOEFFING: Okay. So, I will --

MR. MANN: And also, to that extent, any sequestration order should extend to them looking at any kind of journalism that might be posted on a daily basis from here --

JUDGE SOEFFING: Okay. Thank you, Mr. --

MR. MANN: -- at least from their case.

JUDGE SOEFFING: All right. Thank you, Mr. Mann.

As there's no issue regarding sequestration during the Government's presentation of its case, I'm not going to order sequestration at this point.

I will make a ruling on sequestration during the Respondent's case before they put

their case on. I want to look at the case that Mr. Mann cited. So, I will revisit that before the Respondents put on their case in terms of Dr. Elder, and Mr. Anderson, Mr. Hennessey, Dr. Jaster, and Dr. Ramos.

Dr. Palamar, I'm not going to permit him to sit in via VTC. There were specific guidelines given for who could participate via VTC. It was for testifying witnesses only. There was no motion previous to these proceedings for an exception for him to sit in as an expert. So, I'm going to deny allowing him to sit in on the VTC. If he wants to come in person, he's certainly welcome to come in person like everybody else here. Okay?

MR. PHELPS: One quick question on that. Since the Court is reserving ruling on the other sequestration, would we be permitted to potentially submit briefing on that prior to the presentation of our case?

JUDGE SOEFFING: No, I'll hear from you again orally, but --

MR. PHELPS: Okay.

JUDGE SOEFFING: If you want to present something orally, but I'm not going to

take written briefs now.

MR. PHELPS: Okay. Thank you, Judge.

JUDGE SOEFFING: Okay.

All right. A second issue arose last week when the Government submitted an out-of-time motion seeking to substitute a new proposed exhibit, proposed Government Exhibit 7A, for its timely proposed Government Exhibit 7.

The Government indicated that it had mistakenly included as proposed Government Exhibit 7, a 2021 version of a document which was updated in 2023, as represented by proposed Government Exhibit 7A.

The tribunal will decide this issue at such time as the Government seeks to offer proposed Exhibit 7 and/or 7A into evidence.

MR. PHELPS: And sorry to interrupt, Your Honor, I just wanted to let you know we had initially opposed that. We now have no objection to that substitution.

JUDGE SOEFFING: Okay. Very good. Thank you.

Well, then, we'll address it as to whether you want to put in both or just one of those exhibits when the time comes, Mr. Mann.

Thank you, Mr. Phelps.

Okay. Mr. Mann, you had another issue you wanted to talk about regarding Panacea?

MR. MANN: Your Honor, Panacea -- the Government would argue that Panacea has now waived its right to participate in this hearing. 1301.43(d) says that, if such person so files and fails to appear at the hearing, such person shall be deemed to have waived their opportunity to participate in the hearing unless such person shows good cause for such failure.

I understand that Mr. Heldreth has claimed that he's ill, but Mr. Heldreth is not the party here. The party is Panacea Plant Sciences. And there's been no arrangements to have a representative from Panacea Plant Sciences appear in this hearing either virtually or in person. I do not know how many employees Panacea has. I believe -- and I could be mistaken -- that he, that Mr. Heldreth claimed there were eight employees, but he was the only full-time employee.

I am looking at a filing of an annual report with the Washington Secretary of State, and it lists two governors, Mr. Heldreth and a

Robert Heldreth. So, it doesn't appear that Mr. Heldreth is the only person who works for Panacea Plant Sciences.

No employee has appeared in any way, shape, or form and Mr. Heldreth has not appeared either virtually or in person. So, I believe that he can be deemed to have waived his participation in the hearing, or Panacea has been deemed to waive its participation in the hearing, notwithstanding Mr. Heldreth's illness.

JUDGE SOEFFING: Okay. Mr. Phelps, would you like to say anything on that at this point?

MR. PHELPS: Yes, Your Honor, our position is that Panacea has shown good cause through the illness of their party representative. So, we would concur with his motion to be able to -- or we would not oppose his motion to be able to submit as he requested.

JUDGE SOEFFING: Okay. I'm going to defer ruling on this until after the Government's case is concluded, case-in-chief -- until such time as Panacea would be allowed to present its case. If he's not here, then I'll rule at that time.

All right. Any further questions before we proceed to opening statements?

Mr. Mann?

MR. MANN: No, Your Honor.

JUDGE SOEFFING: Okay. And, Mr. Phelps?

MR. PHELPS: No, Your Honor. However, we would actually defer our opening statement to prior to our presentation of the evidence today.

JUDGE SOEFFING: Okay. So, you'll put on your opening statement before --

MR. PHELPS: Yes.

JUDGE SOEFFING: -- you call your first witnesses?

MR. PHELPS: Yes, Your Honor.

JUDGE SOEFFING: Very good. Thank you, Mr. Phelps.

MR. PHELPS: Thank you.

JUDGE SOEFFING: Okay. Mr. Mann, you may make your opening statement.

MR. MANN: Thank you, Your Honor.

May it please the Court.

In any action under the Controlled Substances Act, the goal is to ensure that harmful and potentially dangerous substances

don't fall into the wrong hands.

By the same token, the CSA ensures that patients are not deprived of safe and useful medications, and that researchers have the ability to develop those safe and useful medications.

This scheduling action is about 2,5-dimethoxy-4-iodoamphetamine, also known as DOI, and 2,5-dimethoxy-4-chloroamphetamine, also known as DOC. These are hallucinogenic substances, also known as psychedelics, a word that means mind manifesting. They are defined as of, relating to, or being drugs capable of producing abnormal psychic effects, such as hallucinations and sometimes psychotic states.

You've heard of psilocybin, mescaline, LSD. You may have even heard of DOB or DOM, a drug that was often referred to as STP. These are all psychedelics. They are all Schedule I controlled substances. They have been Schedule I controlled substances for decades, and they are very similar to DOI and DOC, which are extremely potent.

And those are not my words. Listen to the man who developed DOI and DOC decades ago,

Alexander Shulgin.

Of DOI, he said, quote, the general nature of the experience was depressing with a sad view of life. I was at full crashing for about three or four hours. It lasted a really long time. I was distinctly aware of residual stuff going on well into the next day.

Of DOC, Mr. Shulgin wrote, I was disconnected. Everything is there in spades with few of any of the subtle graces, the gentle images, and gentle fantasies. There are visuals and there are interpretative problems with knowing just where you really are. Anyone who uses this better have 24 hours at their disposal. This is the works.

The Government's case here will consist of the following:

Under 21 USC 811(c), the Government's expert will walk DOI and DOC through an eight-factor test. This will determine whether DOI and DOC should be scheduled at all.

The expert will then walk us through a three-part test, at 812(b)(1), to show that DOC and DOI can only be placed in Schedule I, primarily because neither drug has a currently

accepted medical use. This will be plainly obvious because neither drug has ever been clinically tested in humans.

You will also hear that DOC is now part of the 1971 Convention on Psychotropic Substances. So, according to our UN Treaty obligations, it has to be scheduled.

But, of course, that's not the whole story. The Government anticipates that those opposed to this scheduling action will likely claim that this will hinder and halt all research into DOC and DOI. Not true.

Plenty of psychedelic drugs are currently being researched as we speak, and some are even being given to humans. And these were placed in Schedule I decades ago.

When the Drug Enforcement Administration schedules a drug, it becomes part of a closed system of distribution. This is a system designed to prevent the diversion of drugs into unlawful channels, while ensuring an adequate supply for legitimate purposes.

Right now, DOI and DOC are far outside that closed system. These drugs can be manufactured, sold, distributed, and even abused.

And they are too much like other drugs that have already been placed in Schedule I because of their potential to cause strange and dangerous effects and behaviors. Harm to not only those who abuse them, but harm to others. It's time to bring them into that closed system where they can be made safe.

Thank you.

JUDGE SOEFFING: Thank you, Mr. Mann.

Mr. Mann, you may call your first witness.

MS. KREINHEDER: The Government will call Heather Achbach.

And we would request a moment to contact her to get her logged in on VTC.

JUDGE SOEFFING: Very good.

(Pause.)

Ms. Achbach, can you hear me?

MS. ACHBACH: Yes, I can. Can you hear me?

JUDGE SOEFFING: Yes.

Mr. Reporter, can you hear the witness?

COURT REPORTER: Yes, Your Honor.

JUDGE SOEFFING: Okay. All right.

Ms. Achbach, please raise your right hand.

WHEREUPON,

HEATHER ACHBACH

was called for examination by Counsel for the Government, and having been first duly sworn, was examined and testified as follows:

JUDGE SOEFFING: Please state your first name, your last name, and spell them both for the record.

THE WITNESS: My name is Heather Achbach. The first name is H-E-A-T-H-E-R. Last name is A-C-H-B-A-C-H.

JUDGE SOEFFING: And, Ms. Achbach, during your testimony, you should not look at any materials or documents, except exhibits you are directed to look at by counsel or me. Do you understand?

THE WITNESS: Yes, I do.

JUDGE SOEFFING: Okay.

Counsel, you may inquire.

DIRECT EXAMINATION

BY MS. KREINHEDER:

Q Good morning, Ms. Achbach.

A Good morning.

Q Who are you currently employed by?

A I am currently employed by the Drug Enforcement Administration --

Q And --

A -- under their Diversion Section.

Q And how long have you been at the DEA?

A I've been at the DEA since August of 2012.

Q What previous assignments have you had with the DEA?

A I was previously a diversion investigator. I was assigned to the Seattle Field Division in -- starting in January of 2013, after doing my training at Quantico.

And then, I transferred to Headquarters as the Lead Staff Coordinator in 2021, and then, converted to a Policy Analyst last year.

Q And what is your current title?

A I am currently the Acting Section Chief of Diversions, Regulatory Drafting and Policy Support Section.

Q Can you tell me a little bit about what your section does?

A Of course. So, the Regulatory

Drafting and Policy Support Section is in charge of drafting all of the non-scheduling rulemaking that DEA does for our Diversion Section or Diversion Office. So, we implement all of the new laws that come out of Congress. We update the regulations as needed, and then, I, myself, in addition to overseeing the section as a whole, I am responsible for liaisoning with The Federal Register, ensuring that documents from DEA that need to be published for public view get published, and then comments are appropriately managed.

Q Can you explain some of the responsibilities of a Federal Register Liaison?

A Of course. So, the Federal Register Liaison, when we receive a document that's been signed by the Administrator, which means it's approved to publish, our responsibility is to review and ensure the document doesn't have any track changes in it, as that would hang up the Federal Register.

We, then, add a Federal Register Liaison statement to the Word document, electronically sign it in Word, and submit it to the Federal Register through their online portal.

And then, once the Federal Register has scheduled that document and published it, we are then responsible in the back-end system, which is called the Federal Docket Management System. We are responsible for managing all of the comments that come in and ensuring that they are posted to public view, and then, at the end of the comment period, downloaded and transferred to whomever is responsible for that specific rulemaking.

Q Great. Thank you.

Could you please open up the document that I sent to you that is marked for identification as Government's Exhibit No. 1?

A Yes. I have that in front of me.

Q Okay. Do you recognize this document?

A Yes, I do.

Q And what is it?

A This is my declaration for the purpose of this court hearing that I am the person that reviewed all of these comments and pulled them off of the FDMS system.

Q Could you please describe the document in a little more detail?

A It is detailing my position as the Acting -- Acting Section Chief at DPW; that there

was a December 13th Notice of Proposed Rulemaking published in the Federal Register on behalf of DEA that requested that all comments be submitted electronically or in paper, with a deadline of January 12th.

I have reviewed the previous -- previously numbered Government Exhibit 2 as a true copy of that NPRM, and that I was also attesting that there were approximately 151 electronic comments, which we downloaded from the Federal Register e-portal, and that those comments were to serve an important role in informing the Agency of any potential issues or information that we may lack, which is the purpose of notice and comment.

Q Is this the same declaration you emailed to me and signed on August 12th, 2024?

A Yes, it -- yes, it is.

Q Is this a true, accurate, and complete copy of that declaration?

A Yes, it is.

MS. KREINHEDER: Your Honor, the Government would like to move to bring this into evidence as Government Exhibit No. 1.

JUDGE SOEFFING: Any objection, Mr.

Phelps?

MR. PHELPS: No objection, Your Honor.

JUDGE SOEFFING: Government exhibit marked for identification No. 1 has offered. In the absence of objection, it is received in the record as Government Exhibit 1.

It's in. You may use it.

(Whereupon, the document previously marked as Government Exhibit No. 1 for identification was received in evidence.)

BY MS. KREINHEDER:

Q You can close that document now.

A Okay.

Q Ms. Achbach, were you the Federal Register Liaison during the time before the December 13th, 2023 Notice of Proposed Rulemaking was published?

A I was one of two Federal Register Liaisons.

Q Was the process that you described before followed in the case of this notice?

A Yes, it was.

Q What was your involvement in that publication?

A I was not involved in the actual

publication, although I was copied on all of the transmittals. So, we did receive the document cleared for publication and signed from the Administrator, and my predecessor is the one who validated everything and signed as the liaison and submit it.

MR. PHELPS: I'm sorry, just a quick question for clarification. Are you referring to this current one or the -- or the previous file?

MS. KREINHEDER: I was asking the witness about the December 13th, 2023, notice.

MR. PHELPS: Okay. Thank you.

JUDGE SOEFFING: Okay.

BY MS. KREINHEDER:

Q Ms. Achbach, who signed the notice on DEA's behalf?

A Scott Brinks.

Q And who is Scott Brinks?

A Scott is the former Section Chief of the Regulatory Drafting and Policy Support Section and was the second of the two Federal Register Liaisons.

Q And who replaced Scott Brinks when he left?

A I am currently his acting replacement.

Q Did you receive a copy of this notice from December 13th after it was published?

A I received a copy of it from the Federal Register and I received a copy from you, yes.

Q Could you please open what I sent to you that's labeled for identification purposes as Government's Exhibit No. 2?

A Yes. Open.

Q Do you recognize this document?

A Yes, I do.

Q And what is that?

A This is the Federal Register published document for the Notice of Proposed Rulemaking from the December -- December 13th, 2023 volume of the Federal Register.

Q And what agency issued this notice?

A This is issued by the Drug Enforcement Administration.

Q Who signed off on the notice?

A The Federal Register Liaison is Scott Brinks. The Administrator signed the rule.

Q Is this the same document that was submitted to the Federal Register at the direction of your section around December of

2023?

A Yes, it is.

Q Is it a true, accurate, and complete copy of that notice?

A Yes, it is.

MS. KREINHEDER: Your Honor, I'd like to offer this as Government's Exhibit No. 2.

JUDGE SOEFFING: Mr. Phelps, any objection?

MR. PHELPS: No objection, Your Honor.

JUDGE SOEFFING: Okay. Typically, I will note that this Government Exhibit 2 is identical to ALJ Exhibit 1. Typically, we don't admit duplicate exhibits, but because it is referenced in the declaration, to maintain clarity of the record and have a completeness of documents as to what was referenced in her declaration, I will admit it.

So, Government exhibit marked for identification No. 2 has been offered. In the absence of objection, it is received in the record as Government Exhibit 2.

It's in. You may use it.

(Whereupon, the document previously marked as Government Exhibit No. 2 for

identification was received in evidence.)

BY MS. KREINHEDER:

Q Ms. Achbach, can you briefly explain what that Notice of Proposed Rulemaking says about comments?

A This Notice of Proposed Rulemaking requests that comments are to be submitted either via paper or electronically to the www.regulations.gov website, where they will receive a comment tracking number.

Q What does the notice say about public posting of the comments?

A It says that the comments will not be instantaneously viewable. So, there is no need to submit the same comment.

Q What was the stated comment period in the notice?

A The comments were to be submitted to DEA between December 13th, which was the date that it was published, and January 12th; needed to be received by 11:59 p.m. on January 12th.

Q And what purpose do these comments serve?

A These comments serve to help the Agency receive additional information during a

rulemaking session that they may not otherwise have had at the time that the rule was published, which is why it is a Notice of Proposed Rulemaking. So, it serves an opportunity for the public to not only be notified of what the Agency is planning, but also to let the Agency know if there are any concerns or if they are in agreement with the Agency.

Q Can you explain what happened to the comments that DEA received in this case?

A Of course. So, DEA received the comments, the electronic comments, in through the Federal Docket Management System, which is the Agency-viewable side of regulations.gov. Those comments are received into that portal through the docket for the rule, at which point they are not yet posted on public view. The Agency is responsible for posting those comments to public view, which we generally do within 48 to 72 hours, unless there are weekends or holidays in play.

When we are reviewing those comments, all we're looking for is whether anybody had information in there that they requested to be redacted.

Q How did you receive the comments?

A We received them all through the Federal Docket Management System electronically, with the exception of one comment that I believe was mailed to the Agency directly.

Q And how many comments were there?

A A hundred and fifty-one.

Q Were any comments received after the comment period?

A Not to my knowledge.

Q And what did you do next with the comments?

A Once the comment period closed, I downloaded all of the comments to, into a file, and transmitted them to the Drug and Chemical Evaluation Section's representative.

Q Were any alterations made?

A No.

Q Could you please open the document that I sent to you that has been marked for identification as Government's Exhibit 3?

A Yes, I have it open.

Q Do you recognize this document?

A Yes, I do.

Q What is it?

A These are the downloaded comments for this rulemaking. This is all of the electronic comments that we received into the Federal Register system.

Q Is this the copy of the comments that you sent to DOE?

A Yes, it is.

Q Is it a true, accurate, and complete copy of those?

A Yes.

MS. KREINHEDER: Your Honor, I'd like to offer this exhibit as Government's Exhibit No. 3.

JUDGE SOEFFING: Mr. Phelps, any objection?

MR. PHELPS: No objection, Your Honor.

JUDGE SOEFFING: Okay. Government exhibit marked for identification No. 3 has been offered. In the absence of objection, it is received in the record as Government Exhibit 3.

It's in. You may use it.

(Whereupon, the document previously marked as Government Exhibit No. 3 for identification was received in evidence.)

BY MS. KREINHEDER:

Q Ms. Achbach, does DEA usually respond to the commenters?

A We do not respond individually to commenters. Response to comments is done in a final rule, which is the opportunity for the Agency to respond to the comments en masse and to the themes that were received during the comments.

Q So, has DEA responded to these comments yet?

A Not to my knowledge.

Q Okay. Thank you.

MS. KREINHEDER: I have no further questions.

JUDGE SOEFFING: All right. Mr. Phelps, would you like to conduct cross-examination?

MR. PHELPS: Yes, Your Honor. Thank you.

CROSS-EXAMINATION

BY MR. PHELPS:

Q Good morning, Ms. Achbach.

A Good morning.

Q Nice to meet you. My name is Brett Phelps. I'm one of the counsel here for Students

for Sensible Drug Policy.

So, you stated that before your current, before your current position, you worked as a diversion investigator?

A Yes, that's correct.

Q And where did you, where did you do that?

A I was a diversion investigator in Seattle, Washington, from 2013 until 2021. And prior to arriving in Seattle, I briefly was in Denver, which I had moved out of after completing my time in Quantico.

Q And what exactly did that position entail?

A Diversion investigators are tasked with ensuring compliance with the Controlled Substances Act. So, we conduct a variety of regulatory and administrative investigations and inspections of DEA registrants and prospective registrants.

Q And what drugs did you investigate?

A Primarily, they were the drugs in Schedules II through V, were the drugs that we handled in my office, although any controlled substance -- any drug scheduled under the

Controlled Substances Act or under the chemical acts could have fallen under our purview.

Q Okay. And in your experience in that position, did you ever encounter DOI or DOC?

A I do not recall encountering DOI/DOC, but we had very limited experience with Schedule Is as diversion investigators, since those are not generally chemicals or drugs that are used by DEA registrants.

Q Okay. As part of that, did you -- as part of that diversion investigation division, did you deal with any analogue substances?

A I do not recall dealing with analogue substances.

Q Okay.

MS. KREINHEDER: Objection. That is beyond the scope of the direct testimony.

JUDGE SOEFFING: It's already been asked and answered.

So, you may proceed. Overruled.

BY MR. PHELPS:

Q And outside of your, your office, were you aware of any active investigations into DOI or DOC in the diversion office?

A I am not aware of investigations.

That is outside of my purview.

Q Okay. Are any seizures or submissions of DOI or DOC --

MS. KREINHEDER: Objection. She's not being offered to establish any facts related to DOI or DOC.

MR. PHELPS: We can move on, Your Honor.

JUDGE SOEFFING: Okay. I'll sustain the objection.

BY MR. PHELPS:

Q So, Ms. Achbach, you were -- you were responsible for compiling and providing to the Agency the public -- all the public comments that were submitted, correct?

A I was in charge of the electronic comments.

Q Okay. And so, did you review the comments that were submitted?

A I -- my -- the only extent of review that I did was to ensure that there was no personal identifiable information or confidential business information that needed to be redacted. So, I did not read them for content, only for the personal information.

Q Okay. So, of those, of the 152 comments, you wouldn't be aware of how many were in support of scheduling or opposed to scheduling?

A I did not read them for that information, no.

Q Okay. And you also testified that the purpose of the public comments is, it serves an important role in informing the Agency of potential issues and of information the Agency may lack, correct?

A That is correct, yes.

Q Okay. And to your knowledge, was the Agency informed of any potential issues in the public comments?

A That was also outside my purview. I didn't read them for that.

Q Okay. So, you also wouldn't be aware of any new information that they lacked prior to receiving those comments?

A I am not aware of that information.

Q Okay. And to your knowledge, has the DEA ever changed its position based on public comments that were received?

A For this?

Q No, in --

A Please clarify, please.

Q In general.

A In general, on rulemaking, non-scheduling rulemaking, yes, we have. I can't speak to scheduling.

Q Okay. Because you haven't worked with that? Or why? Why couldn't you speak to that?

A That isn't my section. I am -- I work in the non-scheduling section. So, that is not something that I can authoritatively speak to.

Q Okay. And you said that the DEA's procedure in this is not to respond to comments individually?

A That is the federal government procedure overall. That is not limited to DEA. The federal rulemaking process does not require the individual response to comments. The response comes during the final rule stage. That is rulemaking at the federal level.

Q Okay. So, an agency can -- can respond individually if they so choose, but are not required?

A We are bound -- we, as an agency, are bound by certain laws and precedent within the

Department of Justice to keep us from responding individually, unless we have a compelling reason.

Q And what would be a compelling reason?

A That would be a decision above my pay grade.

Q Fair enough.

And how long have you served in this current section, the DPW?

A I have been with DPW since August of 2021.

Q Okay. And so, were you also involved in the original attempts to schedule DOI and DOC in 2022?

A I'm aware of it, but I was not involved with it at that time.

Q Okay. And what is -- what is -- when you say you're aware of it, what do you, what do you know about that?

A I know that there was a publication.

Q Okay. And are you aware that the DEA actually dropped scheduling at that point due to what they -- what they described as administrative error?

A That is what is described in the second notice and comment, yes.

Q Okay. But you didn't have any responsibility in that administrative error?

A No.

Q Thank you.

MR. PHELPS: No further questions for this witness, Your Honor.

JUDGE SOEFFING: All right. Thank you.

Government, any redirect?

MS. KREINHEDER: Yes, Your Honor.

REDIRECT EXAMINATION

BY MS. KREINHEDER:

Q Just a quick question for you, Ms. Achbach.

A Uh-hum.

Q Your responsibilities when you were a diversion investigator, can we go over --

A Yes.

Q -- those real quickly?

A Absolutely. As a diversion investigator, we, like I said, we investigate and enforce the Controlled Substances Act and its conforming regulations. So, part of my duties were to liaison with registrants to ensure their compliance with the Controlled Substances Act.

I would conduct both regulatory and enforcement investigations of and inspections of those registrants to ensure their continued compliance with the Controlled Substances Act and the chemical acts. And we would also do pre-registration investigations of those seeking registration with the DEA to ensure that they were prepared for the recordkeeping and security responsibilities to become DEA registrants.

Q Thank you.

