

UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

IN THE MATTER OF:

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

Wednesday,
November 13, 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:

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ALSO PRESENT:

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

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

WITNESS DIRECT CROSS REDIRECT RECROSS

T. Carbonaro		316	390	420
Alaina Jaster	463	513	526	548
Raul Ramos	555			

EXHIBITS MRKD RECD

Government

10	Reddit post		408
11	Microgram Bulletin		409
12	Microgram Bulletin		411
13	Microgram Bulletin		413
14	Microgram Bulletin		415
15	Microgram Bulletin		417
16	Microgram Bulletin		419
17	Twitter Post	552	552

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17	Oxycodone Research		499
18	Psychopharmacology Article		486
37	The Rise (And Fall?) of Drug Discrimination Research		479
77	Jaster CV		464
81	Ramos CV		556
88	challenging experiences after ingesting psilocybin		318

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

2 9:06 a.m.

3 JUDGE SOEFFING: Good morning,
4 everyone. Before we resume the witness testimony,
5 I will address Panacea's motion for written
6 testimony. I heard the positions of the other
7 parties, Mr. Mann, the Government's opposed to
8 that motion.

9 MR. MANN: Our position is Panacea has
10 waived its right to participate in this hearing.

11 JUDGE SOEFFING: Okay.

12 MR. MANN: Therefore, yes.

13 JUDGE SOEFFING: Okay.

14 MR. MANN: Would not be able to submit
15 a written statement.

16 JUDGE SOEFFING: Okay and, Mr. Phelps,
17 the other Petitioners' position?

18 MR. PHELPS: We are not opposed to
19 Panacea submitting their testimony via written as
20 requested in the motion.

21 JUDGE SOEFFING: Okay, all right. I
22 considered the positions of the other parties and
23 Panacea's written motion. Due to the
24 representations made by Panacea that its sole
25 witness is unable to attend, I am going to permit

1 Panacea to make written filings as it has
2 requested to allow some participation in these
3 hearing proceedings since it has been a party and
4 did give notice to the tribunal, Government and
5 the other Petitioners before the hearing started.
6 There will be diminished weight given to whatever
7 it files because there is the inability to cross
8 examine its witness. I'll go ahead and I'll
9 issue that order when we take our morning break.

10 Okay, Dr. Carbonaro, you may retake
11 the stand. Doctor, I remind you that you are
12 still under oath.

13 And Mr. Phelps, you may continue your
14 cross examination.

15 MR. PHELPS: Thank you, Your Honor.

16 Good morning, Dr. Carbonaro. How are
17 you doing today?

18 DR. CARBONARO: I'm well. Good
19 morning to you as well.

20 CROSS EXAMINATION

21 BY MR. PHELPS:

22 Q Thank you. So we left off yesterday
23 discussing an article that you had cited in your
24 analysis. That was in Government's Exhibit 7A.
25 Do you recall us discussing that article

1 yesterday?

2 A I do.

3 Q And have you had a chance to review
4 that article?

5 A I did not.

6 Q Okay. Because I had some specific
7 questions about some other language in that
8 article. Would it help refresh your recollection
9 if you saw the article?

10 A Yes.

11 Q Okay.

12 MR. MANN: Judge, it seems that
13 refreshing recollection only follows if the
14 witness does not recall what's in the article.
15 There's no question being asked here.

16 BY MR. PHELPS: Sure.

17 JUDGE SOEFFING: Okay, I'll sustain.
18 Go ahead and ask a question.

19 BY MR. PHELPS: Absolutely.

20 Q Dr. Carbonaro, do you remember -- the
21 paper is titled, Survey study of challenging
22 experiences after ingesting psilocybin mushrooms:
23 Acute and enduring positive and negative
24 consequences. Do you remember the last sentence
25 that you wrote in the body of that article?

1 A I do not specifically remember the
2 last sentence that's in that paper.

3 Q Okay. Would it refresh your
4 recollection to see that article yourself?

5 A To see the last sentence, yes.

6 Q Yes.

7 MR. MANN: Can I see it?

8 MR. PHELPS: Absolutely.

9 MR. MANN: Thank you.

10 MR. PHELPS: And, Mr. Gleason, I've
11 got two copies.

12 JUDGE SOEFFING: Okay. So why don't
13 you give these to the law, clerk and they'll be
14 marked for identification.

15 MR. PHELPS: Yes, Your Honor. They
16 will be marked for identification purposes as
17 SSDP/Ramos Exhibit 88.

18 (Whereupon, the document referred to
19 was marked as Petitioners' Exhibit No. 88, for
20 identification.)

21 JUDGE SOEFFING: Okay. Mr. Clerk, is
22 that what we're up to, 88, by your count, too?
23 Okay. So we'll mark this --

24 MR. PHELPS: Will the Court mark those
25 or would you like me to write it on there.

1 JUDGE SOEFFING: No, my law clerk will
2 mark those.

3 MR. PHELPS: Okay, great.

4 JUDGE SOEFFING: If you just hand them
5 the copies, he will mark them.

6 MR. PHELPS: Okay, so there's two
7 copies, one for the witness and one for the
8 judge.

9 BY MR. PHELPS:

10 Q So, we -- as we discussed yesterday,
11 in your -- in Exhibit 7A, you had -- you had
12 cited some of what the Government characterizes
13 as, as negative aspects of psychedelics, correct?

14 A Correct.

15 Q Okay, now if you could turn to the
16 last page of this article, 1,277, last page
17 before the acknowledgments and citations. Do you
18 see the last sentence there starting with, with
19 increasing research?

20 A Yes.

21 Q Could you please read that sentence
22 aloud?

23 A With increasing research exploring
24 possible therapeutic uses of psilocybin, Grob et
25 al., 2011, 2013; Johnson et al., 2014, it is

1 important to note that risks of dangerous
2 behaviors or enduring psychological problems are
3 extremely low in laboratory studies of psilocybin
4 with carefully screened, well-prepared
5 participants who are supported during and after
6 psilocybin administration.

7 Q Thank you. So, it appears from this
8 article and what you've said, you've cited a
9 section of the paper for the proposition that is
10 favorable to the Government's position about the
11 danger of psychedelics, correct?

12 A The Eight Factor Analysis is about the
13 dangers of it and this paper does discuss the
14 dangers, so yes.

15 Q Okay, and then the paper concludes
16 with evidence that seems to be not favorable to
17 the position of the dangerousness of
18 psychedelics, correct?

19 A No, I disagree.

20 Q Okay, what -- how so?

21 A So, this is -- segment is specific to,
22 again, laboratory studies, which have a lot of
23 guardrails in place to make it so that they have
24 specific reduces in harm based on the guardrails
25 that are in place for these types of studies.

1 But it's not saying that they're devoid of those.

2 There are many accounts of still
3 having a challenging experience in these
4 controlled settings. There are reports of having
5 cardiovascular effects in these controlled
6 settings. This statement I would not say that it
7 is my statement. This is Dr. Griffiths'
8 statement in this concluding paragraph.

9 Q You're actually the lead author on
10 this --

11 A I am the first author --

12 Q Paper, right?

13 A But there are a number of other
14 authors on there and Dr. Roland Griffiths, it was
15 his lab and there are a lot of workings of his
16 lab and his language in this paper because it is
17 his lab and also his thoughts. It's not just my
18 thoughts in this paper.

19 Q Okay, so just to be clear, it's your
20 position today that this sentence -- concluding
21 sentence in a paper where you are the first
22 author is not representative of your position in
23 this paper?

24 A I mean I do believe that in laboratory
25 studies, with these specific, carefully screened

1 individuals where their cardiovascular system has
2 been assessed, their mental health has been
3 assessed, there are a lot of parameters that go
4 into it. He felt it was important to make this
5 conclusion in this paper. There is some validity
6 to it, but there are also harms that happen in
7 clinical trials.

8 Q Okay. Are there any other places in
9 your report or analysis where you've cited
10 sections of research that are favorable to the
11 Government's position while ignoring or not
12 including unfavorable parts?

13 A Again, this paper was specific to
14 psilocybin as it says in that introductory
15 paragraph, where it talked about hallucinogens in
16 general, including psilocybin. Because there are
17 no clinical trials related to DOI, whether it has
18 medical benefit or not in clinical trials, there
19 is no evidence that I can show specific to DOI
20 because it doesn't have these well controlled
21 clinical trials. These are all specific to
22 psilocybin in this case.

23 Q Okay. All I was asking is if there
24 are any other citations in your analysis that
25 select favorable positions that may be

1 contradictory to the conclusory statement of the
2 research as a whole.

3 A I don't recall any specifics.

4 Q Okay. You testified yesterday that
5 you conducted an analysis of the HHS Report as
6 part of your -- as part of compiling your own
7 Eight Factor Analysis, correct?

8 A Yes.

9 Q What did that analysis consist of?

10 A My analysis of their analysis?

11 Q Yes, your analysis of the HHS Reports.

12 A Most of it I carried over into my
13 Eight Factor Analysis, so my analysis it does
14 concur with theirs, but it did show that it has
15 abuse potential. The DOI and DOC both have abuse
16 potential based on available evidence, that there
17 was no medical use that's been established for
18 DOI and DOC, and that -- in conclusion, based on
19 their analysis and their recommendation, that it
20 should be controlled and placed on Schedule I.

21 Q So, it sounds to me that you're just
22 saying you adopted with HHS said. Did you
23 actually analyze their data?

24 A I did, yes. I went back --

25 Q And how --

1 A And read their papers.

2 Q And how did you analyze it?

3 A I went back and read their citations.

4 Q Okay. Did you verify the veracity of
5 the claims that they make in their paper?

6 A Regarding to what specifically?

7 Q Well, let's go ahead and take a look
8 at what was marked yesterday and admitted as
9 Government's Exhibit 5.

10 A Thank you.

11 Q And the first page of this document is
12 a letter from Brett Giroir, correct?

13 A It is a letter to Brett Giroir.

14 Q Oh, excuse me, excuse me, you're
15 correct. It's a letter from Uttam Dhillon,
16 right?

17 A Yes, the then-acting Administrator of
18 DEA.

19 Q Okay and before we get into the
20 analysis itself, can you kind of summarize or
21 explain what the cover letter here is about?

22 A Yeah, as part of the CSA, the -- as
23 we're evaluating a substance, we asked HHS for a
24 recommendation and scheduling. Scientific and
25 medical evaluation, schedule and recommendation

1 for substances we would like information on.
2 This is that for DOI and DOC, and it compares it
3 to other Schedule I hallucinogens.

4 Q Okay and did they provide verified
5 data to support the claims that they include in
6 their analysis?

7 A In this paper that DEA wrote to HHS?

8 Q In the -- in the analysis that --
9 well, here's my specific question. In the second
10 full paragraph, the second to last sentence
11 starting with specifically, could you please read
12 that aloud?

13 A Specifically, adverse effects
14 following ingestion of DOC and DOI have included
15 seizures, loss of consciousness, rhabdomyolysis
16 and death.

17 Q Okay. Those are very specific claims
18 about instances of DOC and DOI ingestion,
19 correct?

20 A Yes, but this is a document that DEA
21 wrote to HHS. This is a pre-decisional document
22 of information that we have at that time when
23 we're asking the HHS for information.

24 Q Okay and do you know where this
25 information came from about the adverse effects

1 following ingestion of DOC and DOI?

2 A I believe there are those case reports
3 of DOC that do have these intoxications and
4 deaths reported that we discussed yesterday.

5 Q Okay. But specifically, have you
6 provided any data or seen any data about DOI
7 causing seizures, loss of consciousness,
8 rhabdomyolysis or death?

9 A I have not.

10 Q Okay, because this says specifically
11 DOI, there have been instances where that's
12 happened with DOI, right? That's what this
13 letter is saying?

14 A Essentially, yes.

15 Q Okay and you're saying now that you
16 actually don't have any information to confirm
17 that with regards to DOI?

18 A Again, this was a pre-decisional
19 document based on information that they had at
20 the time.

21 Q It's just a yes or no question, ma'am.

22 A Can you repeat your question, please?

23 Q Yeah, do you have any specific
24 instances, as you've stated in this letter, as
25 DEA has stated in this letter, that ingestion of

1 DOI has caused seizures, loss of consciousness,
2 rhabdomyolysis or death?

3 A I'm not aware of any.

4 Q Okay, do you know if -- if you aren't
5 aware of it, do you think that the acting
6 administrator would have been aware of that?

7 A Again, this predates -- I was not on
8 this project at this time, I don't know what the
9 acting administrator understood at that time.

10 Q Okay, but as part of compiling your
11 2023 analysis, you reviewed these documents,
12 right?

13 A I did.

14 Q Okay. And you were generally aware of
15 all the things you had said about DOI yesterday,
16 right, that you testified about in regards to the
17 lack of documented instances of consumption, that
18 type of thing?

19 A Other than anecdotal evidence,
20 correct.

21 Q Okay and within that anecdotal
22 evidence, was there any information about
23 ingestion of DOI causing seizures, loss of
24 consciousness, rhabdomyolysis or death?

25 A I don't specifically remember any.

1 Q Okay. Because there weren't any,
2 right?

3 A Correct and I don't believe that was
4 --

5 Q Okay, this is --

6 A My conclusion.

7 Q Just a yes or no. Thank you. Did
8 that raise any kind of concern to you when you
9 were conducting your analysis and there seems to
10 be an unsupported conclusory statement about
11 effects of consuming DOI, ingesting DOI?

12 A Not based on this letter, no.

13 Q Okay and then that's the cover letter
14 for -- if we can go to page three. This is a
15 title. Can you just explain what this document
16 is?

17 A This document is an Eight Factor
18 Analysis that someone in my section wrote about
19 information that was available about DOI and DOC.
20 A pre-decisional eight factor document.

21 Q Okay.

22 A Or Eight Factor Analysis.

23 Q Would you say that you analyzed this
24 document as part of your assessment and compiling
25 your 2023 Eight Factor Analysis?

1 A I will say that I reviewed it.

2 Q Okay, what did you review it for?

3 A I mean I read through to see what
4 content was in here, what information was
5 provided to HHS that helped them do their
6 analysis, but that's mostly what I used it for.

7 Q Okay. Did you take any steps to
8 identify whether the claims in this report were
9 supported by data?

10 A I did not, again, this is a
11 pre-decisional document.

12 Q What is the significance of it being
13 a pre-decisional document?

14 A It just is information that DEA had
15 available and then the Eight Factor Analysis that
16 came back from HHS is what I considered to have
17 more merit than this pre-decisional document.

18 Q And why -- so, everything that's in
19 here, you just said came from data that the DEA
20 had?

21 A At that time, yes.

22 Q Okay and did you review all that data?

23 A I read this document, yes.

24 Q Okay, but did you review any of the
25 underlying data that one would expect to be

1 present to support the claims made in this
2 analysis? Or did you just read the paper and
3 move on?

4 A I read some of the articles and I have
5 read some of the articles that are cited in this
6 from past experience. I think there were a
7 couple of articles that I read, but mostly I just
8 read and reviewed it.

9 Q Okay. So I'd like to -- I'd like to
10 go through some of the claims made in this paper.
11 I'm trying to understand the analysis of how DEA
12 is making these claims. You're saying they're
13 based on data. They didn't just make these
14 claims. So, let's start on page -- what's page
15 two in the analysis, Factor One, Actual or
16 Relative Potential for Abuse. Law enforcement,
17 forensic and other data.

18 Can you read the first sentence of
19 that paragraph?

20 A Law enforcement data indicate that
21 since 1990s, a number of phenethylamines
22 including DOI and DOC have gained popularity
23 among drug abusers.

24 Q Okay. And so what metrics are used to
25 make the claim that DOI and DOC have gained

1 popularity among drug users?

2 A I believe that would -- I believe at
3 that time from the '90s would be STRIDE or
4 STARLiMS and available NFLIS data.

5 Q Well, this is saying, since the '90s.
6 Right?

7 A Right.

8 Q Okay and so that's going from the '90s
9 up to the time that this document was created,
10 right?

11 A Yes.

12 Q Okay. Did you review any of the
13 numbers of law enforcement data prior to the 2005
14 NFLIS reports that we discussed yesterday?