As a diversion investigator, do you investigate non-controlled substances?

A No, we do not.

Q Okay. Thank you.

MS. KREINHEDER: No further questions.

JUDGE SOEFFING: Okay. Mr. Phelps, any recross?

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

JUDGE SOEFFING: Okay. Thank you for your testimony. You are excused.

I direct you not to discuss your testimony with anyone until the conclusion of the hearing.

THE WITNESS: Thank you, sir.

JUDGE SOEFFING: All right. Good day.

THE WITNESS: Good day.

(Witness excused.)

JUDGE SOEFFING: All right. Mr. Mann, you may call your next witness.

MR. MANN: The Government calls Dr. Theresa Carbonaro.

JUDGE SOEFFING: Okay. Good morning, Doctor.

DR. CARBONARO: Good morning.

JUDGE SOEFFING: Please raise your right hand.

WHEREUPON,

DR. THERESA M. CARBONARO

was called for examination by Counsel for the Government, and having been first duly sworn, was examined and testified as follows:

JUDGE SOEFFING: Please state your first name, your last name, and spell them both for the record.

THE WITNESS: Theresa, T-H-E-R-E-S-A, Carbonaro, C-A-R-B-O-N-A-R-O.

JUDGE SOEFFING: Counsel, you may inquire.

DIRECT EXAMINATION

BY MR. MANN:

Q Good morning, Dr. Carbonaro.

Do you have a business address?

A Yes. 8701 Morrissette Drive, Silver Spring, Maryland 2252.

Q That's your business address? Or?

A That's the mailing address.

Q Okay.

A But Headquarters, 600 Army-Navy Drive.

Q Okay.

JUDGE SOEFFING: Would that be Springfield or Silver Spring?

THE WITNESS: Springfield. My apologies.

JUDGE SOEFFING: Springfield. Okay.

THE WITNESS: Yes. Sorry.

BY MR. MANN:

Q Are you currently employed?

A Yes.

Q And where are you employed?

A The Drug Enforcement Administration.

Q In what capacity are you employed?

A As a pharmacologist.

Q Is that your job title here --

A Yes.

Q -- at DEA?
A Yes.
Q And how long have you been employed at DEA?
A Since September of 2018.
Q And did you start off as a pharmacologist?
A Yes.
Q Now, you're being offered as the Government's expert in this case, and I want to ask you a few questions about your background, experience, and education.
First of all, do you hold any academic degrees?
A Yes. I have a bachelor of arts in psychology and a PhD in biomedical sciences with a specialization in neuroscience and pharmacology.
Q And where is that bachelor of arts from?
A The University of Texas in Arlington.
Q And the PhD?
A The University of North Texas Health Science Center, in Fort Worth.
Q Okay. Do you recall when you acquired

your bachelor of arts?

A May 20, 2006.

Q And your PhD?

A December of 2012.

Q All right. And first of all, your bachelor of arts, in psychology, correct?

A Yes.

Q What type of education generally is required to obtain that type of degree?

A It's a range. It was focused in psychology classes, but also about pharmacology and drugs of abuse. But it included other science classes like chemistry, biochemistry, and other arts and required criteria.

Q And to acquire your PhD, what was required?

A When I required -- when I acquired my PhD, I had two years of additional classes specific to pharmacology and neuroscience and biomedical sciences, and then, an additional period of classes that overlapped with a dissertation project, and then, focused on my dissertation project for the last year and a half.

Q And do you hold any professional

licenses?

A I do not.

Q Okay. If the witness could please be shown what's been marked as identification -- marked for identification as Government Exhibit 4, please?

A Thank you. Okay.

Q First of all, do you -- can you identify this document?

A Yes.

Q And what is it?

A It is my curriculum vitae.

Q And are there any additions to this document, any updates that need to be made?

A Yes. I updated it every couple of quarters.

There were a couple of presentations that I made since April, including one at Harvard for an invited talk about hallucinogens under the Schedule -- under the Controlled Substances Act.

And then, a paper that was left off that we published in conjunction with psilocybin and a PET radiotracer in humans.

And then a couple of -- a couple of presentations for DEA relating to emerging trends

of abuse.

Q In terms of the presentations that are not on here, did any of them have anything to do with DOI or DOC?

A No. Just hallucinogens in general.

Q All right. Is this a -- apart from the additions that you've just mentioned and testified to, is this a fair and accurate representation of your current CV?

A Yes.

MR. MANN: Your Honor, the Government would offer Exhibit No. 4, marked for identification, into the record, please.

JUDGE SOEFFING: Mr. Phelps, any objection?

MR. PHELPS: No objection, Your Honor.

JUDGE SOEFFING: Government Exhibit marked for identification No. 4 has been offered. In the absence of objection, it is received in the record as Government Exhibit 4. It's in. You may use it.

(Whereupon, the document previously marked for identification as Government Exhibit No. 4 was received into evidence.)

MR. MANN: Dr. Carbonaro, I'd like to

go over, first of all, your education. You have a bachelor's in psychology?

THE WITNESS: Yes.

BY MR. MANN:

Q Did you concentrate on any particular area in psychology?

A Not specifically. I started focusing more on drugs of abuse during the end of my time, because I decided I was going to go for a PhD in pharmacology. So I started taking more classes related to psychology related to drugs of abuse.

Q Now, your PhD, is this your pharmacology degree?

A It's technically biomedical sciences, is how the State of Texas did -- any graduate school in Texas got a degree in biomedical sciences, but then there was broken into specializations, based on the university.

Q And does that qualify you to be -- call yourself a pharmacologist?

A Yes.

Q Okay. And did you have a particular concentration or specialty when seeking your pharmacology or biomedical science degree?

A Yes. I investigated mechanisms of

action of two hallucinogens, specifically. Those were N,N-dimethyltryptamine, a Schedule I substance, and another one, N,N-diisopropyltryptamine, which is not a controlled substance.

Q Do they have abbreviations?

A Yes, DMT for dimethyltryptamine and DiPT for diisopropyltryptamine.

Q DMT?

A Yes.

Q And the other is?

A DiPT.

Q DiPT. And you say that DMT is controlled, is that correct?

A Yes.

Q It's been controlled for quite some time, correct?

A Yes.

Q All right. So is it safe to assume that you attained your PhD, or doctorate, in 2012?

A Yes.

Q Now, I'd like to talk about your postdoctoral training. What does that mean, postdoctoral? Is that something that's required

to attain your PhD? Because I assume you've already attained it.

A Right, it's already been attained. It's not required, but it's traditional, to go through the academic pathway, to do a postdoctoral training position that can last one to three years or longer. In this case, I did two. One at the University of Texas Medical Branch in Galveston, Texas, and then another one in Johns Hopkins University School of Medicine, for about three years.

Q Well, let's talk about your postdoctoral training at the Center for Addiction Research at the University of Texas Medical Branch. If you can summarize what you did?

A Sure. That was a one-year postdoc where we were looking at the effects of lorcaserin, which is a weight-loss drug that was approved at that time, looking at mechanisms of actions related to that, to maybe use it for drug treatment. And then, also, making -- we were working with a chemist that was making new molecules to see if they could be used for drug abuse dependence treatment -- in animals, in cells.

Q Now, I didn't hear you used the word "hallucinogens." Did that involve hallucinogens?

A It did, to some degree, yes, because lorcaserin has some activity at some of the same receptors and, based on my experience -- I did do some hallucinogen work there.

Q How about at Johns Hopkins? Can you summarize what your postdoctoral training entailed at Johns Hopkins?

A Yes. So, everything before joining Johns Hopkins was either in cells or rodents. At Johns Hopkins, I started working under the direction of Roland Griffiths, who was researching psilocybin and dextromethorphan in clinical populations, specifically those that have experience using hallucinogens. And we did a trial with 20 participants looking at different abuse liability for psilocybin, dextromethorphan. Cognitive effects and subjective effects were my main duties while I was at Hopkins.

Q So, you mentioned two drugs. I know psilocybin is a hallucinogen, or a psychedelic, how about the other one?

A Dextromethorphan is the active ingredient in cough medicine, but at high doses

it can produce hallucinogenic effects.

Q Okay. Now, in terms of your CV, if you can look at page three, does page three, where it says at the top, summary of duties and responsibilities, does that adequately summarize your work at the University of Texas?

A Yes.

Q And if you can look at page two, at the bottom, summary of duties and responsibilities, does that adequately summarize your work at Johns Hopkins?

A Yes.

Q Now, I'd like to go backwards, or go up on page two, to your work experience. It says here, "Pharmacologist, Food and Drug Administration." Did you work at the FDA?

A I did.

Q For what time period?

A January 2017 through September 2018.

Q And what did you do there?

A I was also a pharmacologist for the Center for Tobacco Products, Office of Science. It was called the Addictions Branch when I joined, but it changed to the Clinical and Behavioral Pharmacology Branch by the time I

left.

Q Any work with controlled substances?

A It was specific to nicotine.

Q Okay. And then, from there, did you come to the Drug Enforcement Administration?

A Yes.

Q And you've been there since -- you've been here since September 2018, correct?

A Yes.

Q All right. And if you can summarize what you've done here at the DEA, I know it's difficult, but -- because you've done a lot -- but if you could tell us what you've done here?

A Yes. So, our section deals largely with controlled substances' analogues. So, we do case support for drugs that might be considered an analogue under the analogue provision. And we also do scheduling actions. So, placing drugs in any schedule is something that our section does. So I've written a number of Notice of Proposed Rulemakings, such as the one we're going to discuss today, and others.

We also monitor drugs to assess if they should be controlled. Like, we monitor drugs to see if there are, like, reports of them

in different databases, if they're causing harm. We work with our interagency partners to monitor what's going on internationally, as well. And also, as part of my duties, I've worked as a point of contact for the UN, for this last year, working on, like, treaty drugs and the processes that are entailed with that.

Q Would it be safe to say that, in terms of hallucinogens, you are DEA's go-to person?

A Yes.

Q That there's no one above you or working with you that would substitute in your role?

A Other than the supervisor, no. I've given briefings to the field and to other parties within DEA about hallucinogens.

Q Okay. I'd like to take a look at your publications. If you could point out for the Court which of your publications actually concern hallucinogens?

A If we go with the top-down, so, these are in order from most recent working backwards. The Shaw deals with a hallucinogen, PCP, and PCP-like substances. Garcia-Romeu is dealing with psilocybin, a hallucinogen. Gatch is

substituted tryptamines, which are hallucinogens. The next with Carbonaro TM is psilocybin, a hallucinogen in humans. The next one is not. Barrett, the last one on this page, is related to psilocybin.

The first one on this page four, with Carbonaro, Johnson, Hurwitz, Griffiths, is related to psilocybin and dextromethorphan. The next one is a review that we wrote about DMT, a hallucinogen. The next one is about challenging experiences with psilocybin, a hallucinogen. Zhang is not.

The next, Carbonaro, Eshleman, et al., is also -- that is my dissertation related to hallucinogens.

The next one, Carbonaro, Forster, Gatch, discriminative stimulus of N,N-diisopropyltryptamine, is a hallucinogen. And then the last -- the next one is not, it's about another substance. And then the last one is related to hallucinogens of different classes.

Q Other than this proceeding, have you ever served as an expert?

A Yes.

Q And can you summarize for the Court in

what capacity did you serve as an expert?

A So, I have served as an expert in the Analogue Act provision. So, I've submitted Rule 16s, or rules of opinion, for various drugs, as they are compared to the pharmacological effects of Schedule I or II substances. And then I also provided testimony in a case earlier this year relating to the sentencing of tapentadol versus what was argued to be -- or it should be sentenced similar to morphine or tramadol as Schedule IV substance.

Q Now, if you can kind of tell the Court what do you mean when you tell -- when you say you've testified in cases involving the Analogue Act. What purpose are you actually serving here?

A So, I've not testified, I've not had to appear for any of those, for the Analogue Act ones.

Q I'm sorry.

A We will write a basis of opinions and then submit those to the court. And then sometimes, or often for my cases, they've stipulated or plea by the time it comes for me to appear, based on the opinions that, like, I've worked with, with the attorney at that time.

Q Now, with respect to DOI and DOC, have you been asked to render an expert opinion regarding DOI and DOC?

A I have not.

Q Have you been asked to do a Eight Factor Analysis regarding DOI or DOC?

A Yes.

Q Okay. And that includes your expert opinions on each of those factors, correct?

A Yes.

Q Okay. Now, have you done an analysis pursuant to 21 USC 812(b) to determine whether DOC or DOI should be placed in Schedule I?

A Yes.

Q And --

JUDGE SOEFFING: Mr. Mann, let me just stop you right there. Do you want to offer her as an expert witness?

MR. MANN: Yes.

JUDGE SOEFFING: You're still --

MR. MANN: I have one more question.

JUDGE SOEFFING: Okay, all right.

MR. MANN: And did you consider whether DOC and DOI have a currently accepted medical use in the United States?

THE WITNESS: Yes.

MR. MANN: At this point, Your Honor, the Government would offer Dr. Theresa Carbonaro as an expert in pharmacology, with a special emphasis in hallucinogenic substances or psychedelics.

JUDGE SOEFFING: Mr. Phelps, any objection?

MR. PHELPS: Just one second, Your Honor.

(Pause.)

MR. PHELPS: Yes, Your Honor, we would request an opportunity to voir dire this witness on a couple of factors before the Court makes that ruling, that designation.

JUDGE SOEFFING: Very good. You may proceed.

MR. PHELPS: Good morning, Dr. Carbonaro.

THE WITNESS: Good morning.

VOIR DIRE EXAMINATION

BY MR. PHELPS:

Q So, you testified that all of your experience is in the field of behavioral pharmacology, right?

A More or less, yes.
Q Okay. Have you received any formal training in the field of epidemiology?
A As part of courses, I've taken statistics and epidemiology classes.
Q Was -- and when did you take those? Was that in -- what part of your --
A During undergrad.
Q Okay, so you took some undergrad statistic classes on epidemiology?
A And statistics, also, in graduate school.
Q Okay. Beyond those courses, any other formal training in epidemiology?
A I mean, I have published on databases that are epidemiology in nature. I've used them, I've evaluated them. When I was working at Hopkins, we would use databases such as the National Survey of Drug Use household use. So, I have training from working with Roland, as well, in how he would use them.
Q Okay. Could you point to where in your CV that those publications are, that work is?
A Yes. During the survey on the single

worst challenging experiences -- let me find it. It's on page four, the third one with the names on it, with Carbonaro, Bradstreet, we used some epidemiology data in that paper. But I also had many conversations with Roland, my postdoc advisor, about using epidemiology data.

Q And did you personally analyze those epidemiological data sets?

A Yes, I pulled them off the website, and we compared them together. But we did -- I did analyze them and then bring our results together.

Q Okay.

A And I believe, also, in one of the papers that we looked at with dextromethorphan also had some survey data, as well.

Q So you were just reviewing data that was already out there and collected?

A I mean, it was collected from survey data, but it was not, like, in a published paper. We, like, pulled the raw data and analyzed it. Some of it ended up in the paper; some of it did not.

Q Okay. And how were -- did you conduct those surveys?

A Not those surveys, no.

Q Okay. That was just data that was provided to you through your research process?

A Like, the CDC surveys are the ones that I'm talking about. Like, those --

Q The ones that you're talking about.

A Yeah, yeah, I did not make those surveys. I just used them and looked at the information that was publicly available.

Q Okay. And so you mentioned that, in the Journal of Psychopharmacology paper, that you used some of that data. Have you published any peer review journal papers in the field of epidemiology?

A I think mine are just -- have been in, like, excuse me, pharmacology-based ones, not epidemiology specifically. Some of them have been in Drug and Alcohol Dependence, DAD, and I think some of that -- they do publish epidemiology studies, and some of these other journals do publish epidemiology studies.

Q Okay, but you have not published, personally, epidemiological studies?

A No.

Q Okay. And do you have any formal

training in epidemiological criminology?

A I do not.

MR. PHELPS: Okay. Thank you, Your Honor. That concludes our voir dire. We would not object to Dr. Carbonaro being admitted as an expert specifically in behavioral pharmacology. However, we would propose that she has not established herself as an expert in the field of epidemiology.

JUDGE SOEFFING: Mr. Mann, I don't believe you're proposing that she be an expert in the field of epidemiology.

MR. MANN: She was not offered, no.

JUDGE SOEFFING: Okay. Would you go ahead and restate what you were offering her as an expert witness in, please?

MR. MANN: She is offered as an expert in pharmacology, with a special emphasis on hallucinogenic substances.

JUDGE SOEFFING: It sounds to me like Mr. Phelps has no objection to that specific offering.

MR. PHELPS: That is correct, Your Honor.

JUDGE SOEFFING: Okay. All right, the

Government has offered Dr. Carbonaro as an expert in pharmacology, with a special emphasis in hallucinogenic substances. In the absence of any objection by the Petitioners, the tribunal accepts the witness as an expert in pharmacology, with a special emphasis in hallucinogenic substances.

You may proceed, Mr. Mann.

BY MR. MANN:

Q Dr. Carbonaro, we've talked about, or we've mentioned, the eight-part tests for controlling a substance, and the three-part test for determining whether -- which schedule it should be placed in. In reaching your conclusions about DOC and DOI and how they fit into the various tests that we've mentioned, can you summarize for the Court what steps you took in reaching your conclusion?

A Yes. So, when I was assigned this project, we had already received an Eight Factor Analysis from HHS, which is their letter of recommendation and scientific and medical evaluation of the substances. So, when I was assigned it, I reviewed HHS's documents, as well as previous documents that went to HHS, and then

reviewed any literature that I could find related to DOI and DOC.

Q Okay. I'd like you to look at what's been marked for identification as Government Exhibit 5.

A Okay.

Q Okay, first off, the first two pages of Government Exhibit 5, can you identify those -- this document?

A Yes, this was a letter that DEA wrote to HHS asking for a scientific and medical evaluation of DOI and DOC and a scheduling recommendation.

Q And pages three through 35 of Government Exhibit 5?

A This was the document of -- that someone else wrote, in my section, of an Eight Factor Analysis that was sent to HHS to help them in their evaluation.

Q And are these documents kept in DEA's system of records?

A Yes.

MR. MANN: The Government would move Exhibit 5, marked for identification, into the record.

JUDGE SOEFFING: Mr. Phelps, any objection?

MR. PHELPS: No objection, Your Honor.

JUDGE SOEFFING: Okay. Government Exhibit marked for identification -- I'm sorry, do you have something else?

MR. PHELPS: Oh, I was just going to ask, once we get -- before she actually gets into that, if we could take a quick restroom break.

JUDGE SOEFFING: Yes.

MR. PHELPS: Okay.

JUDGE SOEFFING: Government Exhibit marked for identification No. 5 has been offered. In the absence of objection, it is received in the record as Government Exhibit No. 5. It's in. You may use it.

(Whereupon, the document previously marked for identification as Government Exhibit No. 5 was received into evidence.)

JUDGE SOEFFING: Mr. Mann, is now a good time to take a break or do you need --

MR. MANN: That's fine.

JUDGE SOEFFING: Okay. All right, we will take a 15-minute recess.

MR. PHELPS: Thank you, Your Honor.

(Whereupon, the above-entitled matter went off the record at 10:26 a.m. and resumed at 10:45 a.m.)

JUDGE SOEFFING: Okay. We are back on the record. Dr. Carbonaro, I remind you you're still under oath. Mr. Mann, you may proceed with your direct examination. One moment, though. Mr. Phelps, you have something you want to bring to my attention?

MR. PHELPS: Yes, just one logistical -- or question, request of the Court. So we as the Petitioners are not able to access the Wi-Fi system here. So we were going to ask if the Court would grant permission for counsel to have a phone on as a Wi-Fi hotspot, put away, not being used for any other purposes so that we can have internet access. We do feel like it's a material disadvantage that the Government is able to access the building internet system and we are not.

JUDGE SOEFFING: Okay. Yes, you may do that.

MR. PHELPS: Thank you. And we are going to work on getting just a dedicated hotspot after today. But we appreciate the --

JUDGE SOEFFING: Okay.

MR. PHELPS: -- Court's consideration.

JUDGE SOEFFING: For purposes of -- just for purposes of accessing internet.

MR. PHELPS: Yes, sir. Yes, sir. That's it. And yeah, we're very clear on the rules otherwise --

JUDGE SOEFFING: Okay.

MR. PHELPS: -- about phone use.

JUDGE SOEFFING: All right. Thank you, Mr. Phelps.

MR. PHELPS: Thank you, Your Honor.

JUDGE SOEFFING: You may proceed, Mr. Mann.

BY MR. MANN:

Q May the witness please see what's marked for identification as Government Exhibit 6. Do you have that before you, Dr. Carbonaro?

A I do.

Q Okay. Do you recognize this page 1 of Government Exhibit 6?

A Yes, this is from the then Assistant Secretary of Health giving HHS's scientific and medical evaluation and recommendation to place DOI and DOC into Schedule I with the concurrence

between FDA and NIDA to place these both in Schedule I.

Q So it's your understanding the process works where DEA asks the Department of Health and Human Services for its recommendation first?

A Generally speaking, yes.

Q And this is a letter from the Department of Health and Human Services, HHS, correct?

A Yes.

Q Okay. And the next page is -- 2 through 15. Do you recognize these?

A Yes, this is their Eight Factor Analysis of their scientific and medical evaluation.

Q All right. Now is this something that's kept in DEA system of records?

A Yes.

Q Is this part of the rulemaking procedure of this particular case?

A Yes.

MR. MANN: The Government would move Government Exhibit 6 marked for identification into the record, please.

JUDGE SOEFFING: Mr. Phelps, any

objection?

MR. PHELPS: No objection.

JUDGE SOEFFING: Government exhibit marked for identification number 6 has been offered. In the absence of objection, it is received in the record as Government Exhibit 6.

(Whereupon, the above-referred to document was received into evidence as Government Exhibit No. 6.)

JUDGE SOEFFING: It's in. You may use it.

BY MR. MANN:

Q Now Dr. Carbonaro, these documents, are they also published in some form in the Federal Register?

A Yes, they were published. This scientific and medical evaluation and letter from HHS was published as part as the NPRM for when it initially was published and then also when it was published again the last time.

Q So it's been published in two separate situations?

A This letter, yes.

Q Okay. And what about the -- pages 2 through 15?

A Yes.

Q And is this something that you reviewed in determining whether DOI and DOC fit into the Eight Factor test?

A Yes.

Q And this is from HHS, correct?

A Yes.

Q Now I'd like you to look at what's marked as Government Exhibit 7A. First off -- I'm sorry.

MR. MANN: Can we give her Government Exhibit 7?

BY MR. MANN:

Q Okay. Let's take a look at Government Exhibit 7 first. Can you identify this?

A Yes, this is my Eight Factor Analysis that I drafted and published with the NPRM to control DOI and DOC.

Q And what's the date on that?

A August 2021.

Q And this is something that you created, correct?

A Yes, yes.

Q And it's in DEA's system of records?

A Yes.

MR. MANN: Right. Your Honor, in order to just create a cleaner record, we would first of all move to admit Government 7 into the record.

JUDGE SOEFFING: Okay. You want to move that --

MR. MANN: Yes, yes.

JUDGE SOEFFING: -- move that in now? Okay. Mr. Phelps, any objection?

MR. PHELPS: No objection.

JUDGE SOEFFING: Okay. Government exhibit marked for identification number 7 has been offered. In the absence of objection, it is received in the record as Government Exhibit 7.

(Whereupon, the above-referred to document was received into evidence as Government Exhibit No. 7.)

JUDGE SOEFFING: It's in. You may use it.

BY MR. MANN:

Q Now I'd like you to look at -- first of all, what is the date on Government Exhibit 7?

A Seven?

Q Yes.

A August 2021.

Q August 2021. Okay. If you could look at Government Exhibit 7A, please.

A October 2023.

Q Well, the question is -- okay, I'll ask the question. What is the date on Government 7A?

A October 2023.

Q All right. And is that something that you created?

A Yes.

Q All right. And is that published in the Federal Register in some form?

A Yes, it is published with the Notice of Proposed Rulemaking to control DOI and DOC.

Q Okay. Can you explain why we have two different documents, one that's dated August 2021 and one that's dated October 2023?

A Sure. So the one that is dated August 2021 was with DEA's action to -- NPRM to control DOI and DOC that occurred in 2022. However, that notice was withdrawn.

And then we published the NPRM again in 2023 -- December 2023. And so I updated very slightly this Eight Factor Analysis. And it was then published with the NPRM.

Q And is Government Exhibit 7A a document you created?

A Yes.

Q All right. And is it kept in DEA's system of records?

A Yes.

MR. MANN: All right. The Government at this point would also move to admit Government exhibit marked for identification 7A. And I have copies if the Court needs more.

JUDGE SOEFFING: We have copies.

MR. MANN: Okay.

MR. PHELPS: Could we get a copy if you have one?

MR. MANN: I sent it to you.

MR. PHELPS: Okay. Actually, you're right. We got it here.

MR. MANN: I can give you more if you want.

MR. PHELPS: We'll take one if you got one.

JUDGE SOEFFING: Mr. Phelps, any objection?

MR. PHELPS: No objection, Your Honor.

JUDGE SOEFFING: Okay. Government

exhibit marked for identification number 7A has been offered. In the absence of objection, it is received in the record as Government Exhibit 7A.

(Whereupon, the above-referred to document was received into evidence as Government Exhibit No. 7A.)

JUDGE SOEFFING: It's in, you may use it.

BY MR. MANN:

Q All right. Before we move on, what are the differences between Government Exhibit 7 and Government Exhibit 7A?

A I believe the only differences were in the National Forensic Laboratory Information System-Drug database, NFLIS-Drug, where I did an updated query for DOI and DOC. And there were five additional encounters of DOC and one additional state. I believe that was Indiana. And then one additional state was noted for DOI which I believe was Nevada.

Q Okay. And the purpose of Government Exhibit 7A was what? This is the current document being used in the rulemaking?

A Yes.

Q Now does Government Exhibit 7A contain

your conclusions with respect to each of the eight factors laid out in 21 USC 811(c)?

A It does and -- based on HHS' evaluation and recommendation.

Q And what other materials did you consult in preparing this document, Government Exhibit 7A?

A Any data that we had related to, I guess in that NFLIS-Drug and encounters we had recorded in that and scientific published papers about DOI or DOC and prior knowledge I have about DOI and DOC.

Q Okay. So we've mentioned this term NFLIS. Do you know what that stands for?

A It's the National Forensic Laboratory Information System. And in particular, the Drug database is the one we're using.

Q And what is that?

A We -- it is a DEA system that collects data about drugs specific to law enforcement seizures and encounters from state, local, and federal labs. They are confirmed positive for that drug. And then -- it's a voluntary system.

So then these laboratories can put information into NFLIS-Drug. And then relating

to the seizures, like, where they're found and other information, that is collected. What information they put into NFLIS-Drug is also voluntary. So whether or not they put it in, whatever information they put into is voluntary. And then we can use that data to assess drug trends.

Q And when you say something is voluntary, are you inferring that it's not required that every single encounter be submitted to NFLIS. Is that correct?

A Yes, that is correct.

Q And is it usual that non-controlled substances would be reported?

A It can happen. It would rely on a lab having a standard for that drug. Not all labs have a standard. There are different priorities based on the region or the state or different law enforcement.

So they may not test a drug for -- to see if other drugs are available. And other than, like, known cutters, like, there are instances of non-controlled drugs put into NFLIS. But it's not required by any stretch to put a non-controlled substance into NFLIS. But we do

have many reports of non-controlled substances.

Q You use the term cutters?

A Like, a -- like, a drug that you could use to -- something like Benadryl is something that can be used in combination with drugs that are sold in the street and labs will test for known agents like Benadryl or others like that.

Q So it's your testimony that your understanding of NFLIS, the data, is it takes information from drug labs that deal with law enforcement, correct?

A Yes.

Q But not all the drug labs to your knowledge actually test for DOI or DOC?

A Correct.

Q Alright. Okay. I'd like you to describe for us what kind of substances are DOI and DOC.

A They're hallucinogenic substances.

Q Are they natural substances?

A They're synthetic.

Q In terms of their molecular structure, are they similar to any other hallucinogens?

A Yes, they're similar to 2,5-dimethoxy-4-methamphetamine or DOM. I may

have messed up -- mixed that chemical name, but DOM and 2,5-4-bromoamphetamine, DOB.

Q Both of them are similar to that?

A Yes.

Q All right. And are they similar in terms of the effect they have on the body and the mind to those hallucinogens?

A Yes, they work through the Serotonin 2A receptors specifically.

Q And can you explain for the court what do you mean by that, work through the serotonin receptors?

A So serotonin is one of the neurotransmitters in the body. And serotonin, I believe, has 17 different receptors throughout the body. It is believed that binding and activity through the specific receptor Serotonin 2A is necessary but not sufficient to cause hallucinogenic effects.

Q And you say they're similar to DOM and DOB?

A Yes.

Q Is that correct? Okay. Now this group of hallucinogens, do we know what kind of adverse health effects they've been known to

cause?

A Yes.

Q And what are they?

A Most commonly it's psychological in nature where they can have very profound effects on, like, fear, anxiety, depression. It can have a very intense challenging experience that can lead to these kinds of effects. And then there are a number of physiological effects that can happen as well with these drugs, particularly related to the cardiovascular system.

Q Would it be fair to say that they could cause paranoia?

A Yes.

Q Depression?

A Yes.

Q Violent outbursts?

A Yes.

Q To your knowledge, are DOC and DOI controlled in any other state in the United States?

A I believe they're controlled in Florida.

Q How about any other countries that you know of?

A DOC because it is now a UN Treaty Drug, I believe it is controlled by all UN members by this point. But specifically, DOI and DOC I know are controlled in Canada and in the United Kingdom.

Q Now are you familiar with the 1971 Convention on Psychotropic Substances?

A Yes.

Q And are you familiar with any action that has been taken with respect to DOC by the Secretary General of the United Nations?

A Yes, it was voted on to be controlled based on UN Treaty.

Q If the witness could please look at Government Exhibit 9, please. Dr. Carbonaro, do you recognize this exhibit?

A Yes.

Q Do you know is this part of DEA system of records?

A Yes, it is.

Q And can you tell the Court what is this document?

A This is a letter that we get from the UNODC after the CND has met, I believe usually in March, where they vote on drugs to see if they

should be controlled internationally. And this is the conclusions of that vote.

Q And looking at page 2 of this document, is there anything in here relating to DOC?

A Yes, on the top.

Q And what is the effect? What is happening here with DOC?

A The Commission decided to include DOC in Schedule I of the 1971 Convention.

Q And so what does that mean for the United States --

A That is --

Q -- to the best of your knowledge?

A -- a member of the treaty that we then must regulate it in a way that would meet the 1971 convention.

Q So the United States would be obligated to schedule DOC in some capacity, correct?

A Yes.

Q If it met its obligations under the treaty?

A Yes.

MR. MANN: The Government would move

Government Exhibit 9 into the record, please.

JUDGE SOEFFING: Mr. Phelps, any objection?

MR. PHELPS: No objection, Your Honor.

JUDGE SOEFFING: Government exhibit marked for identification number 9 has been offered. In the absence of objection, it is received in the record as Government Exhibit 9.

(Whereupon, the above-referred to document was received into evidence as Government Exhibit No. 9.)

JUDGE SOEFFING: It's in. You may use it.

BY MR. MANN:

Q Okay. So if we can go back and look at Government Exhibit 6, please. Do you have that before you?

A Is Government Exhibit Number 6 the letter signed by Brett Giroir?

Q Yes.

A Okay, yes.

Q Okay. So I believe your testimony was that this is HHS's recommendation, correct?

A Yes.

Q And this goes to DEA?

A Yes.

Q And then in response, DEA creates its own document?

A Yes.

Q And that's the document that you created. Is that right?

A Correct.

Q It says here that DEA must determine whether HHS's scientific and medical evaluation, scheduling recommendation, and other relevant data constitutes substantial evidence that a substance should be scheduled. And it talks about considering other relevant data. Can you tell us what's meant by other relevant data?

A Usually, HHS defers to us on law enforcement encounter data since usually we have more information on that. So largely, it's related to law enforcement data. But it could be any other information that is available.

Q Okay. Now I'd like to go over the Eight Factor Analysis in Government Exhibit 7A.

A Okay.

Q First of all, you wrote this report, correct?

A Yes.

Q Are there any changes that you need to make to this report at this point?

A I don't believe so.

Q All right. Now regarding Factor 1, and I'm going to direct you to page 3 of this report, the substance's actual or relative potential for abuse. First of all, what does that mean to you?

A It just means it's usually information that we have that's about a substance's relative potential for abuse using metrics that are established in scientific literature to assess abuse liability and the four factors that are in this as well.

Q And what are the four -- so there's four factors to determine what abuse is, correct?

A Yes.

Q And that's because abuse is not specifically defined in the CSA?

A Correct.

Q So where did you come up with the four factors?

A This goes back to the initiation of the CSA and what was outlined there.

Q All right. Let's look at -- and is

the first factor on page 3?

A Yes.

Q And that would be labeled A. Is that correct?

A Yes.

Q There is evidence that individuals are taking the drug or other substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or to the community, correct? I stated that correctly?

A Yes.

Q And what was your conclusion based on that particular prong of the abuse test?

A Based on HHS's evaluation and law enforcement seizure data that there is evidence that people are using it.

Q Now let's look at Factor B. There is significant diversion of the drug or substance from legitimate drug channels. Is that the second prong of the abuse test?

A Yes.

Q And what was your conclusion regarding that?

A This one generally applies to a drug that has medical use. And since there is no

approved medical use for it, then HHS noted that there is no diversion because it's not approved for anything. But then I also noted that I know that it is used in research, both DOI and DOC.

And to my knowledge, there's been no evidence of it being diverted from legitimate scientific research. But it does not mean that there is not. I'm just not aware of it.

Q So you would agree that DOI and DOC are currently for sale, correct?

A Yes.

Q And they are currently being made and manufactured --

A Yes.

Q -- correct? And they are currently being distributed?

A Yes.

Q And does the CSA control that system of distribution at all?

A They're not since they're not controlled.

Q All right. So for the third prong, individuals are taking the substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to

administer such substance. First of all, what is your understanding of what that means?

A That if people are using it, are they using it under the guise of -- or under the advice of a medical practitioner? Or if not, if people are using it under their own volition.

Q And what did you determine?

A That because they are not in substances that have been approved by the FDA and people -- there is evidence people are using them, then they have to be used not by the medical advice of a practitioner. And there have been no clinical trials to suggest that they have medical utility.

Q So is there any evidence that practitioners are using this drug?

A No.

Q Recommending this drug?

A Not to my knowledge.

Q Prescribing this drug?

A Not to my knowledge.

Q All right. Now you mention here in the middle of the last full paragraph, this is consistent with the data from law enforcement seizures and anecdotal reports indicating DOI and

DOC are available on the street as illicit substances. What do you mean by that?

A That they can be purchased online for people to use recreationally.

Q And then it says DOI and DOC have effects similar to Schedule I substances, LSD and DOB. What are you trying to say there?

A As part of the CSA, we have to -- for these new substances that we control, we show that they have relative abuse potential compared to other substances in the same class, in this case, Schedule I substances. As we mentioned, DOB is chemically similar. LSD is also a known hallucinogen that has activity through the Serotonin 2A receptor. It has other activities as well. But the core Serotonin 2A receptor activity is there.

Q So is it your opinion that based on the similarities between LSD and DOB that there is abuse potential?

A Yes.

Q Now the fourth prong of the abuse test, the drug is a new drug so related in its action to a drug or other substance already listed as having a potential for abuse to make it

likely that the drug substance will have the same potential for abuse as such drugs making it reasonable to assume that there may be significant diversion from legitimate channels. What do you mean there? Or what is your analysis of that particular factor, that prong?

A Again, this allows us to compare the known effects of DOI and DOC compared to substances that are in a similar class and assessing if they have abuse potential based on those findings.

Q And we talked about analogs a little bit earlier. You state here DOI and DOC are analogs of the Schedule I hallucinogen DOM. What is the reason for including that in this part of the report?

A Because DOM is a Schedule I substance.

Q And that you're comparing the two?

A Yes, with a similar mechanism of action.

Q And do you find in your research that the effects of LSD and DOM are similar to DOI and DOC?

A In that they can produce hallucinations and hallucinogenic activity and

have the same potential for the psychological effects that we've noted before and some of the cardiovascular effects, yes.

Q Okay. So we have your report in the record. But I would like to clear up a few definitions just for clarity. You're talking about drug discrimination studies. And I know this is a difficult question. But can you explain to the Court what are drug discrimination studies?

A Yes, these are studies that can be done in rodents, mice, and rats, nonhuman primates, and humans in which generally when we use them in these studies, we use rodents where an animal can receive a drug and then learn to press a lever for a food reinforcer based on the effects of those drugs. And then on another day, they are given saline so a non-drug effect. And then they learn to press the other lever when they get that. And so with several sessions, they're able to discriminate whether they got the drug that they're used to getting, the dose and at that time. And then once they're able to discriminate, then we can do other doses or other drugs of varying doses to see if it has similar

effects relative to that known drug of abuse.

Q And the term, in vivo means?

A In life.

Q So these are --

A So it's a whole body system.

Q These are studying actual animals?

A Yes.

Q Not cell studies?

A Yes.

Q Okay. So I guess to simplify it, what you're doing is you have drug discrimination studies that tell the researcher that the effects of Drug A are similar or the same to the effects of Drug B?

A Yes.

Q And what do the drug discrimination studies tell us about DOI?

A So for DOI, there were different groups of rats that trained to learn to discriminate DOM versus saline, LSD versus saline, and N,N-dimethyltryptamine, DMT from saline. And in all three of those cases, you fully substituted for the discriminative stimulus effects of those three hallucinogens. And then when given stimulants, it did not substitute for

the stimulants.

Q So it did -- the rat or the rodent felt as if DOI was the same as DOM and LSD.

A Yes.

Q But when given methamphetamine, the rat didn't -- or the rodent did not act in the same way?

A Yes.

Q Okay. What about DOC?

A DOC also fully substituted for DOM, LSD, and DMT trained rats.

Q All right. Now do you have any anecdotal -- did you look at any anecdotal reports about DOC or DOI?

A Yes, as did HHS.

Q And what did you conclude from the anecdotal reports?

A That they produce hallucinogenic effects, both seemingly auditory and visual. And there were reports of psychological harm to some degree.

Q Okay. I'm looking at page 5 of the second paragraph. It says here in humans, anecdotal reports suggest that DOI and DOC produce classic hallucinogenic effects, visual

and auditory hallucinations, fatigue, headache, gastrointestinal distress, insomnia, and anxiety. Is that consistent with your research?

A Yes, and HHS's evaluation.

Q And when you cite here Shulgin and Shulgin, who is Shulgin?

A Alexander Shulgin was a medicinal chemist who wrote two books, one about phenethylamine hallucinogens and one about tryptamine hallucinogens and provided chemical analysis of these different hallucinogens and also has anecdotal reports of the effects of each of these hallucinogens by a small party sometimes, seemingly one or a small group of friends about the effects that happen with different doses of these different substances.

Q And did he take these drugs?

A Seemingly.

Q According to his writing?

A Yes.

Q Correct? Okay. You also cite Erowid.org. What is that?

A It is a public post that anyone can write about any of the effects that drugs produce. They can write anything they want about

the drugs that they think that they -- or they think that they took or meant to take or accidentally took, anything like that, basically just an online user forum.

Q And why would someone consult something like that to determine whether DOI or DOC fit into the eight part test. Why look at an online -- looks like an online chat group of some sort?

A I believe HHS uses it as a note to look at post-market surveillance information based on their industry guidance for abuse potential. And it gives us evidence that people are using it, the effects that they're observing, how long a drug may effect in a body. But based on HHS's inclusion of it, I also included it in my Eight Factor Analysis.

Q You wrote here, HHS notes that a use of DOC in combination with other drugs is associated with Emergency Department admissions and one death. Is that correct?

A Yes.

Q And that came from HHS's recommendation?

A Yes.

Q You also have a conclusion here that DOC and DOI have a substantial capability to be a hazard to the health of the user and the safety of the community. How did you reach that conclusion?

A Based on the information that was provided to me by HHS and their similarity to other substances that are in Schedule I, such as DOM, DOB, and LSD and DMT, et cetera, of having the similar mechanism of action, they're likely to be abused and have evidence to create hazard to the health of the user or safety to the community.

Q Okay. I'd like to move on to Factor 2, scientific evidence of the substance's pharmacological effects. First of all, what does this factor call for you to do?

A To evaluate the pharmacological effects of the substances we are reviewing.

Q And are the pharmacological effects of DOI and DOC known?

A To some degree, yes.

Q And explain for the Court what are the pharmacological effects?

A So in this factor, I start with some

basic binding to see -- based on the data that are available to see where DOI and DOC bind to and have activity. In this case, I note the Serotonin 2A receptor because it is again necessary but not sufficient to cause hallucinogenic effects. So I focused on the Serotonin 2A receptor activity. So it does bind in cell studies and does have agonist effects in cell studies, both DOI and DOC.

Q Now I think this -- and this is from in vitro studies. You list here in vitro studies. Those are cell studies, correct?

A Yes, it translates to in glass. So they're just cell studies that have been transfected with a large number of receptors and those cells so you can assess binding and functional data.

Q With respect to DOI, I'd like to direct your attention to the last paragraph on page 5. It says here, DOI had a Kd ranging from .33 to 3.5. Could you tell us what that means?

A It's just one of the metrics that we use in radioligand binding and then a concentration to get that information. Really the information that we look at are the Ki

values. And the smaller the number means like it has greater affinity for a receptor and again a lower concentration.

Q So is this telling you again that DOI acts similar to other scheduled hallucinogens?

A Yes, it gives us information about the affinities and then we can compare it back to the affinities of other hallucinogens that have the same activity.

Q Just for clarity's sake, I'm coming across the word agonist. Can you explain for the Court what that means?

A Yes, an agonist is essentially the way that we show -- that we say that a drug has activity at a certain receptor.

Q So the agonist does something?

A Yes, it, like, initiates a response essentially.

Q And what does the antagonist do?

A It would essentially block a response.

Q So for instance, heroin is an agonist, correct?

A Yes.

Q And what is the antagonist?

A It would be naloxone.

Q In other words, it blocks --

A Yeah, so it would bind to the --

Q -- the activity?

A -- it would bind to the receptor. If it was taken alone, it would have no activity. But if it was given in competition with an agonist, it would block the activity of the agonist.

Q Okay. With respect to DOC, what can you say about the pharmacological effects?

A It also had a high affinity for the Serotonin 2A receptors in different cell types.

Q Similar to other Schedule I hallucinogens?

A Yes.

Q Now this is a small portion here about the central nervous system effects. What did you conclude there?

A So that is the introduction to the then whole body system. So the central nervous system essentially is the brain and spinal cord. And for us to evaluate a drug for abuse potential, it must have activity in the central nervous system.

Q And again, you concluded that DOI and

DOC are similar to DOM or -- also known as STP. Do you concur with that?

A Yes.

Q All right. Now what is the point of the -- what do you mean by pre-clinical studies?

A So those are generally a term for animal studies. But it could be human studies that just doesn't have a clinical indication. It depends on how someone is defining it. But here, I use it for animal studies.

Q What is a psychopharmacological assay?

A It's just a fancy way to say, like, an experiment type.

Q And what is the difference between a pharmacological assay and a psychopharmacological assay?

A Psychopharmacology just denotes that there's some central nervous system effect that has some psychological effect.

Q And with respect to DOI, what did you find in terms of overt or behavioral responses?

A That HHS specifically noted some behavior such as wet dog shakes and back muscle contractions that seem to be induced by activating the Serotonin 2A receptor. They

deduce this by, the study noted, an antagonist. In this case, MDL 100907 was administered in combination with DOI and it blocked the effects that were reported suggesting that they are specific to agonist activity at the 2A receptor.

Q I think we know what a back muscle contraction is. What do you mean by a wet dog shake?

A It's a similar reflex that you might see, like, a dog -- you just give a dog a bath and they shake to remove water from them. It's just a -- it's a behavior that can be seen in rodents when given a drug that binds at the 2A receptor.

Q So if you see someone -- if you see a rodent being given DOM and it manifests a wet dog shake and you see the same thing happening with DOI, what can you draw from that?

A That it likely has a similar mechanism of action. But you would need to do the test specifically with DOI, which was done here.

Q It was done?

A Yes, with DOI.

Q Okay. And the conclusion was it was the same?

A That it seemed to be mediated by the Serotonin 2A receptor.

Q Okay. I'd like to direct you to page 7 of Exhibit 7A. Again, we're talking about discriminative stimulus effects. Is this different than drug discrimination studies?

A No, it's the same. We use that word, discriminative stimulus effects, to help, like, define -- like, whatever the trained drug is, let's say if it's DOM, we call it the discriminative stimulus effects of DOM.

Q Are we still talking about animals pushing levers?

A Yes.

Q And I see here it says, drugs that have discriminative stimulus effects in common with a known drug of abuse are also likely to be abused. There's strong correspondence between the discriminative effects of drugs of abuse in animals and their effects in humans. What did you conclude with respect to DOI and DOC?

A That as we discussed before, an animal is trained to discriminate DOM, LSD, and DMT, DOI fully substituted for those substances. However, in another group of animals, DOI was trained as

the discriminative stimulus. And in those animals, DOM, DOB, LSD, and DMT produced full substitution for DOI showing there's cross substitution for these substances.

Q And did DOI -- would it be a correct term to say did DOI fully substitute for amphetamines?

A Not amphetamine or methamphetamine.

Q Did DOC substitute for MDMA or ecstasy?

A No, it failed to substitute for methamphetamine and partially substituted for MDMA. A partial substitution is not a no effect, and that is still considered to have some abuse potential of partial substitution.

Q Did DOI substitute for DOM and DOB?

A DOI?

Q DOI.

A For DOM? In animals trained to discriminate DOM, DOI substituted. In animals trained to discriminate DOI from saline, DOM and DOB both substituted.

Q How about LSD and DMT?

A Yes, both of those had cross substitution showing that the effects are

similar.

Q So again, what is your conclusion here in this particular section of Factor 2?

A Based on drug discrimination data and again based on HHS' conclusions that it indicates that DOI and DOC have stimulus properties that are substantially similar to DOM, DOB, LSD, and DMT. It is essentially the gold standard for assessing abuse liability in hallucinogenic substances. So we put a lot of weight into drug discrimination for these hallucinogens.

Q How about the effects of DOI and DOC in humans? What were you able to conclude?

A Since there have been no studies in healthy human participants, there's not really much to conclude other than data from, like, online reports.

Q And you're back to anecdotal data. is that correct?

A Yes.

Q Now just to be clear, you have some quotes here on page 8 regarding DOC and DOI. Do you know where those quotes came from?

A Those came from Alexander Shulgin's book, PiHKAL which is Phenethylamines I Have

Known and Loved.

Q And Alexander Shulgin, he did create these two drugs?

A He at least synthesized them in the book. Whether he created them de novo, I don't know.

Q And when you say he synthesized them, what do you mean by that?

A He's a medicinal chemist. So he synthesized a number of drugs. So he basically did chemistry and made these drugs out of precursor chemicals.

Q All right. What is your knowledge of DOI in terms of how long the effect of DOI lasts?

A It can be greater than 24 hours depending on the dose and route of administration.

Q And with something that lasts that long, is there anything you can do? Is there an agonist?

A Well, it is an agonist. But there is not an antagonist --

Q I'm sorry. Is there an antagonist?