15 A I have reviewed it for other
16 phenethylamines, and this statement, I believe,
17 in totality of phenethylamines, not specific to
18 DOI and DOC.

19 Q But it specifically mentions including
20 DOI and DOC, right? This doesn't just say
21 phenethylamines are growing in popularity. It's
22 saying phenethylamines including DOI and DOC.

23 A Correct, but it is also in totality.

24 Q Okay, so does that mean --
25 methamphetamine is a phenethylamine, right?

1 A Yes, a stimulant, yes.

2 Q Okay, and so based on what you're
3 saying, if you're looking at a totality of
4 phenethylamines, does a huge increase in the
5 reported encounters of methamphetamine mean that
6 DOI and DOC have gained popularity as well? Is
7 that what you're saying?

8 A No, not necessarily.

9 Q Okay. And you would -- would you
10 agree that based on the NFLIS data that we looked
11 at from starting from 2005, that that, in fact,
12 did not show DOI gaining popularity?

13 A Well, NFLIS -- STRIDE and STARLiMS
14 predate NFLIS. NFLIS wasn't available in the
15 '90s, and our section has moved against using
16 STRIDE and STARLiMS and NFLIS because there is
17 double reporting, and so we only report on NFLIS
18 numbers. And that's the data that I used moving
19 forward. So, I didn't -- any information that
20 happened in the '90s or pre-NFLIS, I did not
21 consider.

22 Q Oh, that's -- that actually helps me
23 kind of understand this sentence. So, you're
24 saying that this claim is based on the numbers
25 that were provided in the NFLIS data that we

1 discussed yesterday?

2 A No, it's also based on STRIDE and
3 STARLiMS, databases that preceded NFLIS.

4 Q But I thought you just said that your
5 analysis was not based on that.

6 A My analysis in the 2021 and 2023
7 document, not in this document. This document
8 predates my time with this project. I'm
9 reviewing somebody else's work right here and
10 trying to understand it just like you are.

11 Q And how do -- I guess, then how do you
12 understand this claim that DOI and DOC have
13 gained popularity when the numbers we looked at
14 yesterday certainly didn't show that?

15 A This was the opinion of the drafter at
16 that time. I think it's also in totality, but
17 any reports in NFLIS, whether they're considered
18 small by some people, are still significant.
19 Especially, like, drugs that are not DOI and DOC
20 are not often looking for DOI and DOC. They're
21 looking -- they think that it's something else.
22 They think that it's reported as LSD, and then
23 they're finding DOI. So, the fact that there are
24 reports is very significant --

25 Q So, let me --

1 MR. MANN: Objection, she's trying to
2 answer the question.

3 JUDGE SOEFFING: Sustained.

4 If you have more to say, you can
5 finish your answer.

6 DR. CARBONARO: Oh, it's okay. Thank
7 you.

8 BY MR. PHELPS:

9 Q Can you cite to any of the data that
10 you've provided or discussed so far that
11 indicates people thought they were getting
12 another drug and it ended up being DOI?

13 A Yes, in the Microgram publications
14 that I cited, there were some -- essentially
15 blotter paper, where people thought it was LSD
16 and it turned out to be DOI.

17 Q Okay. So, a single incident is what
18 --

19 A No, there are also reports in NFLIS
20 where it was blotter paper and the lab thought it
21 was LSD based on the reports and it turned out to
22 be DOI.

23 Q Okay. In your resources at the DEA,
24 are you able to access the data prior to that
25 2005 NFLIS?

1 A We can request STRIDE and STARLiMS
2 data.

3 Q Okay, but you didn't do that in this
4 analysis?

5 A No, it was determined at some point
6 that often times what was put into STRIDE and
7 STARLiMS was often put into NFLIS as well as time
8 went on. So, instead of trying to combine two or
9 trying to select which database you use, we now
10 only use NFLIS.

11 Q Okay. Could you read the rest of that
12 first paragraph, please?

13 A DOI and DOC are available from
14 domestic and foreign chemical companies and from
15 individuals through the internet. Abusers have
16 purchased these substances on websites and using
17 them for their psychoactive effects. Drugs are
18 often shipped by eCommerce companies that also
19 claim to sell legitimate items.

20 Q Okay and in the data that has been
21 provided or disclosed, can you point to a single
22 specific incident of an individual purchasing DOI
23 from the internet?

24 A I believe in some of the Micrograms
25 that the packaging -- one of the packaging was,

1 like, made in China, so I would consider that to
2 likely have been bought on the internet and
3 shipped to the United States.

4 Q If something says it's made in China
5 that tells -- that is an indicator to you that it
6 was purchased on the internet?

7 A No, it's in a bag and it just says,
8 like, it has the chemical information and it's,
9 like, made in China. It had to have come here
10 somehow, so it's possible.

11 Q So, it's possible, right? But the end
12 user who had this when it was seized or
13 encountered, is there any data showing that the
14 individual that actually possessed the substance,
15 purchased it from a website?

16 A No, but these are, again, not my
17 conclusions.

18 Q Okay, but you adopted this as part of
19 your analysis, right?

20 A I read it. I did not make the same
21 sentence in my analysis. I didn't make note to
22 ship by eCommerce companies in my Eight Factor
23 Analysis.

24 Q So, would you say that that's not
25 accurate based on your review?

1 A Like I said, I don't have specific
2 evidence so I did not put it in my Eight Factor
3 Analysis.

4 Q Okay, because yesterday you testified
5 that people were buying this on the dark web,
6 right? You said there were sites you weren't
7 comfortable sharing.

8 A There -- I know that it is listed on
9 different websites and it has been on and off
10 different websites over time. So, people can
11 order it off websites.

12 Q I'm unclear whether you're agreeing
13 with this statement in the DEA's document that
14 drugs are often shipped by eCommerce companies
15 that also claim to sell legitimate items or not.

16 A I mean they appear they are available
17 for those.

18 Q So, if they're eCommerce companies
19 that also claim to sell legitimate items, that
20 would be -- would that be something you'd find on
21 the dark web or the regular web?

22 A In theory it can be both.

23 Q Okay. Could you give any example of an
24 eCommerce company that claims to sell legitimate
25 items and also sells DOI?

1 A Well, most sites that sell drugs claim
2 that they are legal substances or not controlled
3 substances, so any drug -- licit drug company is
4 going to claim to sell them legitimately.

5 Q Okay.

6 A But again, I don't want to list any
7 names. Like, there are active investigations
8 with eCommerce companies.

9 Q Okay. Of the data provided in the
10 NFLIS documents that we went through yesterday,
11 can you say that any of those encounters were
12 from -- where the drugs came from, online or
13 otherwise?

14 A I don't recall specifically.

15 Q Okay. If you could go down to the
16 next paragraph, you see the sentence that begins
17 with, while drug seizure data?

18 A Yes.

19 Q Could you read the next two sentences
20 going onto the first line of the next page?

21 A Start with while drug?

22 Q Yes, ma'am.

23 A While drug seizure data is not direct
24 evidence of abuse, it allows an inference that a
25 drug has been diverted or abused. Because the

1 primary focus of law enforcement agencies with
2 respect to drugs is on investigating the unlawful
3 distribution of drugs, the incidents in which
4 subjects have been seized in the course of law
5 enforcement investigations supports a finding
6 that the drug is being abused and/or diverted
7 from legitimate channels.

8 Q So, can you explain how you're able to
9 make that inference that just because an item is
10 encountered that that has been diverted or
11 abused?

12 A So, again, I'm not a law enforcement
13 agent, right, so I don't know how they find the
14 drug, but I'm aware that once they're reported
15 into NFLIS and we have evidence that they are
16 being distributed across the United States, that
17 they are being seized often under the guise of
18 other substances. That it is a way to basically
19 infer that the drug is being abused because we're
20 finding it in individuals in different amounts
21 that seem to be based on users. Like, there are
22 reports of LSD-like blotter tabs that are in
23 small squares, would be intended for human
24 consumption, similar to LSD. There are powders
25 that are in little baggies that have been

1 reported and so that suggests that also would be
2 abused.

3 Q Okay, so in that second sentence
4 because the primary focus of law enforcement
5 agencies with respect to drugs is on
6 investigating the unlawful distribution of drugs,
7 the incidents in which substances have been
8 seized in the course of law enforcement
9 investigations...so supports a finding that the
10 drug is being abused. Because law enforcement is
11 the one that's reporting it, that is the sole
12 reason that you're able to determine it's being
13 abused?

14 A It is certainly a factor.

15 Q And then the very last portion of
16 that, and/or diverted from legitimate channels,
17 you testified and provided in your own Eight
18 Factor Analysis that there was no diversion from
19 legitimate channels, correct?

20 A It does not appear so.

21 Q Okay, so did that statement raise any
22 kind of red flags for you in this analysis that
23 claims it's being diverted from legitimate
24 channels when you said in your analysis that was
25 not happening?

1 A I don't believe this paragraph is
2 specific to DOI or DOC. I think this is standard
3 language that we put in many of our documents.

4 Q So, this isn't even specifically
5 related to DOI?

6 A This is just about law enforcement
7 encounters, seizures and what they mean.

8 Q Okay.

9 A And for other drugs, there is clear
10 evidence they are being diverted from legitimate
11 channels.

12 Q Okay. Could you go down to page four
13 in the document? It's actually page six in the
14 exhibit numbers, but it's four in the analysis.

15 A Okay.

16 Q Do you see the header there, anecdotal
17 self-reports posted on the internet?

18 A Yes.

19 Q Okay. Actually, can you go ahead and
20 just read that paragraph, please?

21 A The first paragraph?

22 Q Paragraph starting with discussions on
23 websites.

24 A Discussions on websites known to be
25 popular among drug abusers, e.g., www.erowid.org,

1 suggests widespread interest in a number of
2 phenethylamine compounds, including DOI and DOC.
3 The information that can be found in those
4 websites as in outcome controlled studies and the
5 identity of the drugs has not been substantiated.
6 However, these discussions indicate that there is
7 a demand for the drug by abusers. The
8 discussions on the websites primarily include
9 narratives of the effects resulting from
10 self-administration of what was purported to be
11 phenethylamine substances.

12 Q Okay, so I know we touched on it some
13 yesterday, but I'd like to just -- what is your
14 understanding of what Erowid is?

15 A An online website where users of drugs
16 and chemicals can post the effects of those
17 drugs.

18 Q Okay, is that all that's on the
19 website?

20 A No, there's other information on it as
21 well.

22 Q And what other kind of information?

23 A I believe there's information about
24 the chemical aspects of the drug. I don't recall
25 specifically what else there was.

1 Q Okay, did you actually go onto Erowid
2 yourself to look up the reports relating to DOI
3 and DOC as part of your analysis?

4 A Yes.

5 Q And do you recall how many of those
6 reports there were?

7 A Not specifically, not necessarily a
8 large number.

9 Q Not necessarily a large number, not a
10 number that would indicate widespread interest?

11 A I believe, I mean, again not
12 necessarily, but I mean it's open to
13 interpretation.

14 Q So, it could be what you've described
15 as not a large amount of reports on this could
16 still be proof of widespread interest, is that
17 your position?

18 A I mean this sentence also could be
19 inferred as just widespread use of phenethylamine
20 compounds, not just specific to DOI and DOC, but
21 it also includes those. So, an increase in
22 phenethylamines, but also an increase in DOI and
23 DOC.

24 Q Okay, so this is another instance
25 where DOI and DOC are being lumped in with other

1 phenethylamines whether or not the claim made
2 specifically applies to DOI and DOC?

3 A I believe so.

4 Q Okay.

5 A That's my interpretation.

6 Q Okay. Do you think it's misleading
7 the way that this presented to say including DOI
8 and DOC when now you're saying that it actually
9 does not necessarily include them?

10 A Again this was --

11 MR. MANN: Objection. Your Honor, she
12 has no basis for knowing whether it's misleading
13 or not.

14 JUDGE SOEFFING: Overruled.

15 DR. CARBONARO: I guess it's a
16 pre-decisional document, we just gave any
17 information that we had to HHS so they can make
18 their evaluation. They don't just base their
19 evaluation on this, so I come back to the
20 information here it could be an over
21 generalization, but it's given to help HHS
22 conduct their evaluation.

23 BY MR. PHELPS:

24 Q And then you, in turn, relied on the
25 HHS evaluation to make your own evaluation,

1 right?

2 A Largely, yes.

3 Q Okay, so largely then your evaluation
4 falls back to this evaluation?

5 A No, I believe HHS makes their own
6 evaluation independent of this. They use this
7 information and whatever they have available to
8 them.

9 Q Okay.

10 A I am also aware of more recently
11 Reddit posts that indicate people are looking for
12 DOI and then there are comments of good luck
13 finding it, but people are, like, looking for DOI
14 more currently.

15 Q Do you know when those posts were
16 made?

17 A In the last several months.

18 Q Okay, let's take a step back and talk
19 -- well, yeah, let's talk about Reddit a little
20 bit, because this is where you're getting a lot
21 of your anecdotal data based on your testimony,
22 right?

23 A My anecdotal data, but it was not
24 considered in Eight Factor Analysis.

25 Q Okay, but you're including it as part

1 of your testimony in support of your analysis to
2 date, right?

3 A Based on updated information that I
4 have available now, yes.

5 Q Okay, can you explain what Reddit is?

6 A It's another online forum post or
7 online website where users, not users, users of
8 Reddit can post on any topic from drugs, not
9 drugs and any topic can be discussed.

10 Q Okay.

11 A Yes.

12 Q And those different discussions, how
13 are they broken up on the website?

14 A Based on Subreddits.

15 Q Subreddits, can you explain what a
16 Subreddit is?

17 A It's generally a topic of interest
18 that users will then go talk about that one
19 subject matter.

20 Q Okay and what does it take to post on
21 Reddit? How do you get an account there?

22 A You just sign up.

23 Q You just sign up?

24 A Uh-huh.

25 Q Is there any type of verification?

1 A I don't believe so.

2 Q Okay. Is there any type of fact
3 checking about the posts that are made?

4 A I'm not sure, I don't run Reddit.

5 Q Okay, but you're using what you read
6 on Reddit to support your analysis and your
7 conclusions, right?

8 A Correct.

9 Q Okay and so to use that -- before you
10 made the decision to use that data to support
11 your conclusions, did you look into how truthful
12 that Reddit data may or may not be?

13 A I took at what the poster is saying is
14 truthful. I'm not sure how I can review it any
15 further than that.

16 Q Well, you could review the website
17 general policies, right, to see if there's any
18 kind of verification?

19 A Potentially.

20 Q Okay, but you didn't do that?

21 A I don't believe so.

22 Q Okay, you said that you just took what
23 the -- do people post under their real names on
24 Reddit?

25 A No, they usually have usernames.

1 Q And are those usernames typically
2 identifiable to their offline person?

3 A Not usually.

4 Q It's essentially anonymous?

5 A Correct.

6 Q It's anonymous posting with no
7 verification and no fact checking about the
8 voracity of the post, right?

9 A Correct.

10 Q And your position today is that you
11 were taking those posts about these substances
12 and without any further question, you're just
13 accepting them at face value?

14 A With the caveat that I know that they
15 are anonymous and the drugs are not confirmed,
16 yes.

17 Q Okay. What Subreddit did you find --
18 I guess we can go to one post in general. You
19 referred yesterday to a Reddit post about what
20 was essentially a DOI party, right?

21 A I didn't say it was a party, it was a
22 gathering of sorts, I believe is what the Reddit
23 post said.

24 Q It was a gathering of how many people?

25 A It said, I believe, 200 to 300.

1 Q Two to 300 and they gathered for the
2 purposes of what?

3 A It just said that they used it. It
4 didn't say at the end that it was a gathering of
5 sorts. It didn't --

6 Q So, it was a gathering of a couple
7 hundred people who, based on the description of
8 the post, all got together to consume DOI?

9 A It doesn't say specifically. It just
10 says that there were 200 to 300 people and they
11 seemed to have taken DOI. It doesn't say they
12 specifically gathered for DOI.