A There is not. So, like, we talked about for opioids where you could give Narcan or

naloxone, there is not such a treatment for hallucinogens. So if someone was overdosing, you couldn't stop the effect with a Serotonin 2A antagonist because there's not one approved for that part. But you could do talk down therapy if someone was having a really bad experience or administration of, like, a benzodiazepine to subdue somebody. So those are the only -- the common ways that people will try to, like, stop a challenging experience.

Q And of course, you've heard the term, bad trip, correct?

A Yes.

Q Okay. So when something lasts 16 to 30 hours and it's an unpleasant experience, that's a very long bad trip, isn't it?

A It could be.

Q And I see here that you're again consulting Erowid, essentially the same anecdotal reports. Is that correct?

A Yeah, so these two citations are, again, republished in Erowid. But on Erowid, there are a number of other anecdotal reports specific to DOI and DOC that are on that same page that were evaluated as well.

Q And you note here the organization known as WHO.

A The WHO, yes.

Q World Health Organization?

A Yes.

Q Why is that put in your report?

A Because DOC mentions -- is mentioned in this action. And they did a critical review specific to DOC. So there was additional information from the WHO report.

Q Does WHO say anything about DOI?

A No, it did not evaluate DOI.

Q It says here, WHO notes that the long duration of effects is shared by other structurally related hallucinogens, including DOI. What do you mean by that?

A Oh, so they did compare it in a statement that said that DOI, DOB, and DOM had long durations of action similar to DOC.

Q So what is your conclusion regarding the pharmacological effects of DOI?

A That it is a potent Serotonin 2A receptor agonist that is known to produce very strong psychedelic effects that can vary from person to person and has based on its mechanism

of action and similarity to other drugs that are hallucinogens in Schedule I that it would have a similar pharmacological effect to those drugs.

Q And your conclusion regarding DOC, would that be the same?

A Yes.

Q Okay. All right. If we can move to -- let's go on to Factor 3. The state of current scientific knowledge regarding the substance, in your view, what are you tasked to do here? What are you supposed to find out in order to satisfy or not satisfy this particular factor?

A So Factor 3 would -- could include other scientific information that is available at the time of drafting it. Generally speaking, we leave it to discuss the chemistry of the drug and any medical use relating to that drug.

Q Okay. So in terms of chemistry, is the chemistry known?

A Yes.

Q And based on what, how can you conclude that the chemistry of DOI and DOC are well known?

A They have a molecular formula that's been cited that people have synthesized it. It's

accepted that it is known there are -- like, numbers that are affiliated with them. So if you search for this CAS Number, the structure for DOI or DOC would come up?

Q Okay. I'd like you to turn to page 9 of Government Exhibit 7A.

A Okay.

Q Just for demonstrative purposes, do you have a pencil or a pen with you?

A I do not.

MR. MANN: May I?

JUDGE SOEFFING: You can give it to the law clerk.

THE WITNESS: Thank you.

BY MR. MANN:

Q Do you see the chemical structure drawings for DOI and DOC?

A Yes.

Q All right. If you could, just for illustrative purposes for the Court, could you draw DOM?

A Just on this paper?

Q Yes.

A Okay.

Q Is that --

A Yeah, I can draw.

Q And then initial your drawing.

JUDGE SOEFFING: So in the exhibit?

MR. MANN: Yes.

JUDGE SOEFFING: Okay. The record will reflect that she has been provided a black ballpoint pen.

MR. MANN: And can we put this on the screen? I'm going to ask to get it and show it -- publish it.

JUDGE SOEFFING: Okay.

THE WITNESS: Okay.

MR. MANN: Could I get it?

JUDGE SOEFFING: Let me see it first.

MR. PHELPS: And just a quick request. At some point today, if we can get a copy of that one or have it somehow provided?

JUDGE SOEFFING: Yes, we'll make sure that happens.

MR. PHELPS: Thank you, Judge.

MR. MANN: You can take a picture of it if you want.

MR. PHELPS: I don't know about the phone rules on that.

JUDGE SOEFFING: Yeah, we'll get a

copy.

MR. MANN: I once took a picture in a hearing. Another judge told me to.

BY MR. MANN:

Q Okay. So I'm showing you -- let's see if I can zoom in a little bit. I probably can't. Is there a way to zoom in? Just push it down. We'll do it the old fashioned way. Okay. So Dr. Carbonaro, the diagram on the right is DOI, correct?

A Yes.

Q And that's the diagram that you provided in your report?

A Yes.

Q The diagram on the left is --

JUDGE SOEFFING: Hold on. Hold on one second.

THE WITNESS: Yes.

BY MR. MANN:

Q The diagram on the left is what?

A DOM.

Q So what is the difference between DOI and DOM?

A Where the I is, is an iodine in DOI. It's just a methyl group. So it's just another

carbon with three hydrogens instead. So instead of an I, it's basically a carbon.

Q And your initials, TC?

A Yes.

Q Okay. So it's fair to say that you're initialing a diagram of DOM?

A Yes.

Q Also known as STP?

A Yes.

MR. MANN: And for the record, I would offer to admit that drawing as part of Exhibit 7A.

JUDGE SOEFFING: Mr. Phelps, any objection to that?

MR. PHELPS: No objection just as long as we get the copy. That's fine.

JUDGE SOEFFING: Okay, yeah, we'll get a copy to you shortly. And the record will reflect that it has been made part of Government Exhibit 7A.

(Whereupon, the above-referred to document was received into evidence as Government Exhibit No. 7A, modified.)

MR. MANN: And that is on page 9 of Government Exhibit 7A.

JUDGE SOEFFING: Yes, page 9 has been modified as an exhibit by the handwritten sketch by the witness.

BY MR. MANN:

Q Is there any significance to the fact that both of those diagrams are identical except for one letter?

A In theory, they can have different pharmacology based on a small substitution or modification to a structure. But we would assess, like, the pharmacology and the chemistry of that substance.

Q All right. Let's talk about the medical use of DOI and DOC. What can you conclude about the medical use?

A So I base this on HHS's scientific and medical evaluation in which they said that there were no available approved medical drug products that included either DOI or DOC in the United States or in any country. And so basically, there's no information on their medical uses for treatment for any condition based on the lack of that data.

Q Dr. Carbonaro, what does IND mean?

A Investigational New Drug.

Q And what is that? What does that mean?

A It is a process for someone to study a drug for clinical implications. They need to have FDA submission and essentially approval for them to study that drug. There are regulations in place for ethical and safety evaluations of a drug that's going through clinical trials.

Q To your knowledge, are there any INDs for any hallucinogens?

A There are for psilocybin, LSD, MDMA, and I believe there is now one for 5-methoxy-DMT.

Q And what does the abbreviation NDA mean?

A That's for when a drug is going for the approval process. I believe it's a new drug application is what it stands for.

Q And are there any NDAs for any other hallucinogens?

A Not currently.

Q So the IND generally comes first, correct?

A Yes.

Q All right. So is there any IND for DOI?

A There is not.
Q Is there any IND for DOC?
A Not to my knowledge for either one of them.
Q And the same for NDAs? There's no NDA for either drug?
A No. There was an NDA that was submitted for MDMA. But it was not approved. And so there was one submitted, but it doesn't have approval.
Q I'm asking, though, is there any NDAs for DOC?
A No.
Q Or DOI?
A No.
Q Okay. So next, let's talk about Factor 4. The history and current pattern of abuse, how do you analyze that under Factor 4?
A So here we look at any law enforcement data that we have. And if there were clinical trial information about that, we'd include it. If not, then we do look at anecdotal evidence of its use.
Q Now you explained what NFLIS means earlier, correct?

A Yes.

Q Did you look at NFLIS data in determining the history and current pattern of abuse of DOI and DOC?

A Yes.

Q And what did you conclude?

A That there is evidence that they were seized and encountered and put into the NFLIS drug database.

Q Okay. I want to direct your attention to the statement, each of these phenethylamines -- no.

A Phenethylamines.

Q Phenethylamines is encountered in various forms, powder tablet, capsules, liquid, blotter paper. What is the significance of the form that a drug may be found in?

A It gives a note of how they might be used or abused. And usually since they are not approved products, if they were compounded tablets or just being diverted, like, that information would be useful for an actual approved product. But since these are not, just information that we get.

Q And has DOI and DOC been found in

these forms?

A Yes.

Q All right. Is it important to determine whether people are using -- in assessing the pattern of abuse, is it important to determine whether people are using a drug for the hallucinogenic effect as opposed to some other medicinal effect?

A Since I'm not aware of any medicinal effect, my understanding is that people are just using it for their hallucinogenic effect.

MR. PHELPS: Objection. Speculation.

JUDGE SOEFFING: Sustained.

BY MR. MANN:

Q Have you seen any reports in your studies, in your research of anyone using DOI for a medicinal effect?

A I did see one post on Reddit. It's another online forum post. I don't have evidence of it. But when I was doing research for it, I did see reports of someone who read a scientific paper that was published in animals related to its anti-inflammatory effects and I believe related to rheumatoid arthritis. And then knowing that their mom has rheumatoid arthritis

decided to give it to their mom to treat her rheumatoid arthritis without her knowing. So that was the only case I'm aware of where someone gave it for a clinical use.

Q Did you see any reports of people using DOI for its hallucinogenic effect?

A Yes.

Q Do you look at animal drug discrimination studies to determine the history and current pattern of abuse?

A Since we know that they have similar drug discrimination, then we can use it to suggest that because we know those drugs are used for their hallucinogenic effects, it would likely show cause that these drugs can also be used.

Q And did you look at any of the recommendations from the World Health Organization to determine the history and pattern of abuse?

A Yes, specific to DOC because they had written a critical review for DOC.

Q Okay. I'd like to direct your attention to page 10 of Government Exhibit 7A regarding 16 nonfatal intoxications. Where does that information come from?

A From the WHO report.
Q And that relates to DOC?
A Yes.
Q Did you see any evidence where DOC has been seized in any other countries?
A I don't recall specifically.
Q How about at the bottom of that paragraph?
A That's specific to DOC. And in those countries, there were seizures from Sweden, the United Kingdom, France, Norway, Italy, Belgium, Ireland, et cetera.
Q Now looking at Factor 5, the scope, duration, and significance of abuse, how is that -- first of all, how is that different than the history and current pattern of abuse?
A This one, we looked more for trends with a NFLIS drug.
Q All right. And looking at page 10, you have a chart there. Can you explain for the Court what this chart shows?
A Yes, it's a chart that shows the summary of the NFLIS drug encounters in the United States for both DOI and DOC.
Q And when you say an encounter, what's

your understanding of what an encounter is?

A That might vary from lab to lab. But it's essentially a law enforcement seizure that's been confirmed in analysis. So it's not a presumptive positive. It's a positive for that drug.

Q So the drug has been found by law enforcement.

A Yes.

Q And it's been tested.

A Yes, by a local --

Q And it's tested positive for DOI?

A Yes.

Q And I see here you have a number of states where it's been encountered?

A Yes.

Q And 40 reports since 2005, correct?

A Yes.

Q And the same for DOC. There are 790 reports in a number of states?

A Yes.

Q And it says, the exhibits included drug samples and tablet, capsule, powder, liquid, and blotter paper form, correct?

A Yes.

Q Have you ever seen -- are you familiar with any instance in which a drug is put on blotter? What do you mean by blotter paper form by the way?

A It's -- essentially, paper has been saturated with a drug that's been dissolved in saline or some solvent basically and then impregnated into the paper so that a small piece of paper could be put on the tongue or put in the mouth and then could -- the drug could be administered that way.

Q So you saturate a piece of paper?

A Yes.

Q Take a pair of scissors and cut it up?

A Yes.

Q And every little piece is a separate dose?

A Yes.

Q Have you ever seen that in any kind of legitimate drug, that delivery form?

A Not on paper, no.

MR. PHELPS: Objection. Can we get a clarification on legitimate?

JUDGE SOEFFING: You can save that for your cross examination. Or Mr. Mann, if he wants

to ask it now, he can. But you can save it for cross.

MR. PHELPS: Sure.

BY MR. MANN:

Q When I say legitimate drug, I mean a drug that's been approved for human use?

A I'm not aware of one from paper. There are lozenges or other things but not paper.

Q All right. If we could look at page 11 of your report, I'd like you to explain. You talked about five submissions of DOI and two submissions of DOC reported in the Microgram Bulletin since 2006. Explain for the Court what is the Microgram Bulletin.

A The Microgram Bulletin was something that the DEA Office of Forensic Sciences used to publish on a routine basis. They no longer publish that, but they include information related to drug seizures.

Q And does this relate to DEA activity?

A Yes, generally speaking.

Q All right. So you wrote a fine white powder of DOI was seized as a residence in DEA by Michigan -- by agents in Michigan. Is that consistent with the Microgram report that you

consulted?

A Yes.

Q And it was believed to be DOB but it turned out to be DOI. Is that correct?

A Yes.

Q All right. The next report is a liquid form of DOI was seized by DEA agents in Madison, Wisconsin in 2007. Is that consistent with the Microgram report that you consulted?

A Yes.

Q All right. And then there's three other law enforcement encounters. Can you describe those for us?

A Those ones were found on a blotter paper. And then they were identified to be DOI.

Q And where were they analyzed?

A Florida, it looks like Orlando, Palm Beach crime laboratory, and Kentucky state police, Western Laboratories.

Q And has DOC been found on blotter paper?

A Yes.

Q Where's that? Where was it found?

A Georgia Bureau of Investigations, Central Regional Crime Laboratory, and Kansas's

Bureau of Investigations, West Region Laboratory.

Q Would the fact that a substance like DOI was in a white powder form lead you to believe that there was evidence of abuse?

A I mean, most drugs that are approved by FDA don't come in a powder. They're usually some sort of, like, tablet or capsule or other formulation. So a powder can suggest that they are intended for other use.

Q All right. Regarding Factor 6, what, if any, risk is there to the public health? How do you analyze this with respect to DOI and DOC?

A Here we will compare it to effects that are published in case reports if they exist. And if not, based on their pharmacological similarity to other Schedule I substances. If they're likely to have risks to public health, that would be similar in fashion to those drugs.

Q And you wrote here relates primarily to the ability to induce hallucinogenic effects and other sensory distortions, impaired judgment, and strange or dangerous behavior. Where does this come from, this information?

A That time, it was taken from a review that David Nichols wrote in 2004 entitled

Hallucinogens.

Q And is David Nichols on the witness list for the Petitioners?

A Yes.

Q And would these be considered adverse health effects?

A Yes.

Q Were there any adverse health effects associated with DOC?

A Yes.

Q And what were they?

A There were three published cases of adverse effects. One involved a 20-year-old man who attended a rave party who was taken to the emergency department. And when he arrived, he was unresponsive with sinus tachycardia, hypertension, dilated pupils, non-responsive to light, and rhabdomyolysis.

He was there for 22 hours and then was released and he seemed to be okay. It seemed that the individual had reportedly ingested MDMA and DOI. But after toxicological analysis, it had actually been MDMA and DOC.

Q Okay. Just for our clarification, sinus tachycardia, is that a rapid heartbeat?

A Yes, more or less.

Q And could you explain the other term? I think you pronounced it --

A It's --

Q Say the term again.

A Rhabdomyolysis.

Q Okay. What is that?

A It's essentially, like, muscles being broken down and then entering the blood stream. And that can cause hepatic -- renal -- kidney failure or kidney toxicity.

JUDGE SOEFFING: Doctor, go ahead and spell that term for the record, please.

THE WITNESS:

R-H-A-B-D-O-M-Y-O-L-Y-S-I-S.

BY MR. MANN:

Q Okay. So the other two incidents involving DOC were what?

A One was a 2014 report where a 37-year-old man had a history of methamphetamine abuse was found dead in his home. He was found partially decomposed. But he was found laying face side with a book entitled Psychedelic Chemistry in his hand. And the only thing that was positive in his blood was DOC and caffeine.

Q And the final one regarding DOC?

A This was an 18-year-old man who experienced hallucinations and agitations, also seizures, shaking, and dilated pupils. He was intubated due to again this tachycardia, hypertension, rhabdomyolysis. And it showed that he had taken DOC but also cannabinoids and opioids.

Q And it lists another symptom here, T-A-C-H-Y-P-N-E-A.

A Yes.

Q What is that?

A It's rapid breathing.

Q How do you pronounce it?

A Tachypnea, I believe.

Q It's rapid breathing?

A Yes.

Q All right.

A I believe so.

Q Okay. I want to move on to -- well, first of all, since we've talked about NFLIS data, could you please take a look at Government Exhibit 8.

JUDGE SOEFFING: That's Government Exhibit 8 for identification. It's not yet been

admitted.

MR. MANN: Yes, Government Exhibit 8 for identification.

BY MR. MANN:

Q Do you see this two-page exhibit?

A Yes.

Q And do you recognize this?

A Yes.

Q And what is it?

A These are aggregate summary data for both DOI on page 1 and DOC on page 2 of the number of encounters broken down by state and year.

Q And who created these charts?

A My section.

Q Your section did?

A Yes.

Q And this is kept in DEA's systems of records?

A Yes.

Q And these reflect the law enforcement encounters regarding DOI and DOC?

A Yes.

MR. MANN: The Government would move Exhibit 8 into the record, please.

JUDGE SOEFFING: Mr. Phelps, any objection?

MR. PHELPS: No objection, Your Honor.

JUDGE SOEFFING: Okay. Government exhibit marked for identification number 8 has been offered. In the absence of objection, it is received in the record as Government Exhibit 8.

(Whereupon, the above-referred to document was received into evidence as Government Exhibit No. 8.)

JUDGE SOEFFING: It's in. You may use it.

BY MR. MANN:

Q All right. Let's move to Factor 7, psychic or physiological dependence liability. What is that?

A Dependence is essentially, like, willingness for someone to repeatedly take a drug even though they have or they know there are harms. Physiological is generally there's a withdrawal associated if someone becomes dependent with it. And so there are markers of withdrawal that may happen with physiological dependence. Like, essentially, the body needs it to continue functioning. Whereas psychic

dependence or a psychological dependence as it's sometimes used is willing to use a substance repeatedly knowing that there are harms.

Q And what did you determine with respect to DOI and DOC in terms of physiological dependence liability?

A That for most hallucinogens that work through the Serotonin 2A receptor, physiological dependence is not really a thing that happens with this group of substances. But there is evidence of psychic dependence.

Q So when you say it's not something that happens, you're saying there's no withdrawal if you stop taking it -- no physical withdrawal?

A I mean, yeah, because most people only take it once. There are reasons why somebody may not become dependent. Like, something happening, like, a long duration of action may reduce its dependence. There are many factors going into it. But because it's usually only taken once, there is generally no withdrawal.

Q Now what about psychic dependence liability with respect to DOI and DOC? Is there evidence of that?

A There is evidence based on people

willingly taking them, knowing that there are dangers that could happen to themselves or others. And because they are similar in pharmacological activity too, DOM, LSD, and DMT which have very well-known psychic dependence that they likely would also have psychic dependence related to those substances.

Q So the fact that there's no physiological dependence does not mean that the abuser would stop taking the drug after one administration?

A No, not necessarily.

Q It could be repeated over and over again?

A Yes.

Q Based on the psychic --

A Yes.

Q -- dependence liability? And you drew this conclusion by consulting what?

A I largely referred to HHS's document on their scheduling of recommendation and scientific and medical evaluation.

Q I see here there's a citation to Buchholz. What is that?

A They also note that these

hallucinogens are not usually associated with physical dependence due to their likely -- or sorry, likely due to their rapid development of tolerance.

Q All right. Now with Factor 8, what is meant by whether a substance is an immediate precursor of a substance already controlled?

A Just if that drug could be used to make a substance but just, like, one chemical reaction away.

Q And does DOI fit that --

A No.

Q -- profile?

A No.

Q Does DOC fit that profile?

A No.

Q So this factor does not apply --

A Correct.

Q -- in your opinion?

A Correct.

Q Now regarding Factor 1, in your opinion, is there substantial evidence that DOI -- of DOI's relative potential for abuse?

A Yes.

Q Is there substantial evidence of DOC's

relative potential for abuse?

A Yes.

Q In your opinion, is there adequate scientific evidence of DOI's pharmacological effects?

A Relating to Factor 2?

Q Yes.

A Yes.

Q And is there adequate scientific evidence of DOC's pharmacological effects?

A Yes.

Q In your opinion relating to Factor 3, does the evidence of DOI and DOC's pharmacological -- I'm sorry. This is still Factor 2. In your opinion, does the evidence of DOI and DOC's pharmacological effects lead you to believe that both these drugs can cause hallucinations?

A Yes.

Q In your opinion, does evidence of DOI and DOC's pharmacological effects tell you that they are similar to DOM?

A Yes.

Q Does it tell you that they are similar to LSD?

A Yes.

Q Does it tell you they are similar to DMT?

A Yes.

Q Now regarding Factor 3, the current state of current scientific knowledge, in your opinion, can you reach a conclusion as to whether the chemistry of DOI and DOC is similar to other Schedule I controlled substances?

A Yes.

Q And what is your opinion, yes or no?

A Yes.

Q Regarding Factor 3, can you reach a conclusion regarding the medical use of DOC?

A Based on HHS's note that DOC -- DOC are not available -- approved human drug products, and there is nothing to suggest that for any condition.

Q How about your conclusion regarding the medical use of DOI?

A It's the same.

Q In your opinion, is there evidence of a history and pattern of abuse regarding DOI?

A Yes.

Q Is there evidence of a history and

pattern of abuse regarding DOC?

A Yes.

Q In your opinion, do the drug discrimination studies that you have consulted support the conclusion that DOC and DOI produce effects that are similar to drugs such as DOM, LSD, and DMT?

A Yes.

Q Is it your opinion that there is substantial evidence that DOM, LSD, and DMT have a history and pattern of abuse?

A Yes.

Q Regarding Factor 5, have you formed an opinion regarding the scope, duration and significance of abuse regarding DOI?

A Yes.

Q And what is that opinion?

A That DOI has evidence of significance of abuse.

Q How about DOC?

A That it also has evidence of abuse.

Q Regarding Factor 6, have you formed an opinion regarding the risk, if any, to the public health posed by DOI?

A Yes.

Q And what is your opinion in that regard?

A That essentially because DOC had reports and it is similar in structure to DOC and other hallucinogens that it would also likely produce serious adverse effects.

Q And the same question for DOC. Do you have an opinion regarding the risk, if any, to the public health posed by DOC?

A Yes.

Q And what is your opinion?

A That there is risk to public health based on the reports.

Q And regarding Factor 7, have you formed an opinion regarding the psychic or physiological liability of DOI and DOC?

A Yes, so there's evidence of psychic dependence liability.

Q In your opinion, do DOI and DOC have a high potential for abuse?

A Yes.

Q Okay. Now I want to direct your attention to the three factors in 21 USC 812(b) that are considered when determining whether a drug is in Schedule I. I believe you just said

it had a high potential -- both drugs had a high potential for abuse. Is that correct?

A Yes.

Q And that is based on what?

A On my evaluation and also HHS's mention that they have high potential for abuse because they're similar to those of DOM, a Schedule I hallucinogen.

Q Okay. Let's talk about currently accepted medical use in the United States. How do you evaluate currently accepted medical use in the United States?

A So we have two ways of doing so. First is to find out if FDA has an approved marketing application for a drug containing DOI or DOC. And if that is not the case, then DEA does a five part test to analyze a medical -- currently accepted medical use.

Q Is Part 1 of that test that the chemistry must be known and reproducible?

A Yes.

Q And what does that mean?

A It means that there has to be significant information related to the chemistry that is available and can be reproduced in a

certain way.

Q And can the chemistry of DOI and DOC, is it known and reproducible?

A It is.

Q Is the second part of the test the fact that there has to be adequate safety studies for DOI and DOC?

A Yes.

Q In your opinion, were there any adequate safety studies done for DOI or DOC?

A No.

Q Why is that?

A There have been no clinical trials related to DOI or DOC that have been published.

Q Okay. Is the third factor that adequate and well controlled studies must prove efficacy. Does that sound familiar?

A That is correct.