13 Q Okay. Would you say it's a reasonable
14 inference that or would you say it would be an
15 accurate characterization of a gathering like
16 that as a party?

17 A I mean a party could be what it was,
18 but it doesn't call it a party. It just says a
19 gathering of sort, I believe.

20 Q Okay.

21 A Like it was questioned if it was a
22 festival and they just said a gathering of sort.
23 That can mean a lot of things.

24 Q Okay. What Subreddit was that post
25 on?

1 A I believe r/Psychonaut.

2 Q Okay and --

3 JUDGE SOEFFING: Can you spell that
4 for the record?

5 DR. CARBONARO: P-S-Y-C-H-O-N-A-U-T.

6 BY MR. PHELPS:

7 Q And just for clarification, can you
8 explain the R part of how that works with the
9 Subreddits?

10 A Yes, so if you go to Reddit.com, it'll
11 take you there and then any Subreddit would be r/
12 whatever that Subreddit is. In this case, it was
13 r/Psychonaut.

14 Q Okay. Who was the user who made the
15 post?

16 A I don't recall the username.

17 Q Okay, did you review that user's
18 profile to see any other posts they've made?

19 A I did not.

20 Q Because that would help you -- well,
21 let's take a step back. If you see a post that's
22 made by a particular username, User X, what steps
23 can you take on Reddit to find out more about
24 that user?

25 A You can see what other posts they've

1 made.

2 Q Okay and they would have a profile
3 page within Reddit?

4 A Potentially, if they choose to make
5 one.

6 Q Every Reddit user comes with a profile
7 page, correct?

8 A Yes, but the information in there,
9 what people put in there, I believe some are more
10 in depth than others.

11 Q Okay, so sometimes you do review
12 profiles then? You're familiar with what a
13 profile is?

14 A Yes.

15 Q And you're familiar with what kind of
16 information is accessible in a profile?

17 A Generally speaking, yes.

18 Q And what is it -- if you go to
19 somebody's profile on Reddit, what can you see?

20 A I don't recall specifically, but
21 there's usually information about, like, some
22 level of interests, other posts that they've -- I
23 don't --

24 Q So, it shows other posts that they
25 made, right?

1 A There are usually links to other posts
2 that they have made.

3 Q Have you ever seen a Reddit profile
4 that did not include previous posts?

5 A If the person has to put previous
6 posts, I believe I've seen new users.

7 Q Oh, so somebody who hasn't posted
8 anything, you wouldn't see any posts on --

9 A Correct.

10 Q Their profile?

11 A Correct.

12 Q Okay, but once something is posted
13 under a username, that stays on their profile
14 page, right?

15 A Correct.

16 Q Okay and that could also give you an
17 idea of what other Subreddits that user might
18 post in, right?

19 A Correct.

20 Q And it also includes comments that
21 that user may have included on other users'
22 posts, right?

23 A Yes.

24 Q So, by looking at a user's profile and
25 their other post history and their comment

1 history, that could help you verify the
2 truthfulness, at least get an understanding of
3 whether somebody knows what they're talking about
4 or not, right?

5 A To some degree yes.

6 Q So, let me put it to you this way, if
7 there was a user profile with no post history,
8 well, are you familiar with karma on Reddit and
9 how that works?

10 A A little bit.

11 Q Can you explain that, please?

12 A I'm not sure that I can adequately
13 describe it.

14 Q You just said you knew what it was,
15 right?

16 A I do, but I don't know that I can
17 describe it in a way that would be respectful for
18 what karma is.

19 Q Could you try?

20 A I, again, would prefer not to.

21 Q Well, I'm not asking if you prefer to,
22 I'm asking can you.

23 JUDGE SOEFFING: She said she can't.

24 MR. PHELPS: Okay.

25 JUDGE SOEFFING: So, we'll take that

1 answer.

2 BY MR. PHELPS:

3 Q When somebody makes a post on Reddit,
4 what actions can other users take to react to
5 that post?

6 A They can upvote it or downvote it.

7 Q Okay and then they can also comment on
8 it, right?

9 A Yes.

10 Q And they can also repost it in other
11 Subreddits, right?

12 A Yes.

13 Q Okay and so what is upvoting and
14 downvoting?

15 A Usually, my understanding is that if
16 people believe that it is important that more
17 people will upvote it and it will go higher up
18 into what is the, like, the online forum, so it
19 could get more awareness or become more visual.

20 Q Okay and the more upvotes you get,
21 that increases your karma level in your user
22 profile, right?

23 A I believe so.

24 Q Okay, so that's how karma works.

25 A Okay.

1 Q Would you agree it's based on the
2 upvotes that you get for your posts and comments?

3 A I believe you, I defer to you.

4 Q Okay and so if somebody has a high
5 amount of karma, what would that potentially tell
6 you about that Reddit user?

7 A Based on your description that they
8 have a lot of posts that were upvoted.

9 Q Okay, so that's one other -- the karma
10 point is something else that you can view in a
11 user's profile, right?

12 A Yes.

13 Q And that's another potential indicator
14 of that person's status or credibility within the
15 Reddit community, correct?

16 A Sure.

17 Q Okay and so going back to the post
18 about the 200-person gathering, would it affect
19 your assessment -- well, would there be any
20 difference in how you view that post coming from
21 a user profile with no other posts, no comments
22 and no karma versus a user who made that post
23 that has a significant amount of post history and
24 evidence of prior related comments or posts and a
25 higher amount of karma?

1 A No, not necessarily.

2 Q It wouldn't make any difference to you
3 in your analysis?

4 A No, I would just, again, I'm just
5 looking for information that's available online,
6 so I would take both.

7 Q But don't have a duty to evaluate the
8 potential accuracy of that data?

9 A Yes, but if it's a new user they can
10 still be credible, they just have not posted that
11 many things yet or people make new posts, like
12 new usernames, all the time so they can make
13 posts about things that are unrelated to their
14 profile. They can have more than one profile.

15 Q Okay, so you're saying that the amount
16 of activity or documented posts in a person's
17 Reddit profile has no impact on your assessment
18 of that person's posts?

19 A I don't necessarily pay that much
20 attention to that aspect of it.

21 Q Okay because you said that you just
22 read it and take it at face value, right?

23 A Yes.

24 Q Okay. If you went onto the
25 r/Psychonaut subthread and somebody said, hey, my

1 wife was diagnosed with cancer and I gave her DOC
2 and it cured her cancer, would you take that at
3 face value?

4 A I would take it as a note that
5 somebody that used DOC at face value, yes.

6 Q Okay, but you're talking about the
7 entire voracity of the post you're taking at face
8 value about the other post you described, right?

9 A Yes.

10 Q So, in that instance, would you take
11 that at face value that somebody gave another
12 person DOI and it cured their cancer?

13 A I would take it that there was an
14 online Reddit post that mentioned DOI or DOC,
15 yes.

16 Q But it wouldn't necessarily reflect
17 any sort of basis in reality just because it's
18 posted there in Reddit, right?

19 A No, it's just evidence that there are
20 online forum posts about DOI or DOC.

21 Q Okay, so it's evidence that people are
22 posting about it. It's not evidence that what's
23 being posted is true, right?

24 A It's just online mentions is what I'm
25 looking for.

1 Q Okay, so you're saying that when you
2 read the post on the r/Psychonaut about the
3 200-person gathering, that you didn't -- you
4 testified yesterday that that was indication that
5 a large amount of people had used the substance,
6 right?

7 A I testified that there is interest in
8 the substance based on that, but it's not
9 included in Eight Factor Analysis, that is
10 updated information that was just posted last
11 month.

12 Q Absolutely, but it's part of your
13 support of your analysis and argument today,
14 right?

15 A I do consider it, yes.

16 Q Okay. So, is posting about a
17 substance online the same in the DEA's analysis
18 as actually ingesting the substance?

19 A Evidence of online forum post is one
20 factor that is considered.

21 Q Okay.

22 A Yes.

23 Q And do you know the username who made
24 the post about the 200-person gathering?

25 A I do not.

1 Q And you didn't bother to check that
2 user's profile?

3 A I did not.

4 Q So you have no idea whether that was
5 someone who frequently posted or seemed to know
6 what they were talking about or someone who had
7 never posted at all?

8 A I do not.

9 Q Okay. I'd like to go to the next
10 paragraph. Could you please read that paragraph
11 aloud?

12 A Which paragraph?

13 Q It starts with adverse symptoms.

14 A Adverse symptoms, such as nausea,
15 paranoia, violent hallucinations, vomiting,
16 muscle ache, flatulence and amnesia were
17 reported. A review of all of the available data
18 shows that DOI and DOC are being trafficked and
19 abused. Law enforcement has encountered these
20 phenethylamines in powder, tablet, capsule,
21 liquid or blotter paper form. These substances
22 are being purchased from companies or individuals
23 through websites or purchased at "rave parties".

24 Q Okay.

25 MR. MANN: Judge, I would just to

1 interject that this is about the third or fourth
2 time that the witness has been asked to read from
3 a document that she did not write and I'm not
4 sure how relevant it is. The document is in
5 evidence. It speaks for itself. She doesn't
6 have to keep reading from something that she
7 didn't write.

8 JUDGE SOEFFING: Mr. Phelps?

9 MR. PHELPS: I'm happy to just refer
10 to the sections if you have a problem with her
11 reading it. I just want to make sure we're all
12 getting the full picture, but I can just refer to
13 the sentences and question her directly about
14 that if that's an issue.

15 JUDGE SOEFFING: Okay, I'll overrule
16 the objection. I think the points Mr. Mann made
17 are well known to the tribunal and us
18 participating here. If you think it's more
19 helpful to read, I'm not going to stop you at
20 this point, but for efficiency, it might move
21 things along quicker if she didn't have to read
22 it all too, so.

23 BY MR. PHELPS: Okay.

24 Q So, the second sentence there, a
25 review of all available data shows that DOI and

1 DOC are being trafficked and abused. How does
2 the DEA define trafficking?

3 A Usually looking at law enforcement
4 encounters.

5 Q What is your definition of
6 trafficking?

7 A The moving of generally illicit
8 substances cross country or over borders.

9 Q Okay. Trafficking specifically
10 applies to illicit substances?

11 A Generally speaking, yes.

12 Q Controlled substances?

13 A Generally speaking, yes.

14 Q So, if DOI and DOC are not controlled
15 substances, how can they be trafficked?

16 A That is a fair question, but they
17 could be implicated by the Analogue Act, so it
18 could still apply.

19 Q Okay, but you testified yesterday that
20 you were not aware of any Analogue Act
21 prosecutions with DOI or DOC, correct?

22 A At least not since I started.

23 Q Okay, that would have been something
24 that you would have reviewed as part of your
25 analysis of all this data, right?

1 A To the information that is available
2 to me, if there are active cases, I don't have
3 access to active cases.

4 Q Okay, but historical cases you do,
5 right?

6 A Again, to some degree.

7 Q Okay, what degree is that?

8 A We have to work with different parts
9 of DEA to request certain levels of data. We
10 don't all have access to that information.

11 Q Okay and as part of your analysis,
12 your Eight Factor Analysis, did you request that
13 data from anywhere in DEA?

14 A I did not.

15 Q So, you did not request that data and
16 you would agree that trafficking here is
17 inaccurate, right?

18 A It --

19 Q The use of the term trafficking
20 specifically in regards to DOI and DOC.

21 A It's language that we use often in our
22 Eight Factor Analysis for new drugs that are not
23 controlled and controlled substances.

24 Q Okay. Trafficking is a crime, right?

25 A Yes.

1 Q And can you be charged with the crime
2 of trafficking a non-controlled substance?

3 A You can be charged under the Analogue
4 Act for having an analogue of a Schedule I or II
5 substance.

6 Q Okay, that wasn't my question. My
7 question is can you be charged with the crime of
8 trafficking DOI?

9 A Not to my knowledge, but I'm not a
10 lawyer.

11 Q Okay. The last sentence there says
12 that -- when it says these substances, I want to
13 be clear because it seems to be some wavering
14 here. When they say these substances, is that
15 referring specifically to DOI or is that
16 referring to all phenethylamines?

17 A It could be either.

18 Q Let me rephrase. Is it reasonable to
19 infer that because there's only mention
20 specifically of DOI and DOC within that paragraph
21 that the phrase these substances is referring to
22 the DOI and DOC mentioned in that paragraph?

23 A It's possible to infer that.

24 Q Okay. Can you explain what rave
25 parties are?

1 A I believe it was a term just to, you
2 know, like large parties or gatherings, if you
3 will, that usually had electric dance music fests
4 or electric dance music playing. I believe it's
5 just a colloquial term where drugs are usually
6 administered at these parties.

7 Q Okay, so you said parties or
8 gatherings, so you're kind of using those terms
9 interchangeably, right?

10 A Yeah, I know, it's more of a party.

11 Q Okay. It's a party, right?

12 A Yes.

13 Q And you said it's a party with maybe
14 large people and electronic dance music?

15 A Generally speaking, but it doesn't
16 have to be.

17 Q Okay and in your review of all
18 available data that you did, did you find any
19 single, specific instance of DOI or DOC being
20 purchased at a rave?

21 A I don't recall specifically.

22 Q Okay because this is a conclusory
23 statement here, right? These substances are
24 being purchased at rave parties, right? That's a
25 conclusion that's being made?

1 A In this document, yes.

2 Q Okay but to your knowledge and based
3 on your review of all the data, you have not seen
4 evidence to support that conclusion that these
5 substances are purchased at rave parties,
6 correct?

7 A I believe there was a Microgram with
8 DOC that noted some sort of festival or party and
9 they got tabs from other people and that's how
10 they were able to confirm the substance.

11 Q That was specifically to DOC?

12 A I believe so.

13 Q And that was a single instance?

14 A I believe so, I'd have to review those
15 Micrograms to know in totality.

16 Q Okay, any evidence whatsoever of DOI
17 being purchased at rave parties?

18 A I don't believe that the Micrograms
19 always noted where they were seized from, just
20 the form that they were seized.

21 Q Okay, but this a conclusion made by
22 DEA saying exactly that, correct?

23 A I did not make this conclusion.

24 Q I didn't ask if you made it, I asked
25 if that's what it was.

1 A Yes, I'm not sure what information
2 they used to make this conclusion.

3 Q But it wasn't anywhere in the data
4 that you reviewed?

5 A I don't recall it.

6 Q Okay, or that was provided through the
7 course of discovery in this proceeding?

8 A I don't recall it, but there may be
9 evidence.

10 Q There may be, but not any that you
11 could speak to?

12 A Not off the top of my head right now.

13 Q I'd like to go down to what's page six
14 in the document. It's page eight in the exhibit
15 pages.

16 A Okay.

17 Q The second paragraph there says, in
18 summary, law enforcement data demonstrates that
19 DOI and DOC are trafficked and abused. Now, you
20 testified yesterday that any use whatsoever of
21 these substances would constitute abuse, correct?

22 A I think it shows evidence that it
23 could be abused.

24 Q I'm just asking because I want to make
25 clear that for this to be a true statement based

1 on your understanding and your position, any
2 proof of use would constitute proof of abuse,
3 right?

4 A Potential of abuse, yes.

5 Q Okay, well, this is saying they're
6 being actually abused. I'm asking because
7 yesterday you said that any use is abuse. Is
8 that still your position today?

9 A Yes, because there is no medical use
10 for these and yes.

11 Q Okay, so any single instance of this
12 drug being ingested you would say falls would
13 support this conclusion, this summary that these
14 substances are abused, right?

15 A Yes.

16 Q Okay. How can you say based on your
17 review of the data and your understanding of how
18 law enforcement works that data demonstrates DOI
19 and DOC are being trafficked?

20 A They're being encountered. Trafficked
21 is maybe not the definition of trafficked that
22 you're using, but they are being encountered.

23 Q So, I think we really need to hammer
24 down then, you're saying my definition of
25 trafficked, what's your definition of trafficked

1 or the Agency's definition of trafficked? Is it
2 based on the criminal definition?

3 A I'm not sure what DEA's definition of
4 trafficked is.

5 Q You're here as the expert on behalf of
6 DEA and you don't have a definition for the word
7 trafficked?

8 A Again, generally it's specific to
9 illicit substances that are being brought over
10 borders or through the country.

11 Q Okay, I'm just trying to understand
12 how in your analysis, right, we have to
13 understand what these terms mean when you use
14 them because now you're saying that it's
15 trafficked because it's encountered. So,
16 trafficking is an encounter, is that what you're
17 saying now?

18 JUDGE SOEFFING: Mr. Phelps, let me
19 just stop you for a moment because she's
20 testified a couple of times now about what
21 trafficked means to her. She's also said that
22 she's not the author of this document, that she
23 was not involved in its preparation. You
24 certainly can cross examine her about it, but I
25 think the limits as to what she can say about

1 this document are becoming apparent, to me
2 certainly.

3 I just want to make those points to
4 you because I think trying to pull information
5 out of her about the meaning of this document
6 that she wasn't involved in has become apparent.
7 I just point that out for your benefit. I don't
8 know how much we're getting out of this
9 particular document with this witness.

10 BY MR. PHELPS: Okay.

11 Q Do you use the term trafficked in any
12 of your own analysis?

13 A I believe it has been used in some of
14 my Eight Factor Analysis.

15 Q Okay and in the document that you
16 wrote, how would you define trafficking?

17 A As the definition that I just said,
18 but sometimes we use it from one Eight Factor to
19 another.

20 Q Okay, so in your own writings, could
21 you just repeat so we're all on the same page,
22 what is your definition or understanding of
23 trafficking in the papers you write yourself?

24 A It's essentially when drugs are
25 brought over the borders or distributed within

1 the United States, usually confined to illicit
2 substances.

3 Q Okay.

4 JUDGE SOEFFING: Let me just ask
5 because I think you had also said previously that
6 would include controlled substances?

7 DR. CARBONARO: Yes.

8 JUDGE SOEFFING: So, would that
9 include potential diversion of controlled
10 substances?

11 DR. CARBONARO: Yes.

12 JUDGE SOEFFING: Trafficking? Okay.
13 Thank you.

14 BY MR. PHELPS:

15 Q And yesterday you talked about -- I
16 guess you said that in your Eight Factor
17 Analysis, you're looking at the totality of the
18 data that's available, right?

19 A Yes.

20 Q And are you giving specific weight or
21 consideration to each of those different sources
22 of data and information?

23 A I give actual scientific information
24 with those substances more validity than others.

25 Q Okay. Would you say that the items

1 we've been discussing today, the parts in this
2 specifically, are specific scientific data?

3 A I mean also NFLIS encounters are
4 scientific data because they are confirmed
5 substances.

6 Q Okay, because you've made very clear
7 that you didn't have anything to do with the
8 preparation of this document, right?

9 A Yes.

10 Q And you didn't necessarily go back to
11 look at the things I pointed out and asked about,
12 you didn't go back and look at the specific data
13 that was underlying those claims, right?

14 A I looked at the Microgram data that
15 were used in this one and I used in my Eight
16 Factor Analysis.

17 Q Okay.

18 A And where it mentions users, I went
19 back and reviewed the user data that HHS provided
20 in their Eight Factor Analysis.

21 Q Okay and you said that when you --
22 well, would you say that would give this document
23 and the conclusions made in it a greater weight
24 in your analysis than an anonymous Reddit post or
25 are they equal in your eyes?

1 A They would just be two components I
2 would consider. I'm not sure I would weigh them
3 necessarily.

4 Q Okay, so what you're saying is you
5 couldn't definitively say that this report is any
6 more necessarily reliable than a Reddit post?

7 A No, it is more reliable than a Reddit
8 post generally speaking, if it's based on
9 scientific information that was available at that
10 time.

11 Q Your Honor, that's all the questions
12 that I have on this particular document. Our
13 next one, I think we're going to be using the
14 technology setup here. I'm looking and it's
15 10:20 now, I don't know if it might be
16 appropriate to take just a brief break and we can
17 get that set up.

18 JUDGE SOEFFING: Okay, let's take a
19 15-minute break. I'll allow you to get that set
20 up during the break then.

21 MR. PHELPS: Thank you, Your Honor.

22 (Whereupon, the above-entitled matter
23 went off the record at 10:20 a.m. and resumed at
24 10:30 a.m.)

25 JUDGE SOEFFING: We are back on the

1 record. Dr. Carbonaro, I remind you you are
2 still under oath.

3 Mr. Phelps, you may resume your
4 cross-examination.

5 MR. PHELPS: Thank you, Your Honor.

6 BY MR. PHELPS:

7 Q So, Dr. Carbonaro, when you are --
8 when you are preparing your Eight Factor Analysis
9 -- well, let's -- were you involved in the
10 decision-making process to begin the scheduling
11 of DOI and DOC?

12 A I am not sure what you are exactly
13 referring to.

14 Q The DEA at some level made a decision
15 one day that they wanted to pursue scheduling
16 these substances, right?

17 A Correct.

18 Q Okay. And do you know when that was
19 decided?

20 A No, that was before my time at DEA.

21 Q Okay. Do you know why it was decided?

22 A That was before my time at DEA.

23 Q So you were tasked with -- that is a
24 no, just to be clear?

25 A I mean, my understanding is that there

1 was evidence in NFLIS or STRIDE STARLiMS at that
2 time when they started reviewing it, that it has
3 a similar mechanism of action, but I don't know
4 exactly when or exactly why it was considered.

5 Q Okay. As part of your independent
6 analysis, did you explore why this process
7 began?

8 A Not specifically, no.

9 Q Okay. There is reference in the
10 documents that we referred to before that there
11 was increased attention being paid in the general
12 public to DOI and DOC, correct?

13 A I believe in conjunction with
14 phenethylamines, generally, yes.

15 Q Okay. So would it -- would that be
16 something -- when that happens, when a drug is
17 starting to become more popular, does DEA --
18 would it be accurate to say DEA considers those
19 emerging drugs of abuse?

20 A Yes.

21 Q Okay. So would it be a fair statement
22 to say that based on the descriptions of the
23 increasing popularity or interest in these
24 substances that DOI and DOC were emerging drugs
25 of abuse?

1 A At one time, yes.

2 Q Okay. Do you know what -- when you
3 say at one time, is there a specific timeline you
4 are referring to there?

5 A No, I just believe like when they are
6 first reported, that is when they are like
7 emerging trends, right? Because that's like
8 their first reports.

9 Q Okay. And then you mentioned some of
10 the data regarding hospital visits or medical
11 reports of people being admitted to hospitals for
12 adverse reactions to DOI and DOC, right?

13 A I believe they were specific to DOC.

14 Q Okay. Was there any other -- other
15 than emergency room reports, was there any other
16 public health data that was gathered and
17 collected? I guess I will break this into two
18 parts. First, by DEA independently.

19 A I am not sure exactly what you are
20 referring to.

21 Q Poison control calls?

22 A Data were looked at for poison
23 control, but based on how that is divided up and
24 not, I don't recall seeing any reports for DOI or
25 DOC based on some of the poison control database.

1 Q So you did independently review the
2 poison control database?

3 A I looked at some of the poison control
4 data.

5 Q Okay. Where do you go to find that?

6 A There are online publications, but we
7 have a repository of data and publications in our
8 shared folders that DEA uses.

9 Q How about at drug treatment
10 facilities?

11 A I did not review any drug treatment
12 facility information for DOI or DOC.

13 Q Okay. Any Centers for Disease Control
14 data?

15 A For Center for Disease Control, I did
16 look at SAMHSA's NSDUH study for some evidence of
17 DOI or DOC.

18 Q And did you find anything?

19 A I stuck mostly to the -- not the item
20 level details. Like I believe there is a
21 question where people can report any lifetime use
22 for DOI or DOC, and the way the survey is, does
23 not include them generally, so it would have to
24 be a write-in. So based on like the overall
25 study, I did not see any, I did not go into the

1 item level details of that question.

2 Q Okay. And so did you -- so you didn't
3 -- you didn't go into it because you didn't find
4 anything related to DOI and DOC?

5 A Again, I was just reviewing it to see
6 if it was mentioned as one of the drugs that it
7 is specifically asked for, and I did not see
8 anything as a drug that was specifically asked
9 about. But I am aware that it could be included
10 into item level details. I did not look at that
11 data.

12 Q Would you say that looking at that,
13 actually looking at that, that item level data
14 could have helped you get a better -- helped your
15 -- assisted your analysis of the potentials for
16 abuse?

17 A Not necessarily. With item level
18 data, that would require someone to put that in,
19 and I mean, it could help, but I don't know that
20 it would have a significant weight.

21 Q So at the time that you began your
22 Eight Factor Analysis, that was, when was that
23 exactly, that you were brought in on this
24 project?

25 A After we received the letter back from

1 HHS with their scientific and medical evaluation
2 and recommendation.

3 Q And do you remember roughly when that
4 date was?

5 A I believe like October of 2020.

6 Q October of 2020.

7 A I believe is when we received that
8 letter.

9 Q Okay. And so around -- so during that
10 time and the time leading -- so, I guess, the
11 report we went through earlier that was compiled
12 by DEA was 2018, right?

13 A I believe so.

14 Q Okay. And then HHS picked it up in
15 2020. Late 2020. That was when they -- excuse
16 me, that was when they provided it to you? They
17 would have started their process --

18 A 2018.

19 Q Okay. And when did you -- when did
20 you complete your Eight Factor Analysis?

21 A I believe my initial draft of the
22 Eight Factor Analysis was within six months of
23 when I was assigned it.

24 Q Okay. So at that time, would you say
25 it is accurate to say that DOI would be

1 considered an emerging drug of abuse over that
2 time period?

3 A I would say it was a drug of concern.

4 Q Okay. Concern for possible control or
5 scheduling?

6 A Yes, and that it could cause harm.

7 Q Okay.

8 MR. PHELPS: Mr. Gleason, can we get
9 the --

10 JUDGE SOEFFING: What would you like
11 to do, Mr. Phelps?

12 MR. PHELPS: Yes. There is a document
13 that I would like Dr. Carbonaro to take a look
14 at, and it is going to be projected on the
15 screen.

16 JUDGE SOEFFING: Is this one of the
17 exhibits already in evidence?

18 MR. PHELPS: It is not, but we are
19 going to lay the foundation of how it is going to
20 be introduced as impeachment evidence, not as
21 substantive evidence.

22 JUDGE SOEFFING: Okay. And do you
23 have a hard copy for the record, or can I get a
24 copy for the record?

25 MR. PHELPS: So we only have a digital

1 copy at this time. It is a graphic. We can get
2 an actual written one, but this was something
3 that came about late notice. So I do have a copy
4 here for the court and for the Government to
5 review. They do have an opportunity to review
6 that prior to the questioning.

7 JUDGE SOEFFING: Right now, all you
8 have is the digital copy to put up on the screen?

9 MR. PHELPS: Yes, Your Honor.

10 JUDGE SOEFFING: Okay. Go ahead and
11 put that up.

12 MR. MANN: Judge, I can't read that.

13 JUDGE SOEFFING: I can't read it
14 either. It is too small.

15 MR. PHELPS: Yeah, we are --

16 MR. MANN: I can't read it no matter
17 how big it looks.

18 MR. PHELPS: All right. There is a
19 copy on here or we can get you --

20 MR. MANN: That doesn't do me any
21 good. I don't have a computer. Can I go over
22 there?

23 MR. PHELPS: As long as there is no
24 communication, we have no problem with him
25 approaching to get a better look at that. It

1 is --

2 JUDGE SOEFFING: Yes.

3 BY MR. PHELPS:

4 Q So, Dr. Carbonaro, can you read the
5 title of what that says?

6 And I don't know, Mr. Gleason, is it
7 possible -- is it on her screen as well? Do you
8 have it there? Okay.

9 A The Controlled Substance Act
10 regulations on schedule and research for
11 registrations and the need to investigate new
12 substances of abuse.

13 Q And was this a document that you
14 prepared?

15 A Yes.

16 Q And you prepared it in conjunction
17 with two other individuals?

18 A Correct.

19 Q So you do -- do you recognize this
20 document?

21 A Yes.

22 MR. PHELPS: Your Honor, we would move
23 to introduce this only for impeachment purposes,
24 not for the purpose of the record. I know the
25 federal rules do not apply, but that would be

1 pursuant to Federal Rule 613. At this point, I
2 do believe that the Government would have an
3 opportunity to review this looking at Subsection
4 B of that rule.

5 Extrinsic evidence of a witness's
6 prior and consistent statement is admissible only
7 if the witness is given an opportunity to explain
8 or deny the statement. An adverse party is given
9 an opportunity to examine the witness about it or
10 if justice so requires.

11 So we will allow the Government an
12 opportunity to that as well. We would -- if we
13 need to have it marked, we would mark it as SS --
14 for identification purposes as SSDP/Dr. Ramos
15 Exhibit 89.

16 JUDGE SOEFFING: Okay. So Mr. Clerk,
17 is that the correct numbering? Okay. So this
18 would be number 89. We will need a paper copy
19 for the record.

20 MR. PHELPS: Certainly, we can --

21 JUDGE SOEFFING: If you could get that
22 after lunch.

23 MR. PHELPS: We can make that happen.

24 BY MR. PHELPS:

25 Q So what -- can you summarize what this

1 -- I guess where did -- what did you prepare this
2 for?

3 A A conference.

4 Q Okay. Do you recall the conference?

5 A I believe this one was at CPDD.

6 Q Okay. What is CPDD?

7 A The College on Problems of Drug
8 Dependence.

9 Q Okay. And do you know when you would
10 have -- when that would have been?

11 A I don't recall specifically which
12 year.

13 Q Okay. Does 2021 sound accurate?

14 A That could be accurate. Yep.

15 Q Okay. If that is what was indicated
16 when it was provided through a Freedom of
17 Information Act request dated 2021, would you say
18 that that would be accurate?

19 A It would be in my --

20 MR. MANN: Objection. Asked and
21 answered.

22 JUDGE SOEFFING: She -- overruled.

23 THE WITNESS: It would be in my CV so
24 I -- if that is what it indicated, I would agree.

25 MR. PHELPS: Okay.

1 JUDGE SOEFFING: Hold on one second.

2 Mr. Reporter, are you able to pick up
3 Government Counsel where he is standing over
4 there?

5 COURT REPORTER: Not really, but he
6 said four words, so I got it. If he is going to
7 say anything more than three or four words, it
8 would be great if he could move to a table.

9 THE WITNESS: Would it be helpful to
10 move this microphone this way?

11 JUDGE SOEFFING: Yeah. I just want to
12 make sure we are capturing everything that is
13 said. So we are okay so far?

14 COURT REPORTER: Yeah.

15 THE WITNESS: Can you still hear me if
16 I talk through -- okay.

17 JUDGE SOEFFING: All right. Let us
18 know if you are not capturing something.

19 BY MR. PHELPS:

20 Q Okay. So you prepared this for a
21 conference presentation that you gave in 2021?

22 A Correct.

23 Q And what was the presentation about?

24 A It was about two things. The
25 Controlled Substances Act regulations in general,

1 and doing research under that. And then I made
2 it most specifically related to hallucinogens,
3 but also included some data on drug trends.

4 Q So this was centered specifically
5 around hallucinogens, or there was a focus on
6 that?

7 A Yes.

8 Q Okay.

9 A For at least some of the data.

10 Q Okay. Would that include -- which
11 data do you see on here that is focused
12 specifically on hallucinogens?

13 A Well, specifically on this category
14 where it says hallucinogens, where there's a
15 number of pictures and a number of researchers
16 that were doing research with those specific
17 hallucinogens. And then some of the list of
18 emerging drugs of abuse below were specific to
19 hallucinogens, but not all of them.

20 Q Okay. So you would say that this is
21 a list of emerging drugs of abuse, specifically
22 hallucinogens?

23 A No, not all of them. I just included
24 some of them.

25 Q Okay. That is on the right side in

1 the white box there, right? Emerging drugs of
2 abuse?