Q All right. And is there any evidence that adequate and well controlled studies proved efficacy regarding DOI?

A No. Again, there have been no clinical trials to my knowledge with DOI or DOC.

Q How about DOC?

A For neither substance.

Q Has DOC or DOI been accepted by any qualified medical experts?

A Without any clinical trials, I don't see how that can be true.

Q And is there any evidence that the scientific evidence of the efficacy is widely available?

A I'm sorry. Can you repeat that again?

Q Factor -- well, first of all, your understanding of Factor 5 that DEA uses, scientific evidence must be widely available. What is your understanding of that factor?

A That there are publications available through, like, research studies, through databases that house those things where, you know, it can be searchable online, that they're not, like, private information.

Q And what scientific evidence are we talking about?

A Those are generally related to clinical trials for that one.

Q Okay. Is there any evidence that that evidence is widely available?

A Since I'm not aware of any clinical trial, I can't see how that's widely available.

Q The third factor in -- I think it was 812 -- is there is a lack of accepted safety for use of the drug under medical supervision. What are your conclusions with respect to that?

A That I agree with HHS's statement that the use of DOC is associated with serious adverse consequences including deaths. And since DOI is structured similar to DOC, it produces effects similar to DOC. It is likely that DOI may produce serious adverse effects as well. And because again there is no currently accepted medical use and it has not been thoroughly investigated as new drugs, their safety for use under medical supervision is not determined.

Q In your opinion, is there any evidence that healthcare providers in the U.S. have widespread experience with the medical use of DOI?

A Not to my knowledge.

Q What about DOC?

A No.

Q In your opinion, is there any evidence that the use of DOI or DOC is recognized by entities that regulate the practice of medicine?

A Not to my knowledge.

Q Dr. Carbonaro, have your opinions regarding whether DOI and DOC, have they been explored here during this examination?

A Yes.

Q Is there anything you would like to add?

A I mean, I know that they are investigated in research, usually basic research, and that DOI more so than DOC. And that data is important to DEA. But generally for these eight factors, we generally rely on the abuse potential data that is available for these, if there's any safety studies in animals.

Like, a safety study in an animal would not necessarily be sufficient to say that it would be safe for use in humans without those. And saying that we have to just look at the data specific for DOI and DOC specifically and not for other -- not for other drugs that may -- like, for abuse potential when we are comparing them, like, head to head. But we can't use data that is not comparing them in a similar fashion. So we try to stick to the data that is available related to abuse potential for these drugs.

Q Is LSD a Schedule I controlled

substance?

A Yes.

Q Is it being researched?

A Yes.

Q Is MDMA a Schedule I controlled substance?

A Yes.

Q Is there research going on with MDMA?

A Yes.

Q Would placing DOI in Schedule I shut down research?

A I don't believe so.

Q Why not?

A So as part of my duties in the section, I also handle the Schedule I researcher program as a backup since I started. And then I was the primary point of contact for some time. And now I just kind of consult.

And so I am familiar with the Schedule I researcher process, how those applications come in through DEA, how we review them, how we work with HHS. I also -- so understanding that process, also working with Schedule I substances in essentially every step of my career before joining government, understanding those from,

like, also a researcher standpoint and using DOI in research before joining DEA that with my experience of being a researcher and in DEA that research can still be done under the Schedule I researcher program. And many of the studies -- even many of the studies that were included as evidence are done in labs that have Schedule I researcher registrations.

MR. MANN: Just one moment, Your Honor. I pass the witness.

JUDGE SOEFFING: Okay. Thank you, Mr. Mann. Mr. Phelps, would you like to start your cross examination or break for lunch?

MR. PHELPS: I think a break for lunch now would be great, Your Honor.

JUDGE SOEFFING: Okay. We will break for lunch. We will return at 1:15. Let's go off the record for a moment.

(Whereupon, the above-entitled matter went off the record at 12:12 p.m. and resumed at 1:27 p.m.)

JUDGE SOEFFING: All right, we're back on the record.

Dr. Carbonaro, I'll remind you you are still under oath. Mr. Phelps, you may begin your

cross-examination.

MR. PHELPS: Thank you, Your Honor. And with the Court's permission, would it be allowable for me to conduct it here at the table still standing, rather than at the lectern?

JUDGE SOEFFING: Oh, if that's easier for you, that's all right.

MR. PHELPS: I think it would, I think it would be easier.

JUDGE SOEFFING: Okay.

MR. PHELPS: Thank you, Your Honor.

Sorry, I want to get this plugged in so my screen's not going black. Okay.

Whenever you're ready, Judge.

JUDGE SOEFFING: Ready.

MR. PHELPS: Thank you.

Good afternoon, Dr. Carbonaro, welcome back. So, I'd first like to point your attention to Government's Exhibit No 6.

THE WITNESS: Thank you. Okay.

CROSS-EXAMINATION

BY MR. PHELPS:

Q And this is the -- this is the letter signed by Brett Giroir, correct?

A Yes.

Q Okay. And in the third paragraph of that letter, the first sentence says, FDA and NIDA, N-I-D-A, have also considered the abuse potential of DOI and DOC. And it goes on from there.

Those -- the FDA and the NIDA analysis, are those -- is that publicly available information?

A FD -- I mean, I think it's in totality with the Eight Factors of Analysis that were submitted with the submissions of the NPRMs. And my understanding is that the FDA sends that to NIDA, and they have a communication within themselves about concurrence. I'm not aware of that being public knowledge, the communication between FDA and NIDA.

Q Okay. And do you -- do you, in compiling your reports, did you review any of that NIDA analysis?

A I reviewed the Eight Factor Analysis that was submitted to me on behalf of HHS that NIDA concurred on.

MR. PHELPS: Okay.

JUDGE SOEFFING: Hold on a second.

Mr. Reporter, are you able to pick up

Mr. Phelps?

COURT REPORTER: Yeah, I am, it's just kind of pointed towards his shoulder and not his mouth.

MR. PHELPS: Okay, not a problem, yeah.

JUDGE SOEFFING: Put that mic a little closer.

MR. PHELPS: That's never been a problem for me in court before, so thanks for -- thanks for letting me know.

Okay, so it's your understanding that NIDA just reviewed and concurred on what was already provided in the other Eight Factor Analysis.

THE WITNESS: Based on what this letter says, and personal communications, yes.

BY MR. PHELPS:

Q Okay, okay, thank you. So I'd like to walk through with you the Eight Factors and some of your previous testimony about those. So Factor One is about the potential for abuse. How did -- you say that this is the DEA's definition for abuse. Is this the only definition for drug abuse?

A It is DEA's definition of abuse. There may be other definitions. But it is the one that has been used previously in legislative history.

Q Okay. And specifically in the legislative history, they go through the four factors that are analyzed here?

A Yes.

Q Okay. And in your previous work prior to being employed by the DEA, was that how you and your colleagues defined drug abuse?

A I mean, to some degree, yes, but not as specific to some of these points.

Q Okay, and what -- which of those points? What do you see different?

A That's a good question. Actually, upon looking at them, I feel like this would still mirror my definition of abuse.

Q Would this mirror Dr. Roland Griffith's definition of abuse?

A I'm not sure.

Q Because you, when you were working with him at Johns Hopkins, you dealt with issues of drug abuse, right?

A We assessed abuse liability.

Q Okay. And so you don't know if that -- if the abuse studies you were doing there used the same definition or something different?

A Oh, we measured like abuse liability metrics. But I don't know what his definition is or was.

MR. PHELPS: Okay. So Factor A says, There is evidence that individuals are taking the drug or other substances in amounts sufficient to create a hazard to their health or the safety of other individuals or to the community. Oh, I apologize, the 7, 7A mixup has -- which one is?

Oh, oh, oh, thank you. Thank you, yes.

JUDGE SOEFFING: Yeah, so we're looking at 6, is what I'm looking at.

MR. PHELPS: Yes, okay.

JUDGE SOEFFING: And what the witness has. It's Government Exhibit 6.

MR. PHELPS: Yes, I apologize, Your Honor. We're finished with that now. We're going to work through the Eight Factor Analysis provided in Government's Exhibit 7A.

THE WITNESS: So I'll give this one back.

BY MR. PHELPS:

Q Okay, and can you please go to page 3 of that report, Dr. Carbonaro?

A Okay, I'm on page 3.

Q Okay, and you see what's the subparagraph A there?

A Yes.

Q Okay, that there's evidence that individuals are taking the drug or other substances in amounts sufficient to create a hazard to their health or to the safety of other individuals or to the community.

So how do you define sufficient amount?

A I think any evidence that produces a psychological or a psychoactive effect that the drug induces. And if there's evidence to show that there are harms associated with it. The sufficient amount is going to be relative to that drug.

We know DOI and DOC are very potent. I think 1-3 milligrams can have an effect. So a small amount of this drug would -- could be very likely to cause significant harm.

Q Okay, so you're specifically referring to the dosage amount that an individual is taking

--

A And --

Q In that --

A In what I just said, yes.

Q Yes, okay, okay. And so, and you said that for DOI or for DOC, something in the amount of several milligrams could be considered a sufficient amount?

A Yes, because it's been shown to cause hallucinogenic properties.

Q Okay, and in any of the law enforcement data, NFLIS, any of the other evidence that you've provided, has any of that shown the amount that people are taking?

A In the public forums and in like the PiHKAL by Shulgin, there are doses that are mentioned of what would cause a strong psychoactive hallucinogenic effect.

Q Okay, and what about in any of the law enforcement data?

A In some of that law enforcement data, there are amounts that can provided within NFLIS-Drug, but it's not necessarily saying how much any one person is using.

Q So that's the amount that is

encountered, right, or seized?

A Or at least tested.

Q Or the amount tested. But it says nothing about the amount that an individual consumed.

A Correct, but it is showing that it is encountered by law enforcement.

Q Okay. So how do you know that people are consuming these substances at a sufficient amount?

A For this factor, I relied on HHS's evaluation, saying that they are used, that individuals are using them in sufficient amounts. But also based on public forums, it does indicate that people are using them in a way that would cause hallucinogenic effects.

Q And HHS's analysis of that was based on the same anecdotal reports, right?

A I believe so,

Q Okay.

A And others. Like on Erowid, not just PiHKAL.

Q Okay. And is -- does that sufficient amount have anything to do with the amount of times that somebody takes a drug, or it's only a

specific dosage on a single use?

A It's not even a specific dosage, and it's -- it just shows the evidence that people are using it. It's not specific to a -- any duration of time of use.

Q Okay, okay. Okay, I'd like to just take, if we turn the page there, to page 4, subsection B.

A I'm sorry, which subsection?

Q Or the subparagraph B there.

A Okay.

Q It says there's -- so this is the factor of if there's significant diversion of the drug or substance from legitimate drug channels.

A Yes.

Q And to be -- what is your -- according to DEA's findings, there's no evidence of diversion from legitimate channels, correct?

A We could not find any evidence, but it doesn't mean that there is no evidence. Like the -- it doesn't happen, we just, we didn't find it in our evaluation.

Q Okay. How broadly do you -- do you evaluate that to make that determination?

A In this case, I mean, we're kind of

limited to what's available online and through some like court prosecutions. But it's very limited. But as I noted in this factor, I said this characteristic of abuse potential is not applicable.

Q Okay. So as far as you know, there's been no criminal prosecutions for that either.

A Not that I'm aware of.

Q Okay. And then down to Part C, paragraph C.

A Okay.

Q Individuals are taking the substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such substance.

So this is where you mentioned about people being able to buy this on the street, right?

A Yes.

Q And during your previous testimony, you testified that people purchase DOI and DOC online for recreational use.

A It seems that way, yes.

Q Where do they purchase it?

A I don't know if I said online

specifically, but there -- people are purchasing it based on having drug encounters with DOI and DOC.

Q Okay, but are you aware of -- are you aware of anywhere that people can purchase these drugs online for recreational use, as you testified?

A I mean, there are many websites where you can purchase DOI and DOC and other chemicals online.

Q Okay. You can purchase them online for research purposes, right?

A No, for a recreational drug. There are many websites on the Clearnet and Darknet where you can buy substances.

Q Okay, and does the DEA have any evidence of sales of DOI and DOC online?

A I'm not aware of any.

Q Okay. So any testimony that it could be done is purely speculative.

A Yes.

Q Okay.

A But they are found on the street in blotter paper. Like there are ways that people are using them. So there is evidence of people

using them and reporting online about their effects.

Q With that, I think I'd like to take a look at Exhibit 8 with you, Doctor.

A Okay.

Q So the first page of this exhibit is specifically about DOI. And you just testified that people are out there buying it and using it. Can you tell me how many people, based on your own data, bought or used DOI in the year 2005, when this study began?

A It's not a study per se, it's just data that were collected. So I wouldn't call it necessarily a study, it's just data that we're able to pull from our database. And again, this is just based on encounters, it's not necessarily based on like specific number of users.

Q Okay. But based on -- based on the data that you collected, you're right, it's not a study. Thank you for correcting that. How many encounters were there with DOI in 2005?

A One.

Q And in 2006?

A Seven.

Q Seven for the year?

A Yes.
Q That would be three in Kansas and four in Wisconsin?
A Yes.
Q Okay. How about 2007?
A Five.
Q Two thousand and eight?
A Two.
Q Two thousand and nine?
A Twelve.
Q Two thousand and ten?
A One.
Q Two thousand eleven?
A Three.
Q Two thousand and twelve?
A Three.
Q Two thousand thirteen?
A One.
Q Two thousand fourteen?
A One.
Q Two thousand and fifteen?
A Two.
Q Two thousand and sixteen?
A I don't believe any.
Q Two thousand seventeen?

A One.
Q Two thousand and eighteen?
A One.
Q Two thousand nineteen?
A Zero.
Q Twenty twenty?
A None.
Q Twenty twenty-one?
A None.
Q Twenty twenty-two?
A None.
Q And twenty twenty-three?
A None.
Q Okay. So would you say that numbers like that indicates that there's a lot of sales going on of this?
A NFLIS numbers, like I said, NFLIS-Drug is a voluntary database. What drugs are tested for and confirmed for and reported back to DEA can vary for different reasons, based on priorities of labs and other caveats.

Just because like these numbers, maybe there are no reports between 2019 and 2024, it doesn't mean that they're not there. It just means they were not recorded into NFLIS.

And these numbers for, especially for non-controlled drugs, tend to be lower than ones that are controlled. And then labs will start testing them. And those numbers will increase once they are controlled.

So since they are uncontrolled, it is very likely these numbers are under-reported. But it shows that there is evidence of them in law enforcement encounters.

Q And how do those numbers compare to other substances you may see in the same type of data?

A It varies from drug to drug.

Q Well, how about some of the other drugs you've testified about today? MDMA?

A It's higher. But it's also a controlled substance. So if it's positive and if a lab finds MDMA, which is a controlled substance, they may stop testing for other controlled substances or non-controlled substances. So I would expect MDMA, LSD, and psilocybin to all be higher than these noncontrolled substances.

Q So what you're saying is this data may not even accurately reflect what's happening out

there with these substances in terms of public --

A It just shows that there's evidence that they are being encountered in seizures.

Q Okay. And you mentioned other than -- other than this data, the other basis that you're using to come to this conclusion about the potential harms of this drug is anecdotal reports, right?

A Based on HHS's evaluation, yes.

Q Okay. And where did those reports come from? You mentioned a few different places today.

A HHS's mostly came from Erowid and also cited PiHKAL's book.

Q Okay. And do you have any information about -- well I guess did you personally review any of the Erowid posts?

A I did.

Q Okay, and do you know the dates of when those were posted?

A Not off the top of my head.

Q Okay. Did you find anything on -- do you know who made the posts?

A Online users.

Q Okay. Any identifying

characteristics?

A Not more than they put out there. Some of them put age, gender, stuff like that. But not any individual information.

Q Okay. So is there -- were you able to, in reviewing those Erowid posts, was there anything in them to indicate that they were reliable, scientifically speaking?

A We routinely review Erowid posts, Reddit posts for, looking for what effects a drug might have on a person. Because it's unethical to give them to humans in a clinical trial to assess abuse liability without the right parameters. So to some degree, we rely on them to see what people are saying.

They did indicate, many of them, that the drug lasted a long time. And that would be not like LSD or other substances that might be similar. So it does give some indication that if it was DOI or DOC, it was something similar to it.

Q Well, anyone who's read PiHKAL would know that this is a long-lasting substance, right?

A Yes.

Q So the fact that they said that doesn't make the -- doesn't make this information inherently reliable, scientifically speaking.

A It's still available, the evidence that we have --

MR. MANN: Objection. The witness is not able to establish reliability on that basis.

JUDGE SOEFFING: Overruled.

MR. PHELPS: Is there any way in any of these posts to verify the veracity of what people are saying?

THE WITNESS: I again relied on HHS's evaluation. It's one of their prongs when they assess post-market surveillance information. And they understand that there are issues with relying on anecdotal evidence. But I did rely on them to review them and I gave them credence in my evaluation.

BY MR. PHELPS:

Q Okay. And what makes -- I'm just trying to figure out how do you know that it was even a human that wrote that?

A I suppose I don't. But again, I defer to HHS on this, on this factor.

Q Okay.

A For this evaluation of the anecdotal data.

Q Okay. And what was it about HHS that made it more reliable than analyzing it yourself?

A Well, I concurred with them after I reviewed the posts as well. But because they are the ones that drafted the medical and scientific evaluation, I do give credence to what they review.

Q Okay.

A And what they submit to us.

Q But they didn't -- they didn't have any additional information regarding the veracity of what's on Erowid, right?

A Not that I'm aware of.

Q Okay, and anyone with internet access can go on Erowid and post whatever they want, right?

A True.

Q Okay.

A But I did see a new Reddit post that was published last month about DOI and about the use of the DOI. And there was an indication that in a, some sort of large group gathering that DOI was used by some two to three hundred people in

this one gathering. So there is other more current evidence that DOI is being used.

Q And was there anything in that post that indicated these people knew they were taking -- that what they were taking was DOI?

A They seemed to, based on the posts that they were saying that DOI was specifically given to two to three hundred people at this gathering. That other people, again, I go back to what I noted earlier about the individual who read a scientific paper in rodents and then sought to get DOI and then gave it to his mother or gave it to their mother to treat rheumatoid arthritis.

So there is some indication that people are seeking it for one thing or another. In the deaths there was, they thought that they took DOI. It turned out to be DOC in one of those cases. So there is some evidence that people are seeking out DOI.

Q Okay. Did that post describe any kind of analytical chemistry, any kind of testing to actually verify that that's what it was?

A In the large gathering?

Q Yes.

A No, it was just a comment on Reddit. But they seemed to know exactly what it was, because it was in relation to is that the drug that DEA is trying to schedule. That's not used by a hundred people. And they're like no, there was a report of it to two to three hundred people. Again, this was just published online.

Q Okay. And other than that, other than that post, do you have any proof that that story is real and not something somebody just made up?

A No, but again, we do -- it is often used to assess abuse liability to see what people are saying about it. Because it would be unethical to give it to a human to ask them what the effects are without knowing how safe or effective it would be.

Q Okay, yeah, that was just a yes-or-no question. Do you have any proof that that story is real?

A No.

Q Thank you. And some of your other anecdotal reports that you mentioned were emergency room reports, right?

A Yes.

Q Okay. And did any of those ER reports

include people who were admitted for only consuming DOI or DOC?

A The DOC was DOC plus caffeine. So essentially just DOI. The person attributed it to DOC specifically.

Q Okay. You -- so let's talk about caffeine for a second then. What are some of the psychopharmacological effects of caffeine on the human body?

A It had stimulant effects.

Q Okay, and the issues that these people were presenting for at the -- at the emergency room were consistent with the side effects of the stimulants, right?

A I believe -- let me look at that factor. Hold on one second. I think the one that was DOC and caffeine was -- he was found dead. And the medical examiner made the conclusion that it was related to the effects of DOC.

Q Okay. So in that case, do you know how long the individual had been dead?

A I do not recall from the paper.

Q Okay. You did testify, though, that his body was already decomposed, right?

A It was partially decomposed, yes.
Q So that would not immediate.
A There was some time. I don't remember if he said how long or gave an estimate.
Q And so can you definitively say that there weren't other substances in his body that had already -- that had already decomposed along with the rest of him, the metabolites had broken down where they weren't testable?
A I know that they tested for a whole number of drugs. But I'm not sure, I'm not a toxicologist.
Q Okay. So yes, it could have been possible that at the time of his death, there was more than just those two substances.
A They didn't seem to think that was the case. The authors of the papers seemed to --
Q It's just a yes or no, ma'am.
A Repeat your question, please.
Q Can you say yes or no that it's possible that there was other substances that he consumed at the time before he died?
A Presumably.
Q Okay. And so the people who presented still alive at the ER --

A Yes.

Q None of those had only DOI or DOC, right?

A Correct. One was MDMA and DOC and the other was DOC with other drugs.

Q Okay. So can you attribute the adverse health effects that they were suffering strictly to DOI or DOC? It's a yes-or-no question.

A Not necessarily.

Q Okay. And the fast-beating heart, the breathing issues, those are also potential adverse health effects of MDMA, right?

A Yes, and DOC as well. And other hallucinogens that work in the 2A receptor.

Q Okay. I'd like to take us back to Exhibit 7A, please. And move on to page 4, paragraph D. Can you please just read the first two lines of that?

A Of which paragraph?

Q What's listed as Section D in italics at the bottom of the page.

A The first two lines?

Q Actually just the whole first sentence, please.

A The drug is a new drug, so related in actions to a drug or other substance already listed as having a potential for abuse to make it likely that the new -- that the drug substance will have the same potential for abuse as such drugs, thus making it reasonable to assume that they may be significant diversion from channels, significant use contrary to or without medical advice, or that it has substantial capability of creating hazards to the health of the user or the safety of the community.

Q Okay. So isn't it true then that that factor specifically applies to new drugs?

A I'm not sure that there's an operational definition of a new drug.

Q Okay. Well, that's what's in your -- that's what's in your standard that you're using here, right?

A Right, but like a new drug may not be, well, it may be like a current -- it could just be a drug that's not controlled and it's being evaluated for that. We use this also for the same Eight Factor Analysis for drugs that go into 2 through 5.

And so it just may be like a drug that

has been around for a while but is now going through that process. New is relative.

Q New is certainly relative. So how does the DEA define a new drug then?

A We just use it broadly to assess any drug that we're reviewing.

Q Okay, so it means it's new to you.

A It's a new drug of concern, yes.

Q Okay. When was Shulgin describing his experiences with DOI? Now when it was published. What were the dates that he was talking about in his lab?

A I don't recall the specific dates.

Q Do you know when the book was published?

A I believe -- I don't recall off the top of my head.

Q Nineteen ninety-one sound right?

A I believe it was in the 90s, that sounds about right.

Q Okay, 1991 according to your citations.

A Yes.

Q And in your understanding of that, when Alexander Shulgin published that book, he

had already been working on these substances for decades, right?

A I believe so.

Q Okay. So it's safe to say that he's referring to when he first synthesized DOI and DOC, sometime decades before 1991?

A It seems likely.

Q And that to the DEA is what qualifies as a new drug?

A Again, I don't know that we have a definition of new being temporal. That it has to be within a certain time period for it to be new. It's just the language that was put forward in the CSA and we have used it since.

Q If it's not temporal, what is new?

A Again, I think it could just be the drug that is what they've called to be under evaluation. There are many drugs that go through the FDA process that have been around for decades and are now being tested for medical use, and we use that same language.

Q That's under the NDAs that you referred to earlier?

A Not during the NDAs, because we only receive it after the NDA has been approved. And

then we get an Eight Factor Analysis and recommendation from HHS at that time.

Q Okay. So it would -- so even though it was synthesized maybe 50 years ago, it was first brought to the public's attention in 1991, say, widely, that still constitutes in your understanding a new drug?

A Yes.

Q Okay. Would this factor still apply to something that's not a new drug?

A Yes.

Q This factor D that specifically says the drug is a new drug?

A Yes, we still do this factor analysis for drugs that may have been around longer and may not be considered new based on your seemingly temporal definition.

Q So essentially what you're saying is it's only a new drug because DEA's calling it that?

A Because the CSA called it -- called it that in our Eight Factor Analysis.

Q The CSA doesn't refer to DOI specifically, right?

A It does not.

Q Okay, so it's strictly your interpretation that makes it -- you and your organization that you're speaking here on behalf of, that makes it a new drug.

A Also HHS's. Like this also is promulgated by HHS's evaluation. So it's not just my opinion, it's language that's used by HHS in their evaluation.

Q Okay. And you specifically mentioned that DOI and DOC are analogues to DOM, correct?

A Yes.

Q And DOM is a Schedule I substance?

A Yes.

Q And can you explain how the DEA prosecutes under the Analogue Act?

A Yeah, under the Analogue Act, a case comes to, usually it comes to us, so we are not involved in like the drug seizure or the information. It's after a drug has been seized and they want to take it to court.

And our involvement, we have to show that a drug has chemical similarity to a drug, pharmacology similarity, and intended for human use.

Q Okay, so, so drugs that are -- that

are prosecuted under the Analogue Act come through you from law enforcement seizures.

A They come to us from Assistant U.S. Attorneys.

Q Okay. So they come to you when the drugs are being used recreationally, not for research purposes.

A As far as I'm aware, yes.

Q Okay. And has DOI or DOC ever been prosecuted under the Analogue Act?

A Not since I -- not to my knowledge since I've joined. I don't know historically.

Q Okay. But a AUSA could bring that to you if they had concerns in their community about it being an issue with recreational use.

A If there were -- if there was a seizure and they wanted to take it forward, they could, yes.

Q Okay. So according to the data that you have, that couldn't have been done in the last five years?

A To DOI or DOC?

Q To DOI.

A It could be possible because not every -- again, it's voluntary, so not every lab gives

us that information.

Q I'm just saying, based on the information that you have.

A Right, I'm just -- and I'm saying that it's still could have happened and just not reported to NFLIS-Drug.

Q Okay, it could have. I'd like to go to the next page of Exhibit 7A, to factor two.

So you testified previously that drug discrimination is a significant indicator of abuse potential, correct?

A For hallucinogens, yes.

Q But not other drugs?

A It is also an indicator for other drugs. But for hallucinogens, it is, it weighs a significant bearing.

Q Okay. Can you just explain a little bit more about how the assays in drug discrimination studies are conducted? What would be the -- what would be kind of your first steps in carrying out a study like that?

A So again, it would depend on the species. But since these were done in rats, I'll stick to rats. Obviously acquiring the rats, giving them some time to habituate to, you know,

having traveled. And then once you have them, you have to train them to press a lever to get a food reinforcer or some other reinforcer, which is in most of these studies sugar pellets.

Q Okay. So how is the drug administered?

A It depends on what the researcher wants. It can vary. These cases, there were all intraperitoneal injections.

Q Okay, and does the -- so they're injected directly into the -- into the rodent, whatever the species is?

A Yes.

Q Okay. So the animals are not choosing to take the drug of their own volition.

A They're not.

Q Okay. They're essentially having the drugs forced on them by a scientist and then they get a reward after they get that drug.

A They get a reinforcer, yes.

Q Okay. So they're not self-selecting to consume those drugs.

A No, and it's not intended to do that in this type of study.

Q Okay, it's just a yes or no. So if

the drugs are being administered to them by humans, how do you determine that it's being abused?

A We are comparing it to drugs of -- that have known abuse potential. And if the animal substitute -- so an animals has learned to press a lever after they've received that drug. There is an effect that's going on in that drug that is tied to pressing a lever.

And then after ten lever presses, say, they'll get a sugar pellet for some time period. And if the animal, let's say DOM was trained, if then you give DOI and it produces all lever presses on the DOM lever, then it's said to have substituted. And based on DOM's known abuse potential, then it can be inferred that DOI would also have abuse potential.

Q Okay, so there's nothing about, other than -- other than that inference, so you're making the leap that's saying this drug is like the other one that we say is potentially abused, there's nothing about the rat pressing the lever itself that's indicative of abuse.

A I mean, it's saying that it's similar to that effect. But this is also something

that's like, people have been doing since like the 70s and 80s. This a well-established study paradigm.

Q Absolutely. And are there other interpretations of this drug discrimination paradigm, other than how you phrased it?

A So it can be used to assess mechanisms of action. And drug discrimination is usually drugs will substitute for drugs that have a similar mechanism of action. So you can do other things with this assay.

You can give an antagonist to see if that blocks the cues of the drug that you've trained or the drug you're testing. You can also do time, like an effect of time with drug discrimination. You can do a lot of things with it.

Q Okay. And were -- were drug discrimination studies created to show drug abuse?

A I'm not sure about the creation of drug discrimination, about the history of the creation of it.

Q Well, you spoke earlier about how it's been done for many, many decades.

A That's good, but I don't know the inception of drug discrimination, what it was initially like.

Q Okay. So you can't say that it was definitively developed for testing drug abuse.

A But that is how it's being used today. I don't know how it was used when it was first inception.

Q Okay, and that's not the only way that it's used.

A Again, you can assess mechanism action, so yes. It is an assay that NIDA uses. They've had contracts for over 30 years to assess abuse liability. FDA has contracts with drug discrimination to assess abuse liability.

Any new drug that might have abuse potential, almost all of them have drug discrimination data. It is an accepted paradigm to assess abuse liability.

Q So without that inference correlating it to something you're previously tested, is there anything about these drug discrimination studies that show potential for abuse?

A It shows that they're similar to known drugs of abuse, a number of them.

Q And you mentioned that it's -- that it's used to, that these studies are used to show psychological dependence and subjective effects.

A I don't use drug discrimination to show psychological dependence.

Q So you don't recall testifying about that earlier?

A I said -- I quoted the data again, saying that because it's similar that it's likely to have psychological dependence. But I didn't say that drug discrimination necessarily was an assay to test psychological dependence.

Q Okay, but that's how you're -- that's, as you just said, you're still linking those things, the psychological dependence based on the -- based on the drug discrimination.

A Because we know DOM, LSD, and psilocybin have psychological dependence and we know that they have effects that are similar too, yes.

Q So can you measure the psychological aspects of the human experience through rodents?

A Drug discrimination actually has really good parallel validity.

Q It's just a yes-or-no question.

A Repeat your question, please.

Q Can you measure psychological aspects of the human experience through rodents?

A Not specifically.

Q Okay, that's a no?

A Not specifically. I don't know what a rodent is feeling.

Q Okay. So you said that drug discrimination is the gold standard for measuring abuse potential, those were your exact words, right?

A And hallucinogens, yes.

Q Are there other ways to measure abuse potential in animals?

A I believe you're getting to self-administration.

Q So who -- is that another, that is another way to measure abuse potential, self-administration?

A Yes, but -- yes.

Q Okay. Can you explain how self-administration tests work?

A Yeah, so generally a cannula is inserted into generally a rodent but it could be a nonhuman primate. And then in that case the

animal responds on a lever, a nose poke to receive additional infusions of a drug.

Q And so those are -- and so can you explain kind of how that's carried out to show potential, abuse potential?

A An animal usually has to press a lever an increased amount of time to receive another administration. And so by them pressing the lever sometimes hundreds of times for a long period of time, will show that as a drug is being self-administered based on the effects that is being produced.

Q Okay, so self-administration studies don't require inferences to other substances. It's a direct.

A Self-administration data can be misinterpreted. Lots of things could change an animal's behavior in self-administration.

Q Okay, but it was -- it was a yes-or-no question. When you're conducting a self-administration study, that doesn't require you to make inferences about drugs, other than the drug being provided to the animal.

A I'm not sure I can give you a yes-or-no answer.

Q You said that self-administration can be misinterpreted. Is it possible that drug discrimination studies can be misinterpreted?

A There are potential for false positives and false negatives. There have been reports of that. But again, in -- for DOI and DOC, they were compared to a number of other hallucinogens. So it's not just relying on one study, it's multiple studies from different labs.

Q And how can drug discrimination studies be the gold standard for testing for potential for abuse when the animals are not self-administering the drugs?

A It's pretty well known that drugs that work for the serotonin 2A receptor don't produce self-administration. It's been published and cited many times. HHS is aware of it.

Again, in their policy document for assessing abuse potential, they specifically note that hallucinogens don't, generally don't cause self-administration. And they say -- they make a note of drug discrimination specifically in their industry document.

Q Okay. So drugs like, well, so DOI and DOC are in self-selection -- in

self-administration studies, you're saying that they aren't producing abuse liability in a valid scientific assay?

A I'm saying that for hallucinogens, self-administration is not necessarily a valid scientific study, based on published data for this drug class.

Q Okay, but they're valid for other classes of drugs, right?

A That have a different mechanism of action, yes.

Q Okay. And what is -- why is this considered not valid?

A Again, it's been published many times that they don't produce self-administration. It's not one that's relied on for hallucinogenic substances.

We know people, when they administer, and they may not administer them the same way like they would like an opioid, but it doesn't mean they don't have abuse liability. Just their pattern of abuse is different.

Q Just because they don't choose to keep taking it, right?

A Depends on the drug.

Q DOI, specifically. When given the opportunity, an animal in a self-administration setting would not choose to continually take the drug itself. Yes or no?

A I'm not aware of a study with self-administration with DOI.

Q Okay. So why is it then that you interpret that as it's not a valid test rather than maybe that's not indicative of potential for abuse?

A Again, based on HHS's document on how to assess abuse liability specific to, they have a note specific to hallucinogens. And they say that it's well known that self-administration is not reported in hallucinogens that work in the serotonin 2A receptor.

Q So wouldn't another reasonable conclusion of the studies be that they in fact aren't -- don't have the same potential for abuse as other drugs?

A Again, we compare it to a drug that is similar to it and we know that LSD and psilocybin have abuse potential.

Q But specifically, specifically regarding self-administration, isn't it true that

one interpretation of that data could be that based on self-administration, it does not show an abuse potential?

A I don't believe so. Because we know LSD is used and abused. Just because it doesn't work in self-administration doesn't mean that then it does not have abuse liability.

Q Isn't the gold standard of whether something is addictive is if animals will keep taking it if you give it to them?

A Addiction is not specifically noted in the Eight Factor Analysis. A drug does not have to cause addiction for it to be -- have abuse potential.

Q Excuse me, I misspoke. Abuse potential. Is -- are there any other classes of drugs that don't have -- that aren't self-administered by animals when given the opportunity?

A I believe there are some benzodiazepines that are not self-administered.

Q Okay.

A In rodent studies.

Q Any other Schedule I substances?

A Again, like I don't believe psilocybin

and DMT are self-administered. And in some studies, MDMA I think was marginal self-administration. But again, it's not -- it's only one component of the Eight Factors Analysis.

Q So what about -- what about DOM?

A I believe there was one study, and it did not produce self-administration that was significant.

Q So are there -- are you aware of any studies with any hallucinogens showing a self-administering effect?

A I believe there was some self-administration with MDMA.

Q Okay. Does MDMA work as a 2A agonist?

A No, it's through a different mechanism. But I also know from personal communications with some individuals that were at Hopkins, there is a tryptamine that produced self-administration in low amounts.

Q So of all the -- of all the drugs that substitute for DOI and DOC in drug discrimination studies, are there any of those who have shown self-administration effects?

A Not that I'm aware of off -- off the top of my head.

Q Okay, so if not a single one of those shows self-administration, what was -- and that's the gold standard for potential of abuse, and everything else is being analogized to those, what was the first drug that they started with that then they linked all these other ones up to?

A Are you talking about self-administration or drug discrimination? I feel you, you bounced.

Q Well, it's two parts, because you're saying that DOI and DOC show a potential for abuse because they are substitutable in the drug discrimination studies with other hallucinogens.

A Correct.

Q And not a single one of those other hallucinogens that it substitutes for show self-administration.

A Correct, but we wouldn't expect them to.

Q So where did you -- so where did you -- what was the first substance that then you can start analogizing all of these under drug discrimination?

A We just took them off of studies that were published, we didn't pick the drug that they

were compared to.

Q Okay. So just we've kind of gone around and around and so I just want to be clear to finish. So of all the drugs that can discriminate for DOI and DOC that they can substitute out for, not a single one of those has shown potential for abuse through self-administration studies. Yes or no?

A Not that I'm aware of. I feel like DOM may have had like a little bit of self-administration.

Q Okay, but nothing significant that you could say?

A No.

Q Thank you. And so you testified that a large reason, one of the significant factors that you were -- that DEA is considering when determining to make these due to schedule -- into Schedule I is due to their hallucinogenic properties, correct?

A Yes.

Q Okay. You also testified earlier today that -- about the drug dextromethorphan.

A Yes.

Q And what is that again?

A It's generally prescribed or used as a cough suppressant, but at high doses it can cause hallucinogenic effects.

Q Is it prescribed?

A It might be in some prescription products.

Q Okay, but it's -- do you -- let me rephrase the question. Do you need a prescription to purchase dextromethorphan?

A No.

Q And dextromethorphan when taken in large amounts acts as a hallucinogen.

A It can, yes.

Q It can. So if hallucinogenic properties of a drug are a major consideration for whether it should be scheduled, why isn't dextromethorphan in Schedule I?

A Well, first, it has a currently accepted medical use. So if it was controlled, it wouldn't be placed in Schedule I, it would be placed in Schedule II through V.

Q Okay. Why isn't it controlled at all?

A When it was approved, FDA deemed that it didn't have abuse potential, that it didn't need to be controlled. And we could evaluate it

today to see if that is still the case or not.

Q Do you know at the time they made that determination they were aware of its use as a recreational hallucinogen?

A No.

Q Okay. Because part of what you said earlier is that the hallucinogenic qualities require these drugs to be put into the scheduling.

A It's also a different mechanism of action. You're talking about a whole different system. And like we're talking about it being specific to the serotonin 2A receptor, which that is not.

Q Is it because of the mechanism of action that DEA thinks this is such a dangerous substance, or is it because of the effects that it causes?

A The effects that it causes, but it has a shared mechanism of action.

Q Okay, but it's not about what it binds to in your brain that makes it dangerous, right? It's the fact that it, according to DEA, it makes you hallucinate.

A Correct.

Q Okay. But dextromethorphan can also make you hallucinate, and that's not considered currently by DEA a drug of concern.

A I'm not going to say it's not a drug of concern, but it's not a -- it's not in the scheduling action.

Q Okay. Because DXM can still cause delirium, right?

A It can.

Q And violent outbursts?

A It can.

Q And psychotic features?

A It can.

Q And the DEA is moving to schedule these substances because those issues are of grave concern to the agency, right?

A Correct.

Q So --

A That's my understanding.

Q So is DEA taking any action regarding the scheduling of DXM when it has these same dangerous qualities?

A I'm not sure I can comment on any active scheduling actions or considerations.

MR. PHELPS: Your Honor, if I could

just confer with my co-counsel for just a moment and we'll resume.

JUDGE SOEFFING: Certainly.

MR. PHELPS: Okay, thank you for that, Your Honor.

Dr. Carbonaro, we're going to come back to our other factors, but I'd like us to go, take a look at the analysis for Factor 5. That's going to be starting on Page 10 of Government's Exhibit 7A.

So, Factor 5 is the scope, duration and significance of abuse, correct?

THE WITNESS: Correct.

MR. PHELPS: So, it says, according to the NFLIS data in the U.S. there has been significant availability, trafficking and abuse of DOI and DOC. How does the DEA define significant?

MR. MANN: Your Honor, Counsel is mischaracterizing what's written here. It says, significant availability, trafficking and abuse of a number of phenethylamines hallucinogens, including DOI and DOC.

MR. PHELPS: Fair enough. That is the full sentence there.

BY MR. PHELPS:

Q But this is specifically about the significance of abuse for DOI and DOC in today's proceeding, correct Dr. Carbonaro?

A Yes. But that's just a summary statement specific to the whole class of phenethylamines hallucinogens.

Q Okay. But this is an analysis of the significance of abuse of these two substances? That's what's in the title of Factor 5.

A Yes.

Q Okay. So I'm asking you, how does you, or your office, or your agency, define significant?

A Oh, I think that varies from drug-to-drug.

Q I --

A I'm not sure we have one definition of significance.

Q So you just determine what's, you don't have a standard for what's considered significant availability, trafficking and abuse?

A I mean, we're just looking for evidence of them in NFLIS drug. And for this part right here. Yes.

Q So any evidence, in your analysis, any evidence of these drugs being seen is -- counts as significant abuse?

A I mean, I would say in totality of these two substances, over 800, reports it's pretty significant compared to some of the other drugs in NFLIS-Drug. And again, this is a voluntary basis. And it's likely largely under reported for both substances.

Q So, if we can't go off the data that you've given us, and you don't have a firm definition of what's significance, would it be accurate to say that a drug becomes significant when you decide to schedule it?

A I would say that the NFLIS numbers would likely increase after a drug is controlled because of it being controlled, and more labs will test for it. So like, the numbers may go up after it. But again, it's based on NFLIS numbers, but also other evidence.

Q The other evidence is the anecdotal reports, right?

A Correct. That HHS provided.

Q Okay. Do you know how many anecdotal reports that looked at?

A Oh, my apologies. The anecdotal report really comes into Factor 6. This is based on other DEA data that were about the seizures and in the microgram report specifically.

Q Okay. But all you have to, I understand you've said it several times that this data can be under reported, but that's, the NFLIS data is all we have to go on, right?

A That there is evidence of these two drugs, yes.

Q Okay.

A And in many states.

Q So would you say that since 2019 there has been significant availability trafficking and abuse of DOI based on the NFLIS data that you're using for your own analysis?

A It's in totality not necessarily specific to a specific period.

Q That, I'm asking specifically since you said you don't have a, you don't have a definition of what's new, that's not tied to time. You don't have a definition of what's significant. I'm asking you, in your scientific analysis would you say that the NFLIS data provided from 2019 to 2023 shows significant

availability, trafficking and abuse, yes or no?

A There are no reports since 2019 for DOI.

Q So is that significant, is that a significant amount zero?

A If you limit it to those years it is not.

Q Okay.

A But we don't limit it to those years we look at it in totality from when it was first encountered.

Q So if you're looking at 40 total seizures over the last 20 years, would you say that two encounters a year is significant?

A Again, that's in totality of the reports and --

Q I'm asking based on the numbers that you have provided.

A I think any evidence is significant.

Q Any evidence?

A Yes.

Q If there had been one seizure in the last 20 years you would say that that shows significant availability, trafficking and abuse?

A It shows that there is evidence of it.

Yes.

Q So any evidence to you is what you consider significant?

A Personally I think. Yes.

Q So that qualifier has no meaning to you, significant?

A I think it's only one part of the analysis and it's in totality. And the numbers we know are under reported.

Q Do you have an estimate on how under reported they are?

A No. It varies from drug-to-drug and the availability of referenced standards and other things.

Q And so you talk about the availability of reference standards. Do you know how these states are testing these alleged DOI substances?

A It varies from state-to-state and from lab-to-lab.

Q But when you're compiling your data and putting this out here as data that you think is extremely relevant in regards to scheduling, do you know how all these states are testing these drugs?

A There are reports that go into

NFLIS-Drug. And they do have their SOPs involved in, and they are confirmed clauses for those drugs.

Q Have you reviewed the SOPs for all of these labs?

A No.

Q Are there nation-wide standards that match up to the DEA standard for identifying drugs?

A Again, it's a voluntary system. Like, anyone could report whatever they tested, whatever they confirmed. There may be DOI or DOC in samples that they didn't test for numerous reasons.

Q Have you ever seen a state and their laboratory testing regime and said that testing isn't up to snuff for the DEA?

A I don't believe so.

Q Okay.

A I'm not aware.

Q Okay. So if they're whole method for testing these things was to ask the guy who got seized with it what it was and that was their SOP and they followed their standard operating procedures, you would still include that in your

data?

A I don't follow your question.

Q I guess my question is, do you have any scientific standards that these other labs have to follow?

A No. When I say standards it's not a standard operating procedure it's actually the chemical that they have to have in the laboratory to confirm that that is the drug.

Q And --

A This is not a controlled substance, it's likely that not all labs have it in the death report. They actually said that they don't usually test for such a substance. And they indicated that we, good to test for.

Q Okay. So the standard that we're talking about, that's the reference data to see if it actually matches up. Did you validate that data yourself?

A I did not.

Q Okay. So it's possible then that without being able to review ever single test that's done it's actually possible that there could be potentially false positives for DOI and DOC?

A I don't believe that to be true.
Q Why not?
A Because they are confirmed positive for each lab. And those data reports are submitted for external review so I don't believe that we have false positives.
Q They're confirmed by who?
A By our contractor.
Q So when they have a positive sample they send it off to someone from DEA that then tests it?
A No. We don't test the sample again, we review the report.
Q Okay. So you would say there is absolutely zero possibility that there could be a false positive for one of these substances?
A Of my understanding of NFLIS, yes. For these drugs.
Q So each of these labs have their own reference standards, right?
A Yes.
Q Okay. And how do they, how do they test those? Can you just explain how you test what a drug is?
A There are different techniques that

labs will use, but for these ones, because they are law enforcement encounters they have to be confirmed positive for that drug. It's not just like a radar test that, or not, I don't think it's radar, like a test that one might use at the border to see if it's positive for something. These are actually tested in labs using various methods that are established that would confirm that drug.

Q And can you describe what some of those methods might be?

A I am not a chemist so I would prefer not to.

Q Does a reference standard ever expire over time?

A It could. Depending on the drug.

Q Okay. And in, and DEA's protocol or review, is that something that you're checking in their data?

A Again, I am not checking the data, I am relying on the contractors to check it. You get different peaks. And so if you had a reference standard you would, for some of the data you would be able to confirm that is the drug. There are ways to confirm that you're

referencing are just still accurate.

Q Briefly I'd like to take a look at Exhibit 7 together with Exhibit 7A please.

A Thank you.

Q Okay. And could you go to Page 10 of both exhibits?

A Okay.

Q And looking at DOI, in Exhibit 7 that's the old data, right, from 2021?

A Correct.

Q How many total reports of DOI encounters were there then?

A Forty.

Q And in what states did those encounters occur?

A Colorado, Florida, Iowa, Indiana, Kansas, Maine, Minnesota, Missouri, North Carolina, Ohio, Pennsylvania, Tennessee, Texas and Wisconsin.

Q Okay. And then that data was updated for Exhibit 7A, right?

A Yes.

Q And can you tell me how many total reports of DOI encounters there were in the 2023 report?

A Forty.

Q And can you tell me the states where DOI was encountered there?

A It was the same states, with the addition of Nevada.

Q So can you explain how there was an additional state where this was encountered and no more total encounters?

A I believe the, it's possible that when I made the list the first time that I left off Nevada. I think it was just a correction when I updated the report.

Q So there actually weren't any new states where it was encountered between 2021 and 2023?

A Just a new state that I noted to be encountered.

Q Okay. But that was something that had already occurred?

A I believe so.

Q So there weren't actually any new encounters between 2021 and 2023?

A That is correct. But we know that during COVID there was a significant reduction in NFLIS reports. So during the years of 2021

through 2023 some of the reports did go down. Like total reports.

Q And remind me again what year was it that COVID hit?

A It started in December of 2019, but March 2020.

Q Okay.

A And data for 2023 are still incomplete.

Q Okay. But there was no data in 2019, right?

A I believe that's correct.

Q Before COVID. And in 2018 there was one, right?

A I believe that is correct.

Q And in 2017 there was one?

A I believe that is correct.

Q And in 2016 there was zero, right?

A I believe so.

Q Okay. So any drop there from one to zero, I mean, there was zeros all the way, could that be attributed to COVID?

A I mean, it is potential for that. But also, this is data that HHS had in their evaluation and still made a determination that it

has significance of abuse.

Q You said that the NFLIS reporting in general was down in 2020?