3 A Yes.

4 Q Okay. Did you discuss much about
5 these or why were these listed?

6 A They were based on some -- at that
7 time, some of the drugs that were reported in
8 NFLIS that seemed to be higher at that time
9 relative to recent history.

10 Q Okay. So they were becoming
11 increasingly popular?

12 A There were NFLIS reports of those
13 drugs.

14 Q Okay. Do you see DOI or DOC on that
15 list?

16 A No.

17 Q Okay. At this time, you would have
18 been well aware of the issues around DOI as you
19 claim the emerging danger of it, right? That is
20 why you were working on scheduling it or
21 preparing your analysis for scheduling?

22 A We also don't discuss ongoing
23 scheduling actions while they are going through
24 the drafting process.

25 Q Okay. What is the reason for that?

1 A I mean, there are many reasons for it,
2 but it is just a general practice that our
3 section does, is we don't generally discuss
4 ongoing actions as they are going through the
5 process, unless we are trying to ask specific
6 information, trying to gather more information
7 that may be available.

8 Q Okay. So these were all substances
9 that you identified in this 2021 presentation as
10 emerging drugs of abuse?

11 A It is a short list. There aren't many
12 others.

13 Q Okay. Let's just have a -- so this
14 would be based on encounters, right? Or NFLIS
15 data is where you are coming up with this data?

16 A Yes.

17 Q Okay. And listing these substances?

18 A Yes.

19 Q And do you know the numbers of
20 encounters roughly of these substances
21 comparative to DOI and DOC?

22 A I do not.

23 JUDGE SOEFFING: Mr. Phelps, where are
24 we going with this?

25 MR. PHELPS: I am just trying to -- I

1 guess she did answer somewhat about the --
2 essentially about whether this was considered a
3 drug of concern based on public presentations and
4 research presented by Dr. Carbonaro in her own
5 analysis.

6 JUDGE SOEFFING: I am not sure where
7 we are going. I mean, you are asking about other
8 substances here that are listed. I am not sure
9 what the purposes of that has to do with the
10 supposed impeachment value of this document for
11 which it was presented.

12 I need some clarity about -- are you
13 using this to impeach something she has said
14 already? Because you will need to get to that or
15 we are going to have to move on.

16 BY MR. PHELPS:

17 Q Okay. So on the left side, there is
18 a graphic with a map there, right?

19 A Yes.

20 Q Okay. And what is the title of that
21 section in the blue?

22 A Drug and Chemical Evaluation Section
23 Activities.

24 Q Okay. So these are some of the
25 indicators of these -- this is how you find the

1 data of these emerging drugs and their trends?

2 A Those are just activities that our
3 section does, not necessarily what you are
4 saying.

5 MR. PHELPS: Your Honor, we -- well,
6 can I just confer with my counsel one second?

7 JUDGE SOEFFING: Yes.

8 MR. PHELPS: Thank you.

9 BY MR. PHELPS:

10 Q So Dr. Carbonaro, if there was
11 widespread illicit use in what you describe as
12 trafficking of DOI and DOC, why isn't that
13 included anywhere in this presentation?

14 MR. MANN: Objection, Your Honor. I
15 think this question has been asked and answered.
16 She testified that they don't discuss ongoing
17 scheduling investigations.

18 JUDGE SOEFFING: Sustained. Mr.
19 Phelps, if you have something in here that shows
20 some sort of conflict with what she has testified
21 to, you are running out of time to show me what
22 it is.

23 MR. PHELPS: At this point, Your
24 Honor, we don't have any further questions
25 related to this exhibit. I would defer to Mr.

1 Mann if he wants to follow up at all on that as
2 he is allowed.

3 JUDGE SOEFFING: Okay. If you would,
4 after the lunch break, get us physical copies of
5 these so that they can be marked and included in
6 the record.

7 MR. PHELPS: Yes, Your Honor.

8 JUDGE SOEFFING: Thank you.

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

11 JUDGE SOEFFING: All right. Very
12 good.

13 Mr. Mann, would you like to conduct a
14 redirect?

15 MR. MANN: Yes, Your Honor. Thank
16 you.

17 REDIRECT EXAMINATION

18 BY MR. MANN:

19 Q Dr. Carbonaro, you were asked
20 yesterday about data from NIDA, N-I-D-A. Do you
21 recall?

22 A I believe so. I believe so.

23 Q Okay. If you can go to Exhibit 6,
24 page 3 of Exhibit 6.

25 A You said page 3?

1 Q Yes, page 3, and that is the HHS
2 recommendation, is that correct?

3 A Yes.

4 Q And does it not discuss NIDA on page
5 3 at the top?

6 A Yes.

7 Q Okay. There were discussions about
8 blotter paper. If a substance is seized in
9 blotter paper form, is there any way to tell what
10 the actual dosage is?

11 A A lab can extract some amount and then
12 make some analysis of how much was in there. It
13 may not be 100 percent accurate, but you can get
14 some information.

15 Q But the blotter paper itself has to be
16 cut up, correct?

17 A Or extracted, right? It could be
18 taken from the paper, but yes.

19 Q Okay. But it is difficult to tell
20 what the actual dose is until the paper is cut up
21 and you see the individual pieces?

22 A Yes.

23 Q All right. Now, we talked about
24 yesterday drug labs.

25 A Yes.

1 Q And it is your testimony that not all
2 drug labs are going to test for DOI, correct?

3 A Correct.

4 Q And not all drug labs are going to
5 test for DOC?

6 A Correct.

7 Q And not all drug labs can test for
8 DOI?

9 A Correct.

10 Q And not all drug labs can test for
11 DOC?

12 A Correct.

13 Q And not all seizures can be tested for
14 DOI or DOC. That depends on the particular lab
15 and that depends on what law enforcement wants to
16 do with the seizure, correct?

17 A Correct.

18 Q Okay. Now, we talked about drug
19 discrimination studies. And I believe that we
20 established that drug discrimination studies are
21 designed to compare the effects of one drug to
22 another. Is that correct?

23 A Yes.

24 Q All right. So, if the drug
25 discrimination studies were done with DOM and

1 DOI, it would be possible to compare the effects
2 of DOM and DOI, correct?

3 A Yes.

4 Q And the same goes for DOC?

5 A Yes.

6 Q And DOM is a known drug of abuse, is
7 that correct?

8 A Yes.

9 Q And we talked about
10 self-administration studies. How effective are
11 self-administration studies when you're talking
12 about hallucinogens?

13 A They are generally believed not to be
14 reliable for this class of substances.

15 Q Why is that?

16 A They are known not to produce or
17 produce very minimal evidence of
18 self-administration in non-human primates or in
19 rodent studies.

20 Q Is that because non-human primates
21 just don't think the way that humans do?

22 A It is just a different behavior that
23 this drug class is known not to produce that
24 effect in those tests.

25 Q Okay. Now, I believe that you were

1 asked about the difference between your two
2 charts, your chart in 2021 and 2023, the
3 encounters, and that you actually added Nevada to
4 that chart.

5 A Correct.

6 Q But there wasn't an additional
7 encounter reported, is that correct?

8 A Correct.

9 Q Is that because you just determined at
10 that point that there was an encounter in Nevada
11 that hadn't been recorded earlier?

12 A I don't recall which was the case.

13 Q Well, let's take a look at Government
14 Exhibit 8, please. So there seemed to be an
15 issue about Nevada not being reported earlier,
16 but in fact, according to this chart, there is an
17 encounter reported and it is attributed to
18 Nevada, is that correct?

19 A Correct.

20 Q Okay. Now, there was discussion about
21 the number of seizures of controlled versus
22 non-controlled drugs. And I believe you
23 testified that the numbers of seizures would go
24 up if DOI or DOC was a controlled drug. Is that
25 because law enforcement tends to focus primarily

1 on controlled drugs?

2 A To my understanding, yes.

3 Q And there was also some discussion
4 about the similarity between DOC and DOM to a
5 substance, you said 2C substances, correct?

6 A I did.

7 Q And 2C-I is one of those 2C
8 substances, is that right?

9 A Correct.

10 Q And 2C-I, does that have a nickname or
11 a street name?

12 A I am not aware of one for that one.

13 Q Pink cocaine?

14 A That would be 2C-B.

15 Q 2C-B?

16 A But it is, again, similar in
17 structure, instead of an iodine, it would be a
18 bromine.

19 Q Okay.

20 A And it would still be pretty similar.

21 Q All right. And are you aware of any
22 incidents involving pink cocaine?

23 A Yes.

24 Q And what was that?

25 A Well, most recently, with the singer

1 Liam Payne, there have been some reports
2 suggesting that he --

3 MR. RUSH: Objection, Your Honor.
4 Relevance.

5 JUDGE SOEFFING: Only one counsel per
6 witness, so it would have to be an objection made
7 by Mr. Phelps.

8 MR. RUSH: I'm sorry, Your Honor.

9 MR. PHELPS: Apologies. We would
10 raise the same objection, Your Honor, relevance
11 to Liam Payne to this proceeding.

12 JUDGE SOEFFING: Okay. Overruled.

13 BY MR. MANN:

14 Q You can proceed.

15 A That the singer had ingested 2C-I,
16 based on some level of data that came out in his
17 tox report, that it had been consumed, and then
18 he fell from a balcony and has died.

19 Q 2C-I or 2C-B?

20 A 2C-B, pink cocaine.

21 Q 2C-B. Let's just establish that. I
22 think you said 2C-I.

23 A Oh, my apologies.

24 Q Okay. All right. Thank you. Now,
25 did you -- I believe there was testimony about

1 the cost of DOI on the market now and the cost of
2 DOM. Was it your testimony that DOM is actually
3 cheaper now than DOI?

4 A Yes, and I went back last night to
5 look at Cayman Chemicals' website and looked up
6 the price for 50 milligrams of DOI, DOC, and --
7 oh, sorry, DOI, DOM, and DOB. And DOM and DOB
8 were less than the cost of DOI. I believe the
9 other two were like \$350 for 50 milligrams, and
10 DOI was closer to \$450. But my numbers might not
11 be accurate.

12 Q Now, regarding your opinions, if a
13 drug has no currently accepted medical use but is
14 being self-administered, in other words, taken,
15 but, you know, the decision of the person is --
16 well, let me put it this way. If someone is
17 deciding to take a drug themselves, and that drug
18 has no currently accepted medical use, would that
19 be consistent with abuse?

20 A Yes. Potentially, yes.

21 Q If a drug is found in a form that is
22 consistent with self-administration, like blotter
23 paper, for instance, would that be consistent
24 with abuse?

25 A Yes.

1 Q There was a lot of discussion about
2 the four-prong test for abuse.

3 A Yes.

4 Q How long has that system been in
5 place, that four-prong test?

6 A So I believe it was included in the
7 1970 bill for the Controlled Substance Act that
8 made DEA. But in the 1970 bill, it references
9 that this definition came from the Federal Food,
10 Drug, and Cosmetic Act for their definition of
11 abuse potential specific to stimulants and
12 depressants. And it was promulgated to include
13 hallucinogens based on the use in the CSA.

14 Q Now, you were asked about the article
15 that you participated in. You were listed as the
16 first author, and I believe Mr. Griffith?

17 A Dr. Griffiths.

18 Q Dr. Griffiths was listed as the last
19 author. There is some significance to being
20 listed as the last author, correct?

21 A Correct.

22 Q What does that usually entail?

23 A Usually it goes to the principal
24 investigator. It is their lab so they get that
25 tail, basically, of citations. It is their

1 money. It is their lab. So generally they are
2 last, but they can also be first.

3 Q And when counsel highlighted this last
4 sentence, this is talking about the risks
5 associated with laboratory tests, correct?

6 A Yes, and specific to psilocybin.

7 Q Okay, so when you compare -- I know
8 that no human clinical trials have been done with
9 DOI, but if you did do human clinical trials with
10 DOI, would they be the same in terms of risk as,
11 for instance, psilocybin? Would everything be
12 the same?

13 A There would be similar risks in terms
14 of the cardiovascular and the psychological
15 effects. And also because of the longer duration
16 of action, it could potentiate those effects.

17 Q So you talked about guardrails,
18 correct?

19 A Yes.

20 Q What do you mean by guardrails?

21 A So when a study is being done in
22 clinical trials, there are extensive inclusion
23 and exclusion criteria that are in place to
24 mitigate risks for the participants in that
25 study. And there is a known dose, a known

1 formulation that is given to participants.

2 In these clinical trials specifically
3 with hallucinogens, there is several hours of
4 prep that go into these experiments so that a
5 person knows what they are taking and what the
6 effects might be.

7 There are doctors either in the room
8 or within 15 or so minutes of those at Hopkins.
9 We had an emergency department directly across
10 the street from us for the trials that we were
11 doing that we could take them if something
12 happened.

13 There are medications that we have
14 like a rescue box that if someone was having a
15 challenging experience or having a cardiovascular
16 effect, that it could be administered if that
17 were to happen. Again, in a way that is
18 mitigated to reduce the amount of risk.

19 Q And that is what you are talking
20 about?

21 A Yes.

22 Q Now, how long is the psilocybin
23 clinical trial going to last?

24 A Per session?

25 Q Yes, per person.

1 A Yeah, it is usually done within about
2 eight or so hours with the active effects being
3 about six hours.

4 Q And how long is, in theory, a DOI
5 clinical trial going to have to last?

6 A It could be 24 hours or more depending
7 on dose.

8 Q Significantly longer, correct?

9 A Yes.

10 Q So significantly more guardrails have
11 to go up during that particular administration if
12 that is what you were going to do?

13 A Yes.

14 Q Same with DOC?

15 A Yes.

16 Q To determine whether a drug has a
17 potential for abuse, is it necessary that the
18 drug causes seizures?

19 A No.

20 Q Is it necessary that the drug has to
21 cause loss of consciousness?

22 A No.

23 Q Is it necessary that it has to cause
24 rhabdomyolysis?

25 A No.

1 Q Is it necessary that it has to cause
2 death?

3 A No.

4 Q When one seizes an amount of drugs in
5 amounts that go beyond what would be considered
6 one-time personal use, could you infer that that
7 drug was being used to be distributed?

8 A You could.

9 Q Now, are you familiar with a document
10 which was originally the Petitioners' document
11 No. 6, which was withdrawn, called the Assessment
12 of Abuse Potential of Drugs, Guidance for
13 Industry, by the U.S. Department of Health and
14 Human Services, Food and Drug Administration,
15 Center for Drug Evaluation and Research, January
16 2016?

17 A Yes.

18 Q Do you recall reviewing that?

19 A Yes.

20 Q And do you recall the statement that
21 post-marketing data may include, but is not
22 limited to, abuse-related information obtained
23 from, among other things, Internet forums and
24 social media sites through which drug experiences
25 are reported and discussed?

1 A Yes.

2 Q That is FDA guidance, correct?

3 A Yes.

4 MR. MANN: All right, that is all I
5 have. Thank you.

6 JUDGE SOEFFING: Thank you, Mr. Mann.

7 Mr. Phelps, would you like to conduct
8 a recross? Mr. Phelps, will you be conducting a
9 recross?

10 MR. PHELPS: No, Your Honor, no
11 further questioning. Thank you.

12 JUDGE SOEFFING: Okay. Mr. Mann, any
13 other witnesses or evidence you wish to present?

14 Q Your Honor, there actually was one
15 more thing I would like to ask her, if I may be
16 allowed to go back for a minute.

17 JUDGE SOEFFING: Yes, yes, you may.

18 MR. MANN: Your Honor, I have a number
19 of exhibits that were discussed during the
20 cross-examination, which I would like to
21 introduce, and they have all been marked. The
22 first one is a copy of the Internet traffic that
23 Dr. Carbonaro referred to from Reddit. I have
24 copies.

25 JUDGE SOEFFING: These were discussed

1 during the cross-examination?