A 2021 and 2020. 2020 as well.

Q Okay. Do you know if the number of encounters for Fentanyl decreased during that time?

A I don't know off the top of my head.

Q Okay. I'd like to talk for just a minute about the microgram bulletin. Can you just remind microgram bulletin is?

A These were reports put together by DEA's Office of Forensic Sciences based on the detection analysis of suspected drugs, controlled and non-controlled.

Q Is that a peer reviewed publication?

A I believe they go through an internal peer review process.

Q Okay.

A But I'm not sure. These predate my time at DEA.

Q So they no longer produce the microgram bulletin?

A Correct.

Q Do you know why that is?

A I do not.

Q And in all the labs that are mentioned in the microgram bulletin claiming to have tested for certain substances, do you know anything about those labs testing protocols?

A I do not. But our Office of Forensic Sciences would, and they're the ones that published it.

Q And you mentioned in your earlier testimony discussing a microgram bulletin, that it mentioned specifically that sometimes these drugs were encountered in powder form, right?

A Yes. At least one.

Q And my colleagues over here, he asked you that the fact that it was in powder form was evidence of its dangers, correct?

A Potentially. Yes.

Q What is it about a drug being in a powder that makes it inherently more dangerous or more subject to abuse than a pill?

A Well, it usually is in reference to an FDA approved product that would come in a pill form. And the FDA, to my knowledge, doesn't have a compound that's been approved to be administered as a powder form. So finding it in

a powder form shows evidence that it's likely to be an illicit substance.

Q Cocaine is an FDA approved substance in certain circumstances, right?

A Yes.

Q Cocaine is typically a powder drug?

A When it's used illicitly, yes.

Q Okay. So you're not aware of any prescribed scheduled drug that is in a powder form, in capsules?

A I mean, in capsules, yes. But they're encapsulated so you would find a capsule not just powder.

Q Okay. But it doesn't just appear as a powder in the capsule, right?

A It has a capsule around it, and then powder within the capsule.

Q Okay. But it starts out as just the powder on its own?

A Yes.

Q Okay. And so, and at that point, so just the fact that a drug is in a powder form at that point doesn't necessarily speak to its inherent danger?

A It just usually suggests that it was

intended for illicit use. Is my understanding.

Q Does encapsulation of powder substances mean that those drugs aren't abused?

A No. Someone can take the powder out of the capsule and abuse it. But if it's in a capsule as an FDA approved product, then there would have been safety and efficacy studies related to that specific formulation and deemed safe and effective.

Q Okay.

A But a powder can be smoked, snorted and not ingested orally as intended.

Q In any of the seizures of DOI, was it ever found in a capsule?

A I believe so.

Q Okay. So does that make it inherently less subject to abuse because it's not in a capsule?

A No, because it's not an FDA approved product. So finding it, generally speaking, would suggest that there would be harm related to any use of it.

Q Okay. So being in a capsule or being in a powder, based on what you just said, doesn't necessarily indicate that something is subject to

abuse?

A I think being in a powder does show evidence that it can be used and abused.

Q Other research drugs, research chemicals that are ordered from the same types of labs where researchers are getting DOI and DOC, those also come in powders, right?

A Often times, yes.

Q Okay. And so, does the fact that those drugs come in powders when they're getting sent to labs, is that indicative of significant abuse or potential for abuse?

A No. They're in adequately labeled bottles and packaging with information about their chemical nature. And generally pharmacology data that is available for those drugs.

Q So the microgram bulletin that you're going off of that refers to these being found in a powder, did it say what the powder was in?

A I don't recall.

Q It didn't say that it wasn't in a labeled, sealed bottle?

A I don't recall.

Q So NFLIS could report an encounter of

DOI if they walked into a university laboratory and saw a labeled bottle of powder DOI in the safe?

A I'm not sure I'm following. Like agents don't necessarily go into safes looking for drugs to then seize.

Q Okay. Well let's, yes, let's, the drugs that are seized, do you know anything about the context in which they're seized?

A Sometimes. But not always.

Q Okay. Of the 40 seizures of DOI since 2005, do you know the context of, let me rephrase that question.

Just because something is reported as an encounter doesn't mean, on its own, that the drug, that the substances are being used in an illegal way, yes or no?

A I suppose not.

Q Okay. And just because it says that it was found in a powder without any other information about what that powder was contained in, you don't have any knowledge other than it was a powder?

A Sometimes there are other item level details about that encounter specifically.

Q Okay. But in general it's not required?

A Again, it's, everything in NFLIS is voluntary.

Q Okay. And right now these, well, can you say with certainty that possession of a substance means that it's been consumed?

A I mean, if it's ceased and it hasn't been consumed, correct?

Q Or that it's going to be consumed?

A Not necessarily.

Q Okay.

A But often times it seems that way.

Q Okay. But just based on the fact that it was encountered doesn't tell you anything about consumption?

A No but it, not specifically but it does show that it is encountered, and we can see other drugs that it's encountered with. And we can get some evidence from NFLIS in that regard as well.

Again, these are law enforcement seizures so they're from state, local and federal labs. So often times they are meant for consumption.

Q So when drugs are seized that's because they're illegal substances, right?

A Not necessarily.

Q So what basis is required for law enforcement to seize a legal substance?

A I'm not a law enforcement agent, I don't know.

Q Okay. So do you know how they're, how these drugs get seized if they're not illegal?

A I know that different like local, state, federal law enforcement seize them at different parts. It could be border entry, it could be in different, different instances. And they're assessed for what the drugs are.

Q Okay.

A Or presume to be.

Q And so, since these drugs are currently legal to possess, right?

A Yes. They are not controlled currently.

Q Okay. So the fact that it was seized doesn't necessarily indicate that that individual was doing anything illegal?

A Again, that would be case specific.

Q Okay. But in general, just the fact

that it was seized doesn't tell you anything, doesn't tell you anything about the broader context of how they came to be seized?

A It would, again, depend on the seizure and the case.

JUDGE SOEFFING: Mr. Phelps, is now a good time to take our afternoon break?

MR. PHELPS: Yes, Your Honor.

JUDGE SOEFFING: Okay. Let's go ahead and take a 15 minute recess for our afternoon break.

(Whereupon, the above-entitled matter went off the record at 3:03 p.m. and resumed at 3:25 p.m.)

JUDGE SOEFFING: Okay, we are back on the record.

Dr. Carbonaro, I remind you you're still under oath.

THE WITNESS: Okay.

JUDGE SOEFFING: And Mr. Phelps, you may continue with your cross examination.

(Pause.)

MR. PHELPS: Yes, thank you, Your Honor, and Dr. Carbonaro.

BY MR. PHELPS:

Q I just wanted to follow up or clarify on a couple of points you mentioned before. Do you know specifically where DOI is available to purchase?

A There are companies that sell it for research purchases such as Cayman Chemical or others, but also there are other online websites that can be purchased from.

Q Let's focus on the Cayman and those -- those type. What exactly is Cayman Chemicals?

A It's a company that sells substances that are generally used for research to -- to labs.

Q Okay. And is it the -- is it the only business of that type or are there other similar, similar companies that do the same --

A There are similar companies.

Q Okay. Any estimate on how many of those may be available?

A The number of companies available?

Q Yes.

A I'm not sure off the top of my head.

Q Okay. And Cayman Chemicals, do they have a DEA license?

A Yes.

Q And is a DEA license for selling chemicals different than the types of licenses you've described before regarding the research?

A Yes.

Q And what specifically goes into a company like Cayman getting that -- that license? What do I have to do if I want to start a lab and sell chemicals?

A There are regulations put forward in the CSA to follow those. I don't deal with registrations related to companies.

Q Okay. Do you know as part of them -- well, that license is not permanent, correct? It can be taken away?

A Correct.

Q And with this license, who is Cayman able to sell to?

A In theory, anyone that purchases from their website or from their online source.

Q So does the DEA have any protocols in issuing licenses to control who companies like Cayman can sell to?

A I'm sure they do. Again, that's outside my scope, so I don't know what those are.

Q Can they sell to people to use

recreationally?

A In theory, yes.

Q Would that be a violation of their license?

A If it's a non-controlled substance, then it wouldn't be a violation because it's not a controlled.

Q So it's the DEA's position that if Cayman Chemical posted on these Reddit forms, hey, guys, we've got your DOI, come get it, the DEA would have no problem with that?

A Again, that's not something --

MR. MANN: Objection, Your Honor. I don't know where this is going, but it seems way outside the scope of direct.

JUDGE SOEFFING: I agree. I sustain the objection. Is there --

MR. PHELPS: Yes, yes. I was using that for demonstration purposes.

BY MR. PHELPS:

Q They're sold for research, right?

A From Cayman Chemical --

JUDGE SOEFFING: So I'm going to sustain the objection just to be clear on that. You're talking about DEA registrations. We've

been talking about licenses, but you're talking about DEA registrations, that was really not any part of the direct and I think she said that she doesn't handle DEA registrations. So if you could wrap it up and move on.

MR. PHELPS: Yeah, certainly, Your Honor.

BY MR. PHELPS:

Q I just way that to contrast to -- you testified before that there's other places that people who want to use DOI recreationally can purchase DOI, right?

A Yes, based on my evaluation over time, yes.

Q Okay. And what are those places?

A I'm not sure that I can say what those websites are. They're internationally recognized as websites that sell companies, but I don't feel conformable naming companies that sell illicit substances.

Q So they're out there, but you can't tell us who they are?

A Again, I don't feel comfortable giving names of those companies.

Q In all the data and discovery that was

provided, was there any numbers about how much is being sold at these places that you can't tell us about?

A Again, that's outside my scope. That would be related to an agent or a diversion investigator.

Q Well, your analysis relates to the significant trafficking, so this would be part of -- that would be considered part of the significance of the trafficking, right?

MR. MANN: Objection, there's no term significant trafficking used in direct.

JUDGE SOEFFING: I'm going to sustain. I'm not sure what you mean by trafficking. I'll sustain the objection. You can rephrase.

MR. PHELPS: Absolutely, Your Honor. Give me just one second and I can read it right off the -- on Page 10 of Government's Exhibit 7A, beginning of Factor 5, the significance of abuse.

Do you have that there, Doctor?

THE WITNESS: Yes.

BY MR. PHELPS:

Q Okay. It says according to NFLIS-Drug in the U.S. there has been significant availability, trafficking, and abuse of a number

of phenethylamine hallucinogens including DOI and DOC?

A Correct.

Q Okay. So my question then and the point I'm trying to get at is if you're stating here that there is significant availability in trafficking, can you give us any numbers about what's being trafficked out there in these places that you can't tell us about?

A Again, that was a summary statement, not specific to just DOI and DOC, but the phenethylamine hallucinogens in totality and DOI and DOC make up a part of that total.

Q Do you have any idea how much of that totality DOI and DOC make up?

A It's just a general introduction statement. I don't have a number to reference.

Q In general, based on the seizure data that you have, do you know how significant DOI and DOC are in the broader hallucinogen seizure data?

A I know there are others that are in Schedule I that have a higher number of reports. But again, they're Schedule I, so more like to be reported into NFLIS.

Q Certainly, because you mentioned that the number of seizures is indicative of usage, right?

A It is a component of it, yes.

Q Okay. And you also said that if DOI and DOC were moved in Schedule I that the number of seizures would go up, right?

A Likely, yes.

Q So does that mean that scheduling these substances, by your own words, would lead to an increase in usage?

A Not necessarily, just an increase of reports that may have been missed previously.

Q Okay, but you said the numbers of reports are indicative of the amount of usage?

A I'm not sure I said that.

Q Okay. We can move on. Those are the ones that I wanted to follow up on just a little.

I'd like to go to Page 8 of Government Exhibit 7A, Factor 3. Factor 3 is the state of current scientific knowledge regarding the substance and just wanted to be clear, the CAS number for DOA, or excuse me, DOI, is 42203-78-1, correct?

A I believe so.

Q Okay. And the CAS number for DOC is 123431-31-2, correct?

A I believe so.

Q Okay. Would you say that accuracy is important in scientific testing?

A Yes.

Q Okay. And does the form of a compound determine its pharmacological properties?

A The form does not, but the route of administration would, which would vary by form.

Q Can the -- so the pharmacological properties can change based on the form of the compound?

A And route of administration, yes.

Q Okay. Does the salt form of a compound alter its solubility?

A Yes.

Q How does solubility alter pharmacokinetic properties?

A It again would depend on the solvents that's used and having a salt form would solubilize in saline more easily, but it would depend on what the solvent is. And that solvent could have different pharmacological activity.

Q So the form, if it's a salt or a free

base, that is important in regards to its pharmacokinetic properties?

A Yes.

Q Okay, and the cited CAS number for DOI, do you know is that the CAS number for the salt or the free base form?

A It might be for the salt. I'm not sure.

Q Okay. And the molecular weight that you listed there, the 321.16 grams per mole, is that the molecular weight for the salt form or the free base form?

A I am not a chemist. I'm not sure. I also -- we have chemists that reviewed this and wrote this part of this document.

Q Okay. So did you review this prior to sending it out?

A I reviewed it.

Q Okay. And did you review specifically the numbers of the molecular weight for DOI?

A I did not. I deferred to the chemists in my section.

Q Okay. And --

A It also may have come from HHS's evaluation. Sometimes they put in different CAS

numbers. I'm not sure.

Q So you don't even know where this number came from?

A Again, a chemist writes that section for us, so I'm not sure.

Q Okay.

A I'd have to go back and look at the HHS evaluation.

Q Okay. So you wouldn't know whether that 321.16 is the free base weight or the salt weight?

A I do not. I defer to the chemists.

Q And do you know in the studies that are cited about DOI whether they're using the salt or the free base weight?

A Generally, the salt version.

Q Do you know what the difference is in the free base versus the salt weight?

A HCl does not have a large weight, but I don't know what that number is.

Q Okay. Because what's listed here is --. Okay. So what's described here as the DOI salt in this analysis, right?

A The melting point, specifically, yes.

Q Okay, okay. The CAS number that's

listed there, do you know if that's for the salt or the free base of DOI?

A Again, I do not.

Q Okay. And you don't know the difference between the weights there?

A I don't know the weight of HCl.

Q Okay. So could that be possibly why the CAS number describes the DOI salt, but the weight given is, in fact, the free base weight?

A Again, I defer to the chemists in this portion.

Q Okay, but you've adopted the chemists' findings here as your own, right?

A I adopt -- I mean they are in this document. This document is reviewed by other people outside of me, as well.

Q Okay. And so do you know, did the DEA get it wrong here with the salt CAS number and the free base weight?

A Again, I defer to the chemists, but if you're saying that that CAS number is for the salt and the weight is for the free base, then yes.

Q Okay. And those two different forms could significantly alter the pharmacokinetic

effects, right?

A But this is relating just to the chemical information of it. It has nothing to do about the pharmacological activity of it.

Q Certainly. Okay, thank you for breaking that down for us, Doctor.

(Pause.)

Okay, I think that's all on -- well, I guess one other -- one other question regarding Factor 3. This is the state of current scientific knowledge regarding the substance, right?

A Correct.

Q And how would the -- does the DEA have a definition for what they consider current scientific knowledge?

A This section usually is left for chemical activity -- sorry, chemical knowledge of it and largely any medical use that's associated with it. But it could be open to other things, but generally, it's limited to a couple of items.

Q Okay, but how do you -- when you're talking current, how current are we talking?

A In theory it could be any information that's available about the substance.

Q Okay. So the -- as far as current research -- what was the most recent research that was considered as part of this 2023 analysis?

A In Factor 3? I don't have any paper studies, any papers cited.

Q Just in general.

A I'm not sure.

Q Okay. How do you ensure that you're up to date on current scientific knowledge?

A I routinely read papers that are published in scientific journals related to drugs of abuse.

Q Okay. So current is what's known to the DEA. It's not necessarily what's the most absolutely up to date research?

A I mean DEA would know about like current research that has been published.

Q Okay. Was any other research that's been done on DOI in the last five years included in this evaluation?

A Likely not --

Q This assessment? Likely not? So, current, under the DEA's definition means at best five years old?

A No. When I drafted this section, I relied on what HHS provided us in their section and I mirrored this very closely to their recommendation. And since I relied on them for scientific and medical evaluation, if they didn't feel inclined to put it in theirs, I didn't take a step further to add it into ours.

Q Okay, so are you aware of medical research around DOI and DOC that HHS wasn't interested in including?

A I am aware of scientific research with DOI and DOC -- DOI.

Q Okay. And research that's more up to date than five years old, correct?

A I am of research that has been published.

Q Okay. But you chose not to include that as part of your analysis on it?

A Yes, I deferred to what HHS put it in their Eight Factor Analysis.

Q Okay. Is that because the research that you're aware of personally conflicts with the desired outcome of HHS?

A No. I don't believe that it does conflict.

Q Okay. I'd like to go to the next page here. We can use the updated 7A. This is the one with your drawing on it.

So these are two-dimensional diagrams, right?

A Yes.

Q And these substances exist in a three-dimensional world, right?

A Yes.

Q So this is a pretty gross simplification of what a molecule actually looks like, right?

A It's a small molecule. I mean sure it's gross, but it's not unfair. Again, I'm not a chemist, but this is generally how chemists draw their structures.

Q And you were comparing the DOI and the DOC to DOM in your drawing, right?

A Yes.

Q And it was one -- it was a minor change between the DOI and the DOC and the DOM, right?

A Correct.

Q But isn't it true in chemistry that a minor adjustment to one element of a compound

like this can have significant impacts on the pharmacological effects of that substance?

A Yes, this is why we have to assess each drug.

Q Okay. So just because a non-scientist like myself may look at these and say wow, those look awfully similar, that doesn't necessarily mean that they couldn't have vastly different effects?

A Correct.

Q Okay. Because you could make another minor change to this DOI molecule and yield amphetamines, correct?

A It would be three changes, so not as minor.

Q Okay. So three versus one, but that would change it into something that is an FDA-approved chemical?

A Yes.

Q Okay.

A But I could also make another very small change and turn it into a 2C series of substances and those are Schedule I substances by removing a carbon.

Q Okay. So could changing one element

of this chemical render it non-psychoactive?

A It could.

Q So there's a lot of things that a small change could do to these chemicals here?

A Correct.

Q Okay. And not all of those would necessarily lead to other controlled substances or even psychoactive substances?

A I believe so.

Q Okay. So the last part of Factor 3 is -- actually, we'll move on from that.

Okay, moving on to Factor 4, we've covered some of this, but I want to address a few things that we haven't gotten to. And that is the WHO report. Can you describe what that report was?

A Yes. DOC was up for potential international control, so as part of that, the WHO gets -- collects information from United Nations what is available in their countries and will combine data and publish a report related to what data is available internationally.

Q Okay, did that WHO report include anything about DOI?

A I believe there may have been a

mention to it, but it was not largely focused on DOI.

Q Okay. And this is information across all of Europe, correct, many countries?

A The U.N., not just Europe.

Q Okay. So a couple hundred countries, give or take?

A I don't know the number.

Q Okay. And across all those countries, there was indicated -- well, I guess first of all, do you know anything about the U.N.'s toxicology portal?

A I know that it exists.

Q Okay, do you know how it functions?

A I don't. It's not a database that I often use.

Q Okay. Is it comparable to the NFLIS?

A I believe that there are international reports within it. There are other people in my section that use it more so than I do.

Q Okay. In that they said that across all of the U.N. countries in a ten-year span, 2008 to 2017, there was 16 non-fatal intoxications, correct?

A That's what the report said.

Q Okay. Do you know, what is a non-fatal intoxication?

A It just means that someone likely received, like, emergency care but did not result in a death.

Q Could it be anyone that tested positive for the substance? Does it have to have been an emergency room?

A It does not have to. Again, would depend on that data.

Q Okay. So without further data, we don't know anything about those 16 non-fatal intoxications other than they were recorded in somebody's bloodstream?

A I would have to go back to the WHO report. I don't remember anything specific.

Q Okay.

A There may be specific case information related to those.

Q And why is -- this is about scheduling DOI and DOC here in the United States, right?

A Yes.

Q So why is the U.N.'s input on this significant?

A So that we meet treaty obligations.

Q Okay. And can you explain how those treaty obligations work?

A Other than if it is controlled by the U.N. and we have like the treaty obligations -- I don't know specifics. I just know that we have to -- if they vote to control something, we have to act in kind and regulate it.

Q Okay. And that's supposed to be -- that's not specific to DOI or DOC, right?

A The treaty obligations?

Q Yes, ma'am.

A No.

Q Okay. It includes all the substances that the U.N. schedules?

A Yes.

Q Okay. The U.N. schedules cannabis, right?

A Yes.

Q And it's Schedule I?

A It is -- the U.N.'s Schedules don't necessarily mirror our Schedules. Like where they put it in theirs, may not be the same place where we put ours. Their Schedules are independent.

Q Okay. So because DOC is in Schedule

I in the U.N. doesn't mean that you couldn't recommend it be Schedule IV or V?

A Except that it has no medical use.

Q Okay.

A So there is no other place to put it other than Schedule I.

Q Okay. The reason that I ask -- so the United States isn't -- doesn't have to follow these identically?

A Yeah, whether it's Schedule I or II in the U.N. is not the same as Schedule I or II or I through V for the United States.

Q Okay. And that's how the DEA is able to get around those treaty obligations in regard to rescheduling cannabis?

A I have no comment on that.

MR. MANN: Objection, Your Honor, way outside the scope.

JUDGE SOEFFING: Sustained.

MR. PHELPS: We'll move on.

BY MR. PHELPS:

Q So, you testified that you are familiar with the issuing of research licenses through the DEA, right?

A Schedule I researcher registrations.

Q Schedule I researcher registrations, and you testified earlier that a Schedule -- moving DOI into Schedule I wouldn't inhibit research because researchers could get these licenses, right?

A Correct.

MR. MANN: Objection, that was not her testimony. I think the question was will it halt research.

JUDGE SOEFFING: The transcript will reflect what it was, but she's answered the question, so overruled.

BY MR. PHELPS:

Q Can you tell us a little bit about what -- if I wanted to apply for a Schedule I researcher license, what would I need to do?

A The regulations are put forward in the CSA, but you would have to, depending on the type of study, there's special -- certain information that would need to be submitted to DEA, no different than doing a research, a bona fide research study itself.

So, that would be things like name, address, a protocol, the amount of drug, where the drug is coming from, institutional approval,

a CV and papers among other things, and then there are -- there would be state and other regulations that would apply as well.

Q Would I have to have a very specific research project in mind or could I get a Schedule I license for exploratory research?

A It depends how you wrote your protocol.

Q Do you know approximately the cost of obtaining a Schedule I license?

A From a DEA it costs -- an actual registration fee is often waived. For institutions, universities, it usually is private entities that have to pay for one, and it's, I believe, currently less than $300 for the registration fee.

Q Okay, do you have any idea of the cost regarding -- well, I guess, what are the -- you have to do a lot more than just write it out on paper, right? There has to be steps taken within your facility?

A As would any bona fide research, yes.

Q Okay, but specifically, you have to install specific safes, right, or secure --

A Yes.

Q -- areas? Okay.

A There are safe requirements.

Q Okay, and those aren't required as an unscheduled substance, right?

A Correct, unless they were controlled by a state and working with them in a state.

Q Okay, do you know approximately how long it takes to get a Schedule I license?

A From when, like from once it is submitted to DEA through the approval process? Is that your question?

Q Yes, ma'am.

A It varies from protocol to protocol, but I think currently, we're about under three months for DEA to approve a Schedule I researcher registration.

Q So, three months would be the fastest depending on the protocol?

A Oh, no, average.

Q Average. Okay, do you know how -- what the maximum time it could take could be?

A Again, that would vary depending -- often, when applications come to us, they're incomplete, and we have to reach back and forth with the investigator to get a complete protocol

package, because we cannot submit some of our package to FDA for their analysis until it's complete, and so that back and forth with the investigator or them not responding back to us can make that timeline much longer.