2 MR. MANN: Yes.

3 JUDGE SOEFFING: Okay. So I think
4 maybe it would be best if you and Mr. Phelps got
5 together to look at those?

6 MR. MANN: I have marked them by hand.
7 Sorry about that, but I have copies for everyone.

8 JUDGE SOEFFING: How many documents,
9 Mr. Mann, do you have?

10 MR. MANN: We have a total of this one
11 and then five others.

12 JUDGE SOEFFING: All right. So what
13 I am going to do is I am going to recess and get
14 off the bench. I am going to allow you and Mr.
15 Phelps to go through the five documents so I can
16 get Mr. Phelps' opinion or position as to whether
17 he has any objection to the introduction of these
18 into the record. And then my law clerk will let
19 me know when you all are ready. Maybe we can do
20 that in 10 or 15 minutes, Mr. Mann?

21 MR. MANN: Yes, we are fine. I am
22 giving him all these.

23 JUDGE SOEFFING: Okay, so we are at
24 recess.

25 Mr. Phelps, did you want to say

1 anything before we go into recess?

2 MR. PHELPS: No, Your Honor. If we
3 could just receive copies of those five exhibits
4 that we can take a break and review.

5 JUDGE SOEFFING: Okay, why don't you
6 do that? My law clerk will bring copies to me in
7 camera so I can look at them as well.

8 MR. PHELPS: Okay, sure.

9 (Whereupon, the above-entitled matter
10 went off the record at 11:27 a.m. and resumed at
11 11:49 a.m.)

12 JUDGE SOEFFING: All right. We are back on
13 the record.

14 Dr. Carbonaro, let me remind you that you're
15 still under oath.

16 Mr. Mann, you may continue to ask your
17 additional questions on your now reopened
18 redirect examination.

19 MR. MANN: Thank you.

20 REDIRECT BY MR. MANN:

21 Q Dr. Carbonaro, could you look at
22 what's marked for identification as Government
23 Exhibit 10, please?

24 A Yes. Can I give you these ones?

25 Q And can you identify that for the

1 Court, please?

2 A Yes. This is the Reddit post that I
3 was talking about.

4 Q And does this reflect -- Did you
5 create this document?

6 A I did.

7 Q Is there -- Is your initials on it?
8 Or some, something that shows that you printed
9 this out?

10 A Yes, on the last page.

11 Q Okay. Is this -- or this reflect the
12 Reddit comments that have been discussed here
13 during your cross examination?

14 A Yes.

15 Q Okay. The Government would move
16 Government Exhibit 10 into the record.

17 JUDGE SOEFFING: Mr. Phelps, any objection?

18 MR. PHELPS: Not necessarily an objection,
19 just one point of clarification in regards to
20 foundation. If this is the entirety of the
21 comments on this post.

22 JUDGE SOEFFING: Okay.

23 Mr. Mann, would you like to ask that
24 question?

25 BY MR. MANN:

1 Q Is this a select -- Is this altered or
2 edited in any way?

3 A No, this was what was found on
4 November 1st.

5 Q Okay. And November 1st of this year?

6 A Yes.

7 MR. PHELPS: So, it's the complete --
8 it's the complete post, then?

9 THE WITNESS: As it was on November
10 1st of this year.

11 MR. PHELPS: Okay, thank you.

12 We're -- No objection then, Your
13 Honor.

14 JUDGE SOEFFING: Okay. All right.
15 Government Exhibit marked for identification
16 Number 10 has been offered. In the absence of
17 objection, it is received in the record as
18 Government Exhibit 10. You may use it.

19 (Whereupon, Government Exhibit 10 was
20 admitted into evidence.)

21 BY MR. MANN:

22 Q If you could look at Government
23 Exhibit 11, please?

24 (Pause.)

25 A Okay.

1 Q And do you recognize this -- this
2 document?

3 A Yes, it's from the Microgram Bulletin
4 that I referenced, my a factor.

5 Q And is this something that you
6 reviewed for your report?

7 A Yes.

8 Q Is this an official government -- a
9 document kept in the system of records at DEA?

10 A Yes.

11 Q Government would move Exhibit 11 into
12 the record.

13 JUDGE SOEFFING: Mr. Phelps, any
14 objection?

15 MR. PHELPS: I am taking a look here.
16 We have a 12, 13, 15, 16. Just wanted to make
17 sure we had the 14.

18 Just making sure we have 11, because
19 I am not seeing that one here. So, we have 14.

20 Your Honor, I don't believe I see an
21 exhibit marked 11. We got 12, 13, 14, 15, and
22 16. Which one is on the -- the -- What does the
23 cover of 11 look like? Let me just make sure
24 that --

25 (Pause.)

1 MR. MANN: I may have given that away
2 to the clerk.

3 JUDGE SOEFFING: It looks like
4 somebody from counsel --

5 MR. PHELPS: Oh, wait --

6 JUDGE SOEFFING: -- maybe had it back
7 in the --

8 MR. PHELPS: Okay, apologies. We do
9 have Exhibit 11. No, no objection. Thank you.

10 JUDGE SOEFFING: All right.
11 Government Exhibit marked for identification
12 Number 11 has been offered in the absence of
13 objection. It is received in the record as
14 Government Exhibit 11.

15 (Whereupon, Government Exhibit 11 was
16 admitted into evidence.)

17 BY MR. MANN:

18 Q Dr. Carbonaro, if you could look at
19 page five.

20 A Yes.

21 Q And when I say page five, I'm talking
22 about handwritten page five.

23 A Okay.

24 Q And is this -- Is this the part of the
25 Microgram that you consulted for your report?

1 A Yes.

2 Q Starting with the -- An intelligence
3 alert for 4-chloro-2,5 dimethoxyamphetamine DOC?

4 A Yes.

5 Q And is it fair to say that this
6 discusses the seizure of DOI?

7 A Yes. And DOC.

8 Q If you could look at Government
9 Exhibit 12, please?

10 A Oh. And here's your paperclip.

11 Q And can you recognize that document?

12 A Yes.

13 Q And what is this?

14 A It is another Microgram Bulletin.

15 Q And did you consult this document in
16 preparing your report?

17 A Yes.

18 Q And is this part of DEA system of
19 records?

20 A Yes.

21 Q Okay. Government moves Exhibit 12
22 into the record.

23 Oh, is this a fair and accurate
24 representation of the Microgram that you
25 consulted?

1 A Yes.

2 Q Any alterations or changes?

3 A No.

4 Q Government moves 12 into the record,
5 please.

6 JUDGE SOEFFING: Mr. Phelps, any
7 objection?

8 MR. PHELPS: No objection, Your Honor.

9 JUDGE SOEFFING: Governor --
10 Government Exhibit marked for identification
11 Number 12 has been offered in the absence of
12 objection. It is received in the record as
13 Government Exhibit 12, it's in, you may use it.

14 (Whereupon, Government Exhibit 12 was
15 admitted into evidence.)

16 BY MR. MANN:

17 Q And I'd like to direct you to the page
18 five, handwritten page five.

19 A Okay.

20 Q Do you see at the top, a bulletin says
21 4-iota-2,5-dimethoxyamphetamine DOI in Madison,
22 Wisconsin?

23 A Yes.

24 Q And is this the doc -- Is this the
25 portion of the document you consulted for your

1 report?

2 A Yes.

3 Q And is it fair to say that this is,
4 involves another seizure of DOI?

5 A Yes.

6 Q If the witness could please see
7 Government Exhibit marked for identification
8 Number 13?

9 A Okay.

10 Q Do you identify -- Do you can you
11 identify that document?

12 A Yeah. Another Microgram Bulletin from
13 March 2008.

14 Q And is this something you consulted to
15 create your report?

16 A Yes.

17 Q And is it a fair and accurate copy of
18 the DEA Microgram?

19 A Yes.

20 Q Is it altered and changed in any way?

21 A No.

22 Q And is this kept in the DEA system of
23 records?

24 A Yes.

25 Q The Government moves Exhibit 13 into

1 the record, please.

2 JUDGE SOEFFING: Mr. Phelps, any
3 objection?

4 MR. PHELPS: No objection, Your Honor.

5 JUDGE SOEFFING: Government Exhibit
6 marked for identification Number 13 has been
7 offered in the absence of objection. It is
8 received in the record as Government Exhibit 13.
9 It's in, you may use it.

10 (Whereupon, Government Exhibit Number
11 13 was admitted into evidence.)

12 BY MR. MANN:

13 Q And Dr. Carbonaro, I'd like you to
14 direct your attention to page four of this
15 particular document.

16 A Yes.

17 Q And is this the portion of the
18 Microgram that you reviewed for your report?

19 A Yes.

20 Q And if you can explain to the Court
21 what -- what happened here?

22 A This was, they encountered by the
23 Kentucky State Police. They received a y square
24 blotter paper that was dropped in foil. They
25 believed it was LSD. When they tested it, they

1 found that it was DOI and DOC -- a mixture.

2 Q Thank you.

3 If you -- If the witness could please
4 see Government Exhibit 14.

5 A Okay.

6 Q Do you identify -- Can you identify
7 that document?

8 A Yes. It's another Microgram Bulletin
9 from June 2008.

10 Q And is this something that you
11 consulted when you wrote your report?

12 A Yes.

13 Q Is it kept in DEA system of records?

14 A Yes.

15 Q Is it altered and changed in any way?

16 A No.

17 Q The Government would move Exhibit 14
18 into the record, please.

19 JUDGE SOEFFING: Mr. Phelps, any
20 objection?

21 MR. PHELPS: No objection, Your Honor.

22 JUDGE SOEFFING: Government Exhibit
23 marked for identification Number 14 has been
24 offered in the absence of objection. It is
25 received in the record as Government Exhibit 14.

1 It's in, you may use it.

2 (Whereupon, Government Exhibit 14 was
3 admitted into evidence.)

4 BY MR. MANN:

5 Q I'd like to direct your attention to
6 page three of this particular document.
7 Handwritten page three.

8 A Yes.

9 Q And is this -- I'm referring to a --
10 a bulletin that says, LSD blotter acid mimics
11 actually containing, and then it says DOI and
12 DOC. Can you explain what's going on in this
13 particular excerpt?

14 A Yes, this is a, another encounter of
15 blotter paper that was suspected to be LSD. This
16 one is in Florida, but it was found to be DOI and
17 DOC.

18 Q Ask the -- Excuse me one moment.

19 (Pause.)

20 MR. MANN: Yeah, so --

21 BY MR. MANN:

22 Q If the witness could please see
23 Government Exhibit marked for identification 15.

24 A Okay.

25 Q And do you recognize that exhibit?

1 A A Microgram Bulletin from March 2009.

2 Q Okay. And does this one begin with a
3 bulletin that says blotter acid mimic actually
4 containing a mixture of DO -- would be DOB. No,
5 DOC. I'm sorry.

6 Q Yes. On page three of the exhibit,
7 the blotter acid mimic DOB and DOC. They were
8 suspected to be LSD as well.

9 And this one comes from Georgia.

10 Q From Warner Robins, Georgia?

11 A I believe that's what this says. Yes.

12 Q Just want to make sure I'm looking at
13 the same thing you are.

14 A Yes.

15 Q Okay, is this a document that you
16 consulted when putting together your report?

17 A Yes.

18 Q And is it in the DEA system of
19 records?

20 A Yes.

21 Q And was it altered and changed in any
22 way?

23 A No.

24 Q All right, the Government would move
25 Government Exhibit marked for identification 15

1 into the record, please.

2 JUDGE SOEFFING: Mr. Phelps, any
3 objection?

4 MR. PHELPS: No objection, Your Honor.

5 JUDGE SOEFFING: Government Exhibit
6 marked for identification Number 15 has been
7 offered, in the absence of objection. It is
8 received in the record as Government Exhibit 15.
9 It's in, you may use it.

10 (Whereupon, Government Exhibit Number
11 15 was admitted into evidence.)

12 BY MR. MANN:

13 Q Dr. Carbonaro, what portion of this
14 document did you consult when preparing your
15 report?

16 A The page -- The top of page three.

17 Q And what is -- What -- What is going
18 on in that portion?

19 A It was an exhibit that was suspected
20 to be LSD, but was instead found to be a mixture
21 of DOC and DOB. DOB is a Schedule I substance.

22 Q And what is the date at the bottom of
23 that document?

24 A 2009.

25 Q What month?

1 A March 2009.

2 Q All right. If the witness could
3 please be shown Government Exhibit marked for
4 identification 16?

5 Q And do you -- Can you identify that
6 document?

7 A Yes, this is a Microgram Bulletin that
8 was published in April 2009.

9 Q And is this something you consulted
10 when preparing your report?

11 A Yes.

12 Q Is it part of DEA system of records?

13 A Yes.

14 Q And is it altered and changed in any
15 way?

16 A No.

17 Q All right. The Government would move
18 Government Exhibit marked for identification 16
19 into the record, please.

20 JUDGE SOEFFING: Mr. Phelps, any
21 objection?

22 MR. PHELPS: No objection, Your Honor.

23 JUDGE SOEFFING: Government Exhibit
24 marked for identification Number 16 has been
25 offered in the absence of objection. It is

1 received in the record as Government Exhibit 16.

2 It's in, you may use it.

3 (Whereupon, Government Exhibit 16 was
4 admitted into evidence.)

5 BY MR. MANN:

6 Q Now, what part of this document did
7 you consult to write your report?

8 A Page four, the bottom, with the
9 blotter acid mimic, et cetera.

10 Q And what is happening -- What is being
11 described in this particular entry?

12 A This one is coming from Kansas, where
13 they suspected a piece of blotter paper to be
14 LSD, but instead was -- or sorry, LSD -- suspect
15 to be LSD, and instead, was analyzed and found
16 that it was DOB and DOC.

17 Q Okay. Now, I want to ask you about
18 all these Micrograms that we've discussed here,
19 Exhibits 11 through 16. In any of these
20 Micrograms, is there any indication that the
21 substances came from a legitimate research lab?

22 A Most of these were blotter paper,
23 which I don't believe would be studied in
24 legitimate research.

25 Q Okay.

1 That's all I have. Thank you.

2 JUDGE SOEFFING: Thank you, Mr. Mann.

3 Mr. Phelps, your redirect. Any?

4 MR. PHELPS: Yes, Your Honor. We
5 would -- We would like to do a recross on the
6 Government's --

7 JUDGE SOEFFING: I'm sorry. Recross.

8 MR. PHELPS: Yes, no problem. On
9 Government's Exhibit 10.

10 THE WITNESS: Okay.

11 RE CROSS EXAMINATION

12 BY MR. PHELPS:

13 Q Okay. So, this is the -- this is the
14 Reddit post that you were referring to earlier in
15 your testimony. Correct?

16 A Yes.

17 Q Okay. And can you -- Can you explain
18 for the Court the difference between a post and a
19 comment on Reddit?

20 A The post is generated -- includes the
21 title. And then if there's some comment, some
22 information from the title about -- that would
23 fall under the title. And then comments would be
24 in relation to the, that top section.

25 Q Okay. And so, when -- when somebody

1 -- when somebody creates a post that -- that top
2 heading appears on that page's subreddit.

3 Correct?

4 A Yes.

5 Q And this would have been in the
6 r/Psychnaut subreddit that you mentioned
7 earlier, right?

8 A Correct.

9 Q Okay. So -- So, earlier in your -- in
10 your testimony, you had -- you had described the
11 -- the description of the -- the two or three
12 hundred people that had taken it as a -- as a
13 post on Reddit. But looking at this document,
14 it's -- it's, in fact, actually a comment.
15 Right?

16 A Correct.

17 Q Okay, and is there any, to you -- Is
18 there any significance in -- in that, if it's --
19 if it's the original post or a comment about it?

20 A No, I would take any communication
21 about a substance that we're monitoring, whether
22 it's the actual post or a comment.

23 Q Okay. Do you know what the -- what
24 the terminology is for a -- for an individual who
25 is a -- a user of Reddit, what they refer to them

1 --themselves as, or as are referred to as?

2 A I'm not sure what you're referring to.

3 Q Okay. Are you familiar with the --
4 the term Redditor?

5 A Yes.

6 Q Okay, and what is a Redditor?

7 A Somebody that uses Reddit frequently,
8 has -- has a username, and generally posts a fair
9 amount, but you don't have to. I guess you could
10 be a lurker as well.

11 Q And what is a lurker?

12 A Just somebody that is online and
13 doesn't post and doesn't have -- doesn't make any
14 post, and just reading Reddit.

15 Q Okay. Do you need a -- Do -- Do you
16 need an account to be a poster?

17 A Yes.

18 Q Do you need a Reddit account to be a
19 lurker?

20 A No.

21 Q Okay.

22 Are you a Redditor?

23 A I believe I have an account. Yes.

24 Q You do have an account?

25 A Yes.

1 Q And what is your username?

2 A I don't recall what it is right now.

3 Q And do you post on Reddit?

4 A I believe I have made a post on
5 Reddit.

6 Q A single--

7 A At least one.

8 Q A single post? At least one?

9 A I don't know. I've had the account
10 for a while. I don't recall.

11 Q How long is a while?

12 A I mean, Reddit's been out for a while.
13 I mean, I think I made it like at least ten years
14 ago.

15 Q Okay, so prior to your -- your
16 employment by the DEA?

17 A Yes.

18 Q Okay. But -- and you use that -- You
19 use that Reddit account to do research, like
20 what's been presented here, correct?

21 A I didn't use the account. I just
22 looked at Reddit.

23 Q Okay.

24 A To look for this information.

25 Q Do you -- Do you recall if when you

1 were looking at this, you were logged in in
2 Reddit?

3 A I don't believe so.

4 Q Okay.

5 So, you mentioned that -- you
6 mentioned to, you said you've maybe -- you know
7 you've posted a little bit, but you couldn't put
8 a number amount on how much you posted on Reddit.

9 A I cannot.

10 Q Do you comment on other people's posts
11 on Reddit?

12 A No.

13 Q Okay. Would you consider yourself
14 more of a poster or a lurker?

15 A In this case, a lurker.

16 Q Okay.

17 A Yes.

18 Q What about in other cases?

19 A In general, more lurking than posting.

20 Q Okay.

21 A Commenting.

22 Q Gotcha. Have you ever posted in the
23 r/Psychnonaut subthread -- subreddit?

24 A I have not. But my papers have been
25 posted to r/Psychnonaut.

1 Q Cool.

2 A Yeah, that's -- I mean, I -- my papers
3 have been published, and people have told me
4 about it, like The Challenging Experience, I
5 believe, is posted to r/Psychonaut when it --
6 when it came out.

7 Q Okay. You seem to say that as sort of
8 a point of pride.

9 A No, I just thought it was interesting
10 when someone reads -- when someone else finds
11 your paper and then sends it to you because we
12 found it on Reddit, was it -- was interesting to
13 me.

14 Q Okay. Yeah.

15 Do you say a lot of your job duties
16 and responsibilities are involved in Reddit, or
17 is this --

18 A Oh, no, no. I would not say that at
19 all.

20 Q So this was, yeah, sort of a -- yeah
21 -- surprise occurrence.

22 A Yes.

23 Q Okay. And you said that was
24 specifically about post someone did -- Are you
25 aware -- Did somebody create a thread?

1 A Yes.

2 Q Using your -- your article?

3 A Yes.

4 Q Okay.

5 So, similar to what this post actually is,
6 right? This is a -- What is the title of this
7 post?

8 A Little known psychedelic DOI found to
9 have fascinating effect on cognitive flexibility
10 after just a single dose.

11 Q Okay. And then what do you -- what --
12 what's going on? Down below that, there's a
13 picture, and then there's the looks like an
14 address what?

15 As someone who's -- who's lurked on
16 Reddit, what do you recognize that as?

17 A I'm not sure what exactly you're
18 referring to.

19 Q Well, could you -- could you infer,
20 right? We can't actually click on this, but
21 where it says open, that would be a button to a
22 live link. Correct?

23 A Yes.

24 Q Okay. And could -- so, the person
25 seems to be -- and then it's it -- the link would

1 presumably open to the psypost.org. Correct?

2 Based on the information we see there.

3 A Yes.

4 Q Okay. So, this was a thread created
5 as a posting, presumably a link that includes
6 information about the title of the post, right?

7 A Yes.

8 Q Okay. Did you -- Did you click on
9 that link?

10 A I did, yes.

11 Q And -- And, what did you -- what did
12 you find?

13 A I believe it posted to an article that
14 was recently published about DOI.

15 Q Okay. Did you review that article?

16 A I believe so. I looked at -- So, I --
17 when I made this document was after I had already
18 looked at it. So, I -- I looked at the article.
19 I don't specifically remember which article it
20 was or who the author was, but I did.

21 Q No problem. So, this did link to an
22 article and you actually followed and read that
23 article?

24 A Yes.

25 Q And would you say that the title of

1 this, of this post, accurately reflected what you
2 saw in the article?

3 A I don't specifically recall, but I
4 believe so.

5 Q Okay. An effect on -- on cognitive
6 flexibility --

7 A I believe so.

8 Q Sure.

9 It's hard -- We're going off paper on
10 something on the --

11 A Yeah.

12 Q -- internet. We can't just click it
13 and see it ourselves, but I appreciate you, yeah,
14 trying to remember.

15 Any, anything noteworthy about that,
16 that you recall from the article at all?

17 A Not that I am specifically aware of.
18 I am aware of DOI and other hallucinogens, or
19 serotonin receptor agonists being implicated in
20 cognitive flexibility that I've read in the past.
21 I feel like it was similar in -- in a line with
22 previous papers I had read, but I don't -- again,
23 I don't recall specifically this one. I looked
24 at it like several weeks ago at this point.

25 Q No problem. Yeah.

1 And so -- so, that was -- other --
2 other than the link itself. Is there any text or
3 anything else posted by the original poster on
4 this page?

5 A I do not remember specifically.

6 Q Well look -- looking at it, right?
7 When you, when you see a post on Reddit, if --
8 what else could potentially be included up at the
9 top of a post like that, where, in this case, we
10 see what appears to be a link to an article?

11 A I'm not sure what you're referring to.

12 Q If -- Well, every -- every post that's
13 on -- on Reddit has something in that under the
14 -- the title of the post, right? There's the
15 body of the post itself.

16 A Yes.

17 Q Yes. Okay. And in this case, the
18 entire body of the original post is only the
19 article, right?

20 A I believe so.

21 Q Okay, we can -- we can take a look.
22 I guess, because the first -- Well, you can see,
23 yeah, there's -- there's an up and a down arrow
24 with the number 202 in between it.

25 A Yes.

1 Q Can you explain what that is?

2 A It's the number of votes. I believe
3 it's specific to the number of upvotes in this
4 case.

5 Q And who was -- who was the original
6 poster on this? Can you see that?

7 A Actirastyl. Maybe. I can't --

8 Q If you can just point to --

9 A -- quite read it.

10 Q -- where it is, I know it's a little
11 bit difficult to read --

12 A It's at the very top, under
13 r/Psychonaut. It has a name.

14 Q Okay. And so, so the 202 upvotes as
15 of the time you screenshotted and printed that
16 article that way, that would contribute to that
17 user, Actirastyl's karma, correct?

18 A For this post, yes.

19 Q Yes. Okay. I'm just trying to put
20 some context in, now that we have the picture
21 here of what we were referring to earlier.

22 And then there's a little bubble with
23 a 30 next to it. What does that mean?

24 A The number of comments.

25 Q Okay. And then -- And then there's a

1 share button. And then below that, it says, add
2 a comment, correct?

3 A Correct.

4 Q And so, if someone wanted to -- to
5 comment on this article, they would click that
6 button?

7 A Correct.

8 Q Okay.

9 And so, by -- based on all that, we
10 can see that the only the actual body of the
11 post, in this case, is only the -- the article.
12 There's no commentary about it from the original
13 poster. It goes from the article straight into
14 comments, right?

15 A Yes.

16 Q Okay, okay.

17 And so, this was -- So, can you point
18 to where in the comments on this article you were
19 referring to in your earlier testimony?

20 A Yes, at the top of page two.

21 Q Okay, and can you -- Can you tell me
22 the name -- the username of the individual who --
23 who posted that comment?

24 A Space_ape71.

25 Q Okay. And what did space_ape71 say?

1 A Isn't this one of the compounds the
2 DEA is trying to place in Schedule I, even
3 though, like maybe one hundred people a year
4 global use it illicitly?

5 Q Okay. And so, that -- that was not
6 the, that was not the -- the comment you were
7 referring to in your earlier testimony, right?

8 A I believe I made mention of it, and
9 then the -- the comment about more users was
10 followed up after that comment.

11 Q Okay.

12 A This -- this bigger section following
13 down from the deleted one into w00t4me. Down,
14 downward.

15 Q Okay. So, so, just to be clear, it
16 was, it was user w00t4me is who you were -- who
17 -- that's the, that's the specific comment that
18 you're referring to in your testimony?

19 A I believe I referenced both in my
20 testimony. So, yes.

21 Q Okay, okay. And what did, what did
22 Reddit user, w00t4me, say about this?

23 A Way more than a hundred. I've been at
24 events where two to three hundred did it.

25 Q That's the entirety of the -- the

1 comment?

2 A Yes.

3 Q And -- And what was -- and this was --
4 this was what -- what you testified that you --
5 you took it face value, that that was an accurate
6 post?

7 A Yes, the user was asked if he was at
8 a festival or parent teacher conference, and then
9 he responded back with more of a gathering of
10 sort. So, in his -- that comment and the, the
11 secondary follow up.

12 Q Okay. And that's the entire -- that's
13 the entire context of w00t4me's commentary about
14 this -- this gathering, right?

15 A Yeah, I believe so.

16 Q And -- and I do see he doesn't refer
17 to it as a party. I understand now this was a
18 gathering, right?

19 A Yes.

20 Q Okay. And what did -- what did user
21 breadhater42 comment about w00t4me's description
22 of this event?

23 A A parent teacher conference? Is that
24 the one you're talking about?

25 Q Yes, ma'am.

1 A Yes.

2 Q So, do you take that at face value as
3 well?

4 A I mean, that was not w00t4me's
5 response. It seemed like someone was questioning
6 if it was a parent teacher conference.

7 Q Okay. But there's not any more
8 context in what w00t4me is saying than breadlove
9 -- breadhater42, right?

10 A Except he made a comment that he was
11 at events where many people did it, and they gave
12 more context to that event.

13 Q He gave more context when he said more
14 of a gathering of a sort?

15 A Yes. I'm not reading it as
16 breadhater42 also was at a gathering where two to
17 three hundred people took it. I -- I'm reading
18 it as he is questioning if it was a parent
19 teacher conference.

20 Q And do you think that was a legitimate
21 question by breadhater42?

22 A It appears to be. It -- I mean, that
23 is what is here.

24 Q Are -- Are you aware on Reddit of
25 what's known as trolling?

1 A Yes.

2 Q Or a similar -- What is trolling?

3 A Would you like to define it for me?

4 Q Well, you said you're -- you've been
5 on Reddit for many years. What's -- Based on
6 your understanding and experience with Reddit,
7 how would you describe trolling?

8 A I don't think I have a definition of
9 trolling.

10 Q But you said you knew what it was.

11 A I understand like, I have an
12 understanding of what it is, but it's --

13 Q Okay. So, what's your understanding
14 of what it is?

15 A Just basically people making comments
16 that are not true that are like, sometimes in
17 jest or joke and like, essentially messing with
18 somebody else online.

19 Q Okay. Messing with somebody else
20 online. And trolling can have certain
21 connotations in terms of intent, right? Let me
22 be clear. Sometimes trolling can -- can be mean
23 or mean spirited, right?

24 A Yes.

25 Q Okay. And there's -- there's another

1 Reddit term that's -- that's similar to trolling
2 that you -- are you familiar with what's known as
3 shitposting?

4 A I'm not familiar with that term.

5 Q Okay. Would you describe
6 breadhater42's comment as more likely to be
7 genuine concern about a parent teacher conference
8 or trolling?

9 A It could be either. I'm not inferring
10 anything.

11 Q So -- So, just to be clear, it's --
12 it's your opinion that breadhater42 was genuinely
13 asking if two or three hundred people did DOI at
14 a parent teacher conference?

15 A It's possible. Again, I'm not -- I'm
16 just taking it as a point of fact that there is a
17 comment saying that this person was at an event
18 that two hundred, three hundred people used it.
19 I'm not so worried about breadhater42's comment
20 below it.

21 Q Okay. Well, I'm -- I'm just trying to
22 understand because breadhater42's comment exists
23 in the same context of w00t4me, right?

24 A Correct.

25 Q Okay, and -- and you're giving those

1 posts equal legitimacy in your in your
2 evaluation?

3 A I am taking -- Sure.

4 Q Okay. And then -- and those are all
5 comments specifically to another, to another
6 comment, right?

7 A Yes.

8 Q And you can tell that the way the
9 comments move in on the paper?

10 A Yes.

11 Q Okay. And so, then if you go down to
12 w00t4me -- Well, I guess first of all, do you see
13 any other comments from w00t4me on this post?

14 A I don't believe so.

15 Q Okay.

16 And then below the more of a gathering
17 of a sort, do you see another comment there?

18 A DOI was interesting, but no urge to
19 revisit?

20 Q Yes. And what's your -- what's your
21 evaluation of that comment? What's your
22 understanding of that comment?

23 A That DOI was used, and the experience
24 was unpleasant, that they did not want to
25 continue to use it.

1 Q Okay. Can you go to page three
2 please?

3 A Yes.

4 Q And can you tell us the comment at the
5 top of the page there?

6 A Tried DOI two times. Never again.

7 Q Okay. So -- So, those are two
8 instances of people saying they did try the drug
9 either one or two times, and then we're not
10 interested in trying it again?

11 A Yes.

12 Q Okay.

13 A But that could be related to harms.
14 Like, we don't know why they didn't want to use
15 again.

16 MR. PHELPS: Okay. If I could just
17 have one brief moment with my -- my co-counsel.

18 JUDGE SOEFFING: Yes.

19 BY MR. PHELPS:

20 Q Dr. Carbonaro, I'd like to refer you
21 to the Microgram Bulletins, and each of it --
22 each of these --

23 Well, how, um -- You -- You testified
24 earlier that the -- the micro bulletin --
25 Microgram Bulletin, excuse me, is no longer in

1 publication, correct?

2 A I don't believe that it is.

3 Q Okay. Do you know when it stopped
4 being published?

5 A No.

6 Q Do you know when it started being
7 published?

8 A No.

9 Q Do you know how often it was published
10 when it was in publication?

11 A I'm not clear. It may have been a
12 monthly thing, but I'm not sure.

13 Q Okay. Well, let's -- let's just take
14 a look at what's been marked as Government's
15 Exhibit 13.

16 A Okay.

17 Q And down at the bottom of that page,
18 it says Microgram Bulletin volume 41 number 3,
19 March 2008.

20 A Correct.

21 Q So, there had been at least, up to
22 that point, 41 volumes of the Microgram Bulletin,
23 correct?

24 A Correct.

25 Q And looking at how each of these are

1 identified, the number three is -- is consistent
2 with March being the third month of the year,
3 correct?

4 A Correct.

5 Q Okay. So, that would be consistent
6 with -- with what you said about this was a
7 monthly publication?

8 A I believe it to be.

9 Q Okay.

10 And so -- And what we have before us,
11 we actually have what's marked as Government's
12 Exhibit 16. It gets all the way up to volume 42.

13 A Okay.

14 Q And that would have been the -- the
15 following year. March 2008 and then April 2009
16 for volume 42 number 4, April 2009. Correct?

17 A Yes.

18 Q Okay. So, based on it -- based on the
19 numbering and -- and your understanding of these
20 -- of these publications, could you infer that
21 each year is a new volume, and then those numbers
22 go by month throughout that volume?

23 A It's potentially. But again, I don't
24 know what happened before, like, if it was
25 monthly from the beginning or not.

1 Q Okay. But for the sake of
2 understanding these -- these Microgram Bulletins,
3 every -- everyone here seems that -- you're --
4 you don't have any knowledge of it not being
5 monthly, correct?