Q Okay, and then for researchers, if they're doing this type of Schedule I research, they require more licensing beyond just the DEA license, correct?

A I'm not sure what you're referring to.

Q Like a state-level license?

A Yes, usually.

Q Usually. And if -- and some type of institutional approval or institutional license?

A It's not an institutional license. It's just approval, and oftentimes, if it's coming -- if the institution is reviewing it for ethics, so if it's -- if there -- it's a clinical study and it goes through a university's IRB, or if it's an animal study and it's going through the institutional's IACUC, then that would qualify as the institutional approval.

Q Okay, and all of that is outside or on top of the average three months for the DEA processing?

A Yes, but any protocol would go through those steps. It's not an addition to DEA's registration to meet DEA's qualifications.

Q Well, if it's not scheduled, then you wouldn't have to get a state-level license, would you?

A Again, that would vary from state to state, but I'm speaking specifically to the Ethics Board reviews.

Q Okay.

A Those would be independent and would be needed for any kind of animal or clinical study.

Q Not a cell-based study though, right?

A No, but the institutional approval that we request is just a letter from somebody in the institution that just says they acknowledge that there is a Schedule I substance in their facility.

Q And you did a lot of work in academia before --

A Yes.

Q -- you went to the DEA, right?

A Yes.

Q So, when you say it's just a letter,

you understand that there's a lot of steps that go into getting just that letter, right?

A I never had to achieve such a letter, so I'm not sure, because my PIs both had Schedule I researcher registrations.

Q Okay, so you have no personal experience actually applying for one of these licenses?

A I have not had to apply for one.

Q Okay, do you know, is the DEA required to render a decision within any set time frame for these licenses?

A There are some notes within the CSA, yes.

Q Do you know what those timelines are?

A It's again based on the complete protocol application. The number I told you is in totality of when we receive it and when it's completed, like when it's actually approved, but the date that it's complete may not be day one. It may be several, like, months into it for that to be true. I'm not sure --

It varies for whether it's a clinical protocol versus a non-clinical protocol, but again, the number I gave you is in totality, not

once an application is deemed complete, and most of them come in incomplete.

Q Okay, and that was the three months that you were --

A Yes.

Q -- talking about? Okay, do you know how many applications are currently pending for Schedule I licenses?

MR. MANN: Objection, Your Honor, this is not only outside the scope of direct, but it doesn't relate to any of the eight factors, the five factors, or the three factors.

MR. PHELPS: Your Honor, the court has specifically ruled that the research harm is something to be -- that can be considered. She's spoken on her knowledge of issuing licenses. This is again an attempt by the DEA to act like the research harms in this aren't relevant, but this court has already found otherwise.

JUDGE SOEFFING: Well, I think the Government did ask about the ability to get a researcher registration, so I don't think it's outside the scope. I did rule and say that, you know, you can present witnesses as to research harm. I don't know how much weight that's going

to get because it's not part of the Eight Factor Analysis, but I'll allow you to continue with this line of questioning, so I'll overrule the objection.

MR. PHELPS: Thank you, Your Honor.

BY MR. PHELPS:

Q Dr. Carbonaro, do you know how many applications are currently pending for Schedule I licenses?

A For new applications, I do not.

Q Do you have any ballpark?

A I was in the registration last week, and I think it was that if -- somewhere in the process were maybe 20 new applications.

Q And do you know historically, is that low, high, average?

A It fluctuates.

Q Okay, and do you know what the current wait time is for a license?

A I'm not sure I understand your question.

Q I think we'll go with three months. That's at least as far as what you've established. So, a couple of questions. You said a lot of the DEA approval has to do with

analyzing the protocols of a particular scientific project, right?

A I don't think I said that.

Q That's something that the DEA is looking at is, what are the protocols for?

A We make sure there is a protocol there, yes.

Q Okay, and so, if someone was working with an unscheduled substance that then became scheduled and they had to then apply, what happens to their research while they're waiting for that approval?

A Their research specific to the drug that's being added, after a final rule is published, there will be an effective date that's published, and so research could continue until that effective date, and if it has not been added to their Schedule I researcher registration or if they don't have one specific to that substance, then it may need to be halted while they're undergoing that process.

Q It may be, or it would have to be?

A Again, it would depend.

Q Well, if a substance is now controlled and they don't have that license, they would not

be able to continue legally, right?

A I believe there is some discretion if they're working on getting a Schedule I researcher registration. That would be up to the field's discretion, not headquarters, from my understanding.

Q Who has that discretion?

A I believe the diversion investigators in the fields, the field offices.

Q But they would, in fact, be breaking the law at that point, right?

A If they are actively trying to get it on their registration, depending on where they are, there may be some discretion. Again, that's outside my scope. I only deal with the part that we see at headquarters.

Q Okay, and then once a drug does become scheduled like that, do they then, are they then required to be purchased from specific suppliers?

A Yes, they must be purchased from someone that has a DEA registration.

Q Okay.

A Or they can be synthesized in-house under a Schedule I researcher registration, or can be transferred from one registrant to

another.

Q Okay.

A There are other ways to work within the closed loop of distribution.

Q Okay, did you have any personal experience with that type of licensure in your time in academia, the transferring or other than just applying for a straight license, these other options?

A Again, I didn't apply for a Schedule I researcher registration. I worked for PIs that had one.

Q Okay, so you didn't have any personal experience with these other avenues either?

A No, but we have done it for -- from working at DEA, I have helped people figure the information out.

Q And then once a substance is in Schedule I, DEA then has discretion over how much of that substance can be produced for research, right?

A There will be a quota for it, yes.

Q Okay. And the DEA has full discretion in setting those quotas, correct?

A That is determined outside of my

section. I don't -- that's outside of my purview.

Q Okay, but theoretically, the DEA could schedule a substance and then set a quota of zero for that substance, right?

A I don't believe so.

Q They couldn't do that?

A I don't believe there's evidence of that. They look at the available information to them, from my understanding, from personal communications, and make it based on what's available. And quotas are often increased for different substances, so there's a potential if it is too low, that it could be increased.

Q Okay, do you know what's considered in making those, setting those quotas at all?

A Again, that's outside my scope.

Q Okay. Isn't it true that once a drug does become scheduled, it goes from unscheduled to scheduled, that the costs of that for researchers to purchase increases significantly?

A Not necessarily. As a matter of fact, DOB and DOM seem to be cheaper than DOI on Cayman Chemical's website, similar or cheaper. One was cheaper. I don't remember the other one.

Q Okay. The substances that you were just mentioning, the DOB, do you recall if that was for a research standard amount or for an actual quantity for research purposes?

A I believe it was an actual amount for research purposes. I believe it was 50 milligrams compared to 50 milligrams.

Q Okay.

A I believe, but DOI, if a company so chooses to make a reference standard, they could also do that for DOI and it would be an uncontrolled reference sample as they are many other Schedule I substances. But that would be up to the company's discretion.

Q And you said that you're pretty up to date on the latest research going on with DOI, scientific research?

A I have read many studies about DOI.

Q And if you had to describe in general, what kind of research is being done on DOI now?

A I believe a lot of studies with DOI are using DOI as a reference drug compared to other psychedelics, looking at molecular or mechanisms of action related, like new drugs, comparing them to DOI or just other drugs in

general, using that since it is a known 2A agonist with psychedelic properties.

There are not just cells, but there are animal studies such as head-twitch that use it, again as a reference standard. There are other studies as well going on with it. I know there was a paper published somewhat recently, I don't remember the year, with DOI may be used as an anti-inflammatory, but again, in rodents.

But most of it, all of it is preclinical, so in, I believe, just rodents, and cells, and worms, but I don't think anything -- I don't recall anything in non-human primates or humans in the last -- I don't know, in a long time.

Q So, right now, the research is limited to, like you said, preclinical, right? It's not actually on humans?

A Correct.

Q But the end goal of that research would be to understand how these mechanisms work in humans and related to human diseases?

A Potentially, depending on the study.

Q There --

A Not necessarily.

Q They're not just studying it to find out what happens to rats in the long run?

A I suppose. I don't -- I'm not sure.

Q Okay, and so, in your understanding of general scientific research and how things work, the end goal of this research on serotonin receptors has to do with how it may impact human health, right?

A With certain psychedelics, not necessarily with DOI or DOC.

Q Okay.

A And also non-hallucinogens that activate the serotonin 2A receptor.

Q Okay, and so, are you aware of the order or the standard operating procedure that these researchers go through to get from preclinical studies to approved drugs?

A Generally speaking, early in the drug development process, you would start with some sort of cellular in vitro like binding assay function and then move up through different live body systems, rodents, what have you, and then after there is some level of understanding relating its potential safety, then it is brought into humans for phase one, two, and three

studies.

Q Okay, so what begins as preclinical research very oftentimes, or at least the attempt is to get that through all of those steps you just said?

A Not necessarily. There are -- I mean, it's possible, but a lot of drugs fail during the preclinical phase and never make it to humans.

Q Okay, but every drug that makes it through phase three and is eventually approved begins with preclinical studies, right?

A Most of the time. I'm not going to say every time.

Q Okay, every is maybe -- I'm sure you could find exceptions, but in general, studies that go through phase three began with preclinical studies?

A In general, yes.

Q Okay, so would it be reasonable to infer then that preclinical research does, in fact, have value to, ultimately, medical research on humans?

A Ultimately, it could.

Q Okay.

A But it doesn't mean it has medical

value, but it could attest to that.

Q Yeah, or even at the very least, medical research on humans. Whether that ends up going anywhere or not is --

A I wouldn't say necessarily medical research, as I would just call it clinical research.

Q Okay, what would you say is the difference between medical research and clinical research?

A Medical research usually has some sort of therapeutic metric in mind and they're testing it for some indication. Clinical research may not have that same point. They may just be assessing something else, but not necessarily related to a clinical indication.

Q Okay.

A That's my personal opinion.

Q So, that's not like an industry kind of standard? That's just how you -- that's your personal opinion on those?

A I'm not sure what the industry standard is. I'm not in the industry.

Q Okay, okay, so there can be some value to preclinical research in terms of medicine and

eventually accepted treatment?

A Yes, as a stepping stool, yes.

Q Okay, and are you aware of any studies out there looking at DOI for its anti-addictive properties in preclinical or clinical?

A I'm not sure what you mean by anti-addictive models.

Q That it can be used in treating substance abuse disorder?

A I am aware of self-administration studies in which DOI was given to animals that learned to respond to other drugs that are administered, if that's what you're referring to.

Q Okay, are you aware of any preclinical or clinical studies looking at DOI for its use in treating anxiety?

A I know that it has been used in some models, such as, I believe, forced swim tests and other models that might be markers of anti-anxiety.

Q Okay, and you mentioned before already that you are aware of some studies looking at DOI and its properties related to its anti-inflammatory qualities, right?

A Yes.

Q Okay, are you aware of studies looking at DOI for its pain management properties or its understanding of how pain works in the body?

A Not specific to DOI. I know that serotonin, especially the 2A receptor, has been investigated, but not specifically with DOI.

Q Okay.

A Oh, I retract. I am aware of some, yes, and there are some cases where it increased pain and other cases where it reduced pain, and it mattered like where it was administered.

Q Okay, how about studies looking at DOI for its potential use in treating cluster headaches?

A I am not aware of that off the top of my head.

Q Okay, and so, of those studies that you mentioned that you're familiar with, do you have any knowledge of whether those are being conducted through laboratories that have DEA licenses of any type?

A Yes.

Q Okay.

A Most of them. I'm not going to say all of them, but I am aware that these types of

studies are being done in Schedule I research labs.

Q Okay, some of them are and some of them are not, fair to say?

A I have not reviewed all of them in totality to know.

Q Okay.

A Some of them are also done outside of the United States, so that would be -- that would not be an important factor.

Q And this is a pretty wide range of potential medical benefits we just went through, is that accurate?

A In preclinical models, yes.

Q Okay, and do you know whether that research would have been able to be done if DOI was not currently, if it had always been scheduled back at the same time as DOM or those substances?

A Based on my analysis, it looks like most of the labs that are studying DOI are also studying Schedule I substances. There may be some cases where they are not, so it seems likely that it still would be able to continue.

Q Okay, but you said you're not aware of

the ratio of researchers that are doing with a Schedule I license or not?

A I'm not personally aware.

Q Okay, are you aware of any companies, pharmaceutical or otherwise, that are looking into DOI research?

A I am not, specifically. Like in animals, or in humans, or just generally speaking?

Q Both.

A I am not. We did confer with HHS, and no one has submitted an IND, so if anything, it would be preclinical.

MR. PHELPS: Just one second, Your Honor. Let me confer with my counsel here.

(Pause.)

BY MR. PHELPS:

Q Okay, I'd like to move us now into Factor 7. I'm looking at Government's Exhibit 7A. That would take us to page 12. So, this is psychic or physiological dependence liability, correct?

A Yes.

Q All right, and it's been a long day, so I just want to make sure I've got those two

straight. Physiological -- how would you define physiological dependence liability?

A Well, it's usually the body has made some adaption so that it needs continued use of the drug to maintain, and then usually there is some notion of tolerance or withdrawal that also pairs with physiological dependence.

Q Okay, so it's how it affects your actual body systems?

A Yes.

Q For example, somebody that's physiologically dependent on alcohol that's coming off could have, like, tremors or that kind of thing? That's what we're referring to in general, right?

A Correct.

Q Okay, and there's been, according to HHS and the DEA's own data, there's no evidence of physiological dependence liability for DOI and DOC, correct?

A Correct.

Q And that includes in animals and in humans?

A Correct.

Q So, DEA's position -- and if we look

at -- this is on page two. I think you're going along with us there, right, on Factor 7?

A Yes, page two, yes.

Q Yes, so it says thus, it is not possible -- well, I'll just read through the whole thing. According to HHS, the physiological dependence liability of DOI and DOC in animals and humans is not reported in scientific and medical literature. Do you know, is that something that they've tried to test for?

A I'm not aware of a specific study looking for it.

Q Okay.

A There have been studies of tolerance related to the 2A receptor being downregulated, but I believe that's as far as it's really been investigated.

Q And this kind of ties back into the self-administration studies, right? That could be a way to show physiological dependence?

A It could be used that way, but I'm -- but it could be used other ways.

Q Okay.

A Usually, you give -- if it was an animal study, a chronic injection over some

period of time, multiple times a day or what have you by the protocol and the drug's kinetics, and then try to precipitate withdrawal or let the animal withdrawal themselves and look at the behavioral effects.

Q Okay, and of all of the studies and everything you've seen for DOI and DOC, you haven't seen anyone even trying that or just reporting that it hadn't happened?

A I'm not aware of anyone trying it.

Q Okay.

A But it's also known that hallucinogens of this class don't cause physical dependence, so it wouldn't necessarily be expected that that study would need to be done either.

Q Okay, I'm glad you brought that up because that brings me to the very next sentence there. It says, thus, it is not possible to determine whether DOI and DOC produce physiological dependence following acute or chronic administration.

So, you wouldn't expect there to be evidence of that physiological dependence, right?

A We also don't have to have evidence of physiological dependence to control something.

Psychic dependence alone would meet this criteria.

Q Okay, and could you define for me psychic dependence?

A I generally use it in the way that HHS has reported on it in the past, and that is it's likely to be used, like continued use of these substances even though that they may know that they could cause harm.

Q Okay.

A That would be things like if the drug caused euphoria or markers of like drug liking. Things like that that have been reported with hallucinogens would meet the criteria for psychic dependence.

Q But you testified during direct that in all of your studies and research, almost everyone that takes DOI or DOC only takes it once, right?

A No, I did not testify to that. I think I said that some people will take it once, but I don't know how often people take it.

Q In the Erowid reports, did people indicate a desire to take it again?

A I don't recall all of the Erowid

reports specifically, but I know in some reports, people will say that they enjoy it and will seek out a long-acting phenethylamine hallucinogen.

Q Okay, so you don't recall testifying that most people only take it once?

A I do not.

Q Okay, if --

JUDGE SOEFFING: Mr. Phelps, is there another question?

MR. PHELPS: Yes, Your Honor. We're just -- our whole team had clear notes on this, and I think it's critical in regards to the psychic dependence of Ms. Carbonaro's testimony. I'm just looking at where we're at and where we're at in the day and whether we would need to go back and review the record regarding what she said about that.

JUDGE SOEFFING: Well, I mean, she says she doesn't recall testifying that way. The transcript will show whether she did or not and you can make use of it then, but --

MR. PHELPS: Certainly, okay.

JUDGE SOEFFING: -- as of right now, she says she doesn't remember saying that. I'm not really remembering her saying that either,

but the transcript will reflect what she said.

MR. PHELPS: Okay, no problem. Yeah, we don't need to go digging that up right now. We can include that in any kind of, yeah, post-hearing briefing.

BY MR. PHELPS:

Q So, if it was the case that most people took a drug and didn't want to take it again because of its extremely long-lasting effects, would that qualify as psychic dependence?

A Yes, because there are reports of people seeking out long-acting phenethylamines such as DOM and other drugs that have long-acting effects, so I think it would still meet that definition.

Q So, when you're going through these criteria of psychic dependence or physiological dependence, are you looking at the population as a whole or are you looking at -- does it only take one person to say I really that want to do it again for the whole drug to be classified as creating psychic dependence?

A I'm looking at data in its totality, but then also relating it back to what's known,

again, the drug discrimination data showing that they're similar to other drugs, and they have known psychic dependence.

Q But we did establish that the drug discrimination studies don't show the psychic dependence, correct?

A Correct, I'm not saying that the drug discrimination show, studies, sorry, my apologies, the drug discrimination studies show psychic dependence, but they show that they are similar to other drugs that have known psychic dependence, so it would be reasonable to assume that DOI and DOC could then have the same potential for psychic dependence as those hallucinogens.

Q And --

A And that was a conclusion from HHS that I reiterated, so HHS felt strongly about that statement.

Q Okay, but there's been no studies showing actual dependence, right?

A Again, there have been no clinical trials with DOI or DOC, and we can only go off of the information that is available and what we know that are similar to other Schedule I

substances with the same mechanism of action.

Q And, well, what about actual dependence in non-human subjects?

A Again, we would confer back to the mechanism of action and how it is similar and has the relative potential for the same for drugs that have the same mechanism of action.

Q Doctor, do you have a general definition of dependence outside of the psychic or physiological?

A I'm not sure what you're referring to.

Q Okay, I guess, what actually constitutes dependence?

A Again, that depends on whether you're talking about physiological dependence or psychic dependence.

Q Okay, and so, going back to the factor one, the four factors for abuse, would you say that any use of DOI or DOC constitutes abuse?

A I mean, based on these four factors, it just shows that we need evidence of it, so I guess my answer is, yes, if they're using it intentionally for hallucinogenic effects.

Q And using a drug for hallucinogenic effects could actually have medical benefits,

right?

A I'm not sure where you're going with that. I don't understand.

Q Well, you're saying that any use is -- you're saying that it's abuse because they're using it for hallucinogenic properties, right?

A And also not under like the guidance of like a medical practitioner, so just use on their own for hallucinogenic use.

Q Okay, so in general, right, or if we're looking across other substances, right, just the fact that something has hallucinogenic properties doesn't necessarily mean that that's a bad thing, right? There can be benefits to that?

A It's seen as an adverse effect by HHS, a hallucinogen. Whether that's intended or not intended, it's considered an adverse effect.

Q Okay, but I'm asking you about your personal opinion as an expert in this field. The fact that a substance is hallucinogenic is not an inherently problematic --

A Are you referring to like psilocybin studies and other studies that are going on related to hallucinogens in therapeutic contexts?

Q Sure.

A Okay, I think that there are certain guardrails in place for those studies to happen in a well-controlled setting. There are a lot of things, inclusion and exclusion criteria that are in place to allow these studies to happen.

There are some people that believe that a hallucinogenic effect is important in those therapeutic contexts. There are others that believe activating but not having a hallucinogenic effect would also be important in having a therapeutic effect. I think there's two camps in the hallucinogenic field.

Whether a hallucinogenic effect may be useful is still under investigation, especially for psilocybin, like they're undergoing Phase 3 studies, but there are harms that also occur in these clinical trials.

Q Okay, so in your personal expertise and opinion, which camp do you fall into?

A As a researcher, I'm interested in both.

Q Okay, and the guardrails that you're referring to, that boils down to what's essentially known as set and setting, correct?

A But also the inclusion and exclusion

criteria are very stringent on these studies right now. It's not just set and setting. It is also a known dose, a known dose formulation, the route of administration. It's more than just set and setting.

Q Okay, what are the inclusion and exclusion factors?

A Generally, for exclusion, they have to not come from a family that has a psychosis, like a background of psychosis or other mental conditions largely, other like cardiovascular effects. There are like health things that have to be checked off along the process. Oftentimes, if they're taking other medications, they're excluded from the study, but not always. Again, it depends on the type of study and what the outcome is.

Q So, if we could look at page two of Exhibit 7A, there's a quote from you here. Okay, you're on page two there, Doctor?

A Yes.

Q Okay. On background, the first paragraph, can you read the sentence that starts there on the third line starting with the subjective effects?

A The subjective effects of hallucinogens drive their abuse.

Q And keep reading the next sentence, please?

A The abuse of these substances can lead to a variety of adverse health effects such as paranoia, agitation, depression, and violent outbursts towards self and others.

Q And who is cited there?

A I am.

Q This was a paper that you wrote?

A Yes, with other authors.

Q You were the lead author on that though, right?

A On that paper, I was the first author, yes.

Q The first author, yes, ma'am, and do you remember the title of that paper?

A It was about challenging experiences with psilocybin mushrooms.

Q Was it only challenging?

A I mean, it was related to challenging experiences, but there is more in the title if I can find it.

Q Okay.

A The survey and study of challenging experiences after ingesting psilocybin mushrooms, acute and enduring positive and negative consequences.

Q Positive and negative consequences, because what you're cited here in the paper, and generalizing it to all hallucinogens, you're just talking about the negatives, right?

A I was referring to the negatives, yes.

Q Okay, do you recall what you said in the last paragraph of that paper?

A I don't specifically recall.

Q The office it cites? If I showed you an excerpt of that, would that help refresh your recollection?

A Sure.

MR. PHELPS: May I approach, Your Honor, or I can provide this? We just have a quote pulled from the paper that's being cited.

JUDGE SOEFFING: I'll tell you what. Why don't you print out some copies for tomorrow? Because we're kind of reaching the end of the day today.

MR. PHELPS: Okay.

JUDGE SOEFFING: But I'll need to

probably put that in the record.

MR. PHELPS: Okay, we can make that happen.

JUDGE SOEFFING: So, you can print off some copies that we can all look at tomorrow?

MR. PHELPS: Okay.

JUDGE SOEFFING: All right? We're getting close to 5:00. I'll let you do that tomorrow. Is there any other question you want to ask on this --

(Simultaneous speaking.)

MR. PHELPS: I think for now, at this point, if we could -- this was kind of the next route we're going, so I don't think it would make a lot of sense to jump back if we can pick up here tomorrow.

JUDGE SOEFFING: Okay, let's go off the record.

(Whereupon, the above-entitled matter went off the record at 4:53 p.m. and resumed at 4:54 p.m.)

JUDGE SOEFFING: Okay, we will end as we are closing in on 5:00. We will end the testimony for today. Dr. Carbonaro, I dismiss you from the witness stand for today. Please do

not talk about your testimony with anybody during the break until tomorrow.

You're still under oath, and you're still technically on the stand, so you can't discuss your testimony with anybody. And with that, I'll look forward to seeing everybody tomorrow at 9:00 a.m. We're in recess.

(Whereupon, the above-entitled matter went off the record at 4:54 p.m.)

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C E R T I F I C A T E

This is to certify that the foregoing transcript

In the matter of: Schedules of Controlled Subtances

Before: US Drug Enforcement Administration

Date: 11-12-24

Place: Arlington, Virginia

was duly recorded and accurately transcribed under my direction; further, that said transcript is a true and accurate complete record of the proceedings.

Neal R Gross

Court Reporter