6 A I do not.

7 Q Okay. And you said you're not sure
8 when it was -- when it was canceled?

9 A Correct.

10 Q So, it could have been more than 42
11 volumes, but at least 42 based on what we have
12 today?

13 A Correct.

14 Q Okay.

15 So, if we have 42 volumes and 12
16 numbers within each of those volumes, how many
17 total issues of the Microgram Bulletin would that
18 be?

19 A A large number. Can't do the math in
20 my head.

21 Q Can we -- Can we take a second just so
22 we can get an actual number to put on that?

23 Okay. Forty-two times 12.

24 MR. RUSH: Five hundred and four.

25 MR. PHELPS: Five hundred and four.

1 BY MR. PHELPS:

2 Q Does that sound accurate?

3 A Potentially.

4 Q Okay.

5 A I mean that math, yes.

6 Q Okay. You -- You would agree --

7 A I agree with the math, yes.

8 Q Okay.

9 A I don't know that there were 512 or
10 whatever you said.

11 Q Sure. But -- But based on it -- based
12 on what we have before us, and what's been
13 provided, that would be a reasonable inference.
14 We don't know for sure the exact number, but
15 based on what we have before us, that could be
16 inferred if, if that was consistent.

17 A Yes.

18 Q It could be a little more, it could be
19 a little less?

20 A Correct.

21 Q Okay. And -- And you said that
22 yesterday, when you were testifying about the
23 Microgram Bulletins, you testified that before
24 these were published, they went through an
25 internal peer review process?

1 A I said I believe they did.

2 Q Okay. Do you have any -- any
3 familiarity with that?

4 A Again, these were done before me. I
5 am familiar to going through the -- the -- that
6 process for other things, but not for these
7 Microgram Bulletins.

8 Q Okay.

9 A And I don't know if it was the same
10 then.

11 Q Okay. Other -- Other comparable
12 internal publications. I guess this wouldn't
13 necessarily be an internal publication, right?
14 Because these are publicly available.

15 A They are -- I believe, publicly
16 available now, yes.

17 Q Okay. Well, in the, in the documents
18 where you have -- Actually, so, can -- when you
19 want to search for something in the Microgram
20 Bulletin, how do you -- how do you do that?

21 A Oh, I didn't search for these.

22 Q Okay.

23 Do you --

24 A I've not searched for anything in
25 Microgram -- in the Microgram Bulletin for

1 anything. These were given to me as part of the
2 record for DOI DOC, when I took over the project.

3 Q Okay. And did you -- when that --
4 when that information was provided to you, did --
5 was there any indication if this was a complete
6 record of references of DOI in that -- in the
7 Microgram Bulletin?

8 A No, they were just given to me.

9 Q Okay. Did you inquire from the person
10 that gave them to you if these were all of the
11 instances of DOI or DOC within the Microgram
12 Bulletin?

13 A I did not.

14 Q Okay. But as of -- as of right now,
15 we've listed five instances of either DOI or DOC
16 being reported in the Microgram Bulletin.

17 A I believe six.

18 Q And -- And that's out of potentially
19 over 500 issues of the Microgram Bulletin?

20 A Potentially, yes.

21 Q The -- Taking a look at Government's
22 Exhibit 13, marked as -- as Exhibit 4, this is --
23 this is an instance --

24 JUDGE SOEFFING: Mr. Phelps, I didn't
25 follow that.

1 MR. PHELPS: Sorry. It's -- It's
2 Government Exhibit 13 and page four.

3 JUDGE SOEFFING: Thank you.

4 BY MR. PHELPS:

5 Q This is a -- the -- this is
6 Madisonville, Kentucky, correct, Doctor? Or the
7 Madison -- Yeah, that's what's in parentheses in
8 the headline. It says Paducah, Kentucky.

9 A Yes.

10 Q Okay. So, this is in Kentucky, and it
11 says the Kentucky State Police Western Laboratory
12 Branch recently received a single white square
13 blotter paper wrapped in foil suspected LSD.

14 Do you know anything about the
15 Kentucky State Police, Western Laboratory Branch?

16 A I do not.

17 Q Do you have -- So, you don't know
18 anything about their -- their protocols or
19 reliability of their testing.

20 A I do not, specifically -- and not
21 dating back to 2008.

22 Q Okay. Does the -- does the DEA, as an
23 agency, have standards for testing protocols that
24 would be accepted or considered valid for DEA
25 when it's reported?

1 A I believe so.

2 Q Okay. And are you aware if -- if this
3 West -- Kentucky State Police, Western Laboratory
4 Branch, or any of the others -- any of the other
5 labs that were taken, followed or met those
6 standards of DEA for legitimate testing.

7 A I'm not a chemist, so I can't comment
8 on that.

9 MR. PHELPS: No further questions,
10 Your Honor. Thank you.

11 JUDGE SOEFFING: All right.

12 Dr. Carbonaro, thank you for your
13 testimony. You are excused. I direct you not to
14 discuss your testimony with anyone else, other
15 than your attorney, until the conclusion of the
16 hearing.

17 THE WITNESS: Thank you.

18 JUDGE SOEFFING: Mr. Mann, anything
19 else?

20 MR. MANN: The Government rests its
21 case in chief.

22 JUDGE SOEFFING: Okay, very good.

23 All right, before we turn to
24 Petitioner's case, I will give my -- give you my
25 ruling on sequestration of witnesses for the

1 Petitioners.

2 Regarding Dr. Ramos, the tribunal
3 finds that he should not be sequestered. He's a
4 named party to the proceedings who personally
5 requested a hearing in the matter. I find he has
6 the right to be present, to confer freely with
7 this counsel, that he and SSDP have chosen to
8 jointly present their cases should not result in
9 sequestration and an ability to remain a counsel
10 table with the proceedings.

11 Regarding Mr. Anderson, Mr. Hennessy,
12 and Dr. Jaster, the tribunal again finds that
13 they should not be sequestered. All three of
14 those individuals are signatories to their quest
15 for hearing filed by SSDP. Each of those
16 individuals could have individually filed a
17 hearing request, as was the case with Dr. Ramos,
18 but decided to jointly file on behalf of SSDP. I
19 find that they have the right to be present, to
20 confer freely with their counsel. Additionally,
21 the decision to jointly file should not result in
22 their ability to present -- to be present for the
23 entirety of the hearing.

24 Furthermore, the Government has been
25 on notice that this tribunal considered Mr.

1 Anderson, Mr. Hennessy, and Dr. Jaster as party
2 representatives since at least July 31st, 2024
3 when the pre-hearing ruling was issued. These
4 three individuals, along with Dr. Ramos, were
5 specifically identified as party representatives.

6 Finally, all -- they've also all been
7 identified as proposed expert witnesses.

8 Pursuant to DEA precedent, I find there's little,
9 if any reason for sequestering those witnesses.

10 Now, that leaves Dr. Elder, who's not
11 a party representative, but is a proposed expert
12 witness. Initially, at the second pre-hearing
13 conference, Mr. Phelps, you agreed to sequester
14 him. You've now changed your position on that, I
15 believe, is that right?

16 MR. PHELPS: That -- That's correct,
17 Your Honor. All in -- in full disclosure to the
18 court, I don't know that he's going to be in the
19 -- the courtroom outside of his own testimony
20 anyway.

21 JUDGE SOEFFING: Okay. All right.

22 I -- You know, he is proposed as an
23 expert, but the Government permitted him to be
24 here without objection for the Government's case,
25 which I think is probably what is most relevant

1 to the testimony that he needed to view and be
2 present for. So, I will sequester him. To the
3 extent that he's here and not testifying, I'll
4 order that he be sequestered.

5 MR. PHELPS: Understood, Your Honor.
6 Thank you.

7 JUDGE SOEFFING: Okay. All right,
8 let's go off the record.

9 (Whereupon, the above entitled matter
10 went off the record at 12:41 p.m. and resumed at
11 12:41 p.m.)

12
13 JUDGE SOEFFING: Back on the record.
14 Mr. Mann?

15 MR. MANN: Aren't there other
16 witnesses?

17 JUDGE SOEFFING: I don't believe
18 there's any other witnesses for the Petitioners
19 who are testifying in present, right? They're
20 all VTC, so the sequestering is not an issue for
21 them.

22 There was the Dr. Palamar, I think, I
23 dealt with earlier. You asked for him to be able
24 to attend via VTC. Mr. Phelps and I stated that
25 he would not be able to participate and view

1 testimony from the VTC -- that they -- anybody
2 who wants to do that has to be here in person.

3 Was there another witness that I
4 missed, Mr. Mann?

5 MR. MANN: Wasn't there -- Who else
6 was there. Younkin?

7 I guess the -- I guess the Government
8 wanted some clarity about what does sequestration
9 mean. Does it mean that they are not allowed to
10 watch the proceeding via VTC?

11 JUDGE SOEFFING: Right. There's --

12 MR. MANN: And does it also mean
13 they're not allowed to consult any reports of the
14 proceeding as they're being generated and
15 published?

16 JUDGE SOEFFING: You mean in real
17 time?

18 MR. MANN: Yes.

19 JUDGE SOEFFING: Yes. They should not
20 be doing that.

21 MR. MANN: Okay.

22 JUDGE SOEFFING: That kind of takes
23 away the effect of being sequestered, if they can
24 find out what's going on even though they're not
25 present.

1 MR. MANN: That would be the order
2 that we would seek with respect, all --

3 JUDGE SOEFFING: With respect to --
4 all right.

5 So, Mr. Phelps, can you direct your
6 witnesses who are testifying via VTC, as well as
7 Dr. Elder, that they should not be monitoring any
8 reporting that's going on regarding these
9 proceedings in real time.

10 MR. PHELPS: Sir, you're just -- yeah,
11 just to understand and make sure you're -- you're
12 talking about, like, public -- public reports and
13 things that are out there about what's -- what's
14 coming out? Or what --

15 JUDGE SOEFFING: Well, no, just
16 anything that has to do with what's going on with
17 these proceedings as they're occurring, so to the
18 extent they're circumventing the sequestration
19 order or -- or not being allowed to actually view
20 the proceedings, that they're not getting that
21 information from some other source, even though
22 they're not here. I think that's what Mr. Mann
23 is referring to.

24 MR. MANN: Yeah. I'm just -- I mean,
25 we're interested in them not having any access to

1 any of the testimony that goes on in this
2 proceeding starting now.

3 JUDGE SOEFFING: That -- Would that
4 include the opening statement, Mr. Mann?

5 MR. MANN: I don't think the opening.
6 No.

7 JUDGE SOEFFING: So, anything after
8 the opening statement, any testimony that that
9 the Petitioners' witnesses give, they should not
10 be exposed to --

11 MR. PHELPS: Oh, okay, so that's -- so
12 that's going forward from --

13 JUDGE SOEFFING: After your opening
14 statement --

15 MR. PHELPS: -- from here.

16 JUDGE SOEFFING: -- for all the, for
17 the Petitioners' witnesses --

18 MR. PHELPS: Okay.

19 JUDGE SOEFFING: -- who appear, right?

20 MR. PHELPS: So -- So, just -- just to
21 be clear, for example, and Dr. Palamar's case, we
22 were, he's -- he's proposed as an expert in
23 epidemiology, in that -- that field. If he's
24 going to be I, I just want to be clear.

25 Part of his -- his expert analysis is

1 going to be, or his expert opinion is going to be
2 regarding the -- the methods -- the
3 epidemiological methods and studies presented by
4 Dr. Carbonaro. So, are we -- are we allowed to
5 discuss with him, so that he can offer an expert
6 opinion based on -- on that testimony?

7 JUDGE SOEFFING: No.

8 MR. PHELPS: Okay.

9 JUDGE SOEFFING: I mean that, he
10 should have been -- should have reviewed any of
11 that prior to the hearing. I guess they said he
12 was going to testify about it, but he can't be
13 testifying about another expert's testimony, I
14 guess.

15 MR. PHELPS: Okay, well, will he be a
16 -- So, any -- anything that was filed previous to
17 this so Government's pre-hearing statements,
18 supplemental statements, he could -- he could, if
19 -- if he's recognized, he could potentially opine
20 on what's in there?

21 JUDGE SOEFFING: Yes. And those are
22 ALJ exhibits, so, you're welcome to have him look
23 at those as part of his testimony, if you want
24 to.

25 MR. PHELPS: Okay. Okay, great. I

1 just want to make sure we're very clear. We
2 will, yeah, we will convey that to -- to all of
3 our witnesses. And will -- will not be a
4 problem. We will most certainly abide by the --
5 by the court sequestration order.

6 JUDGE SOEFFING: Okay, thank you.

7 MR. MANN: And the rationale for
8 Jaster, Hennessy, and Anderson is because they
9 signed the hearing request?

10 JUDGE SOEFFING: They are party
11 representatives who, yes, who were part of the
12 original hearing request.

13 MR. MANN: Okay. I understand that.
14 Okay, thank you.

15 JUDGE SOEFFING: Thank you, Mr. Mann,
16 Thank you, Mr. Phelps, let's go off
17 the record.

18 (Whereupon, the above entitled matter
19 went off the record at 12:45 p.m. and resumed at
20 12:46 p.m.)

21 JUDGE SOEFFING: All right, back on
22 the record.

23 We are -- Government has concluded its
24 case. We are recessed until -- for one hour for
25 lunch, until 1:45, at which time the Petitioners

1 will put on their case.

2 (Whereupon, the above entitled matter
3 went off the record at 12:46 p.m. and resumed at
4 1:56 p.m.)

5 JUDGE SOEFFING: Okay. We are back on
6 the record. Welcome back, everyone. Mr. Phelps,
7 would you like to make an opening statement?

8 MR. PHELPS: Your Honor, Mr. Rush is
9 actually going to be handling the openings.

10 JUDGE SOEFFING: Okay. Very good.
11 Mr. Rush.

12 MR. RUSH: Thank you, Your Honor. May
13 it please the Court, the United States is a
14 nation of laws. Those laws direct the Government
15 to provide for our well-being.

16 Congress writes laws. The Executive
17 Branch carries them out. And the Judiciary
18 resolves arguments about what these laws mean,
19 and evaluates whether they're being enforced
20 properly.

21 In reality, these powers overlap at
22 times between the branches of government. And
23 overall the system relies on a certain degree of
24 trust. And we put great trust in the agencies to
25 protect us, to ensure our water's safe to drink,

1 our air is clean.

2 The Controlled Substances Act was
3 enacted to protect the citizens of this country.
4 And we entrust the DEA to safeguard the citizens
5 of this nation and implement the Controlled
6 Substances Act.

7 We do not approach this lightly, the
8 notion of drug scheduling, and the issues of
9 addition and drug use in this country. We
10 realize the impact that it's had on this country,
11 and just how difficult of a task that the Drug
12 Enforcement Agency has, and how challenging it is
13 to accomplish that task.

14 We wish them success in protecting the
15 citizens of this country. But we do not feel,
16 and we will provide evidence that the actions as
17 they're taken regarding DOI and DOC will meet the
18 mission of the CSA.

19 Under the CSA the Agency has authority
20 to promulgate rules, regulations, and procedures,
21 and the Agency deems necessary and appropriate
22 for the efficient execution of functions under
23 the Controlled Substances Act.

24 But in creating these rules we expect
25 the DEA to honor Congress' intent, and to apply

1 the interpretation of the statute that is
2 reasonable.

3 We also expect that the Agency will do
4 their best at implementing and executing their
5 mandate under the CSA to protect all of us, our
6 families, loved ones, our children.

7 The CSA was designed not only to
8 regulate the use, distribution, and manufacturing
9 of certain drugs, but also to ensure that
10 valuable research could continue, particularly in
11 areas like medical, scientific, and
12 pharmaceutical development. Its goal was to
13 balance public safety with the potential for
14 scientific discovery.

15 The Act's classification system, which
16 places stringent restrictions on Schedule I drugs
17 has made accessing some substances more
18 challenging, which has raised concerns among
19 researchers who believe bureaucratic hurdles
20 inadvertently inhibit research.

21 We will provide evidence of just those
22 hurdles, and how impactful they are through our
23 witnesses' testimony.

24 Our witnesses' testimony presented
25 will demonstrate that the DEA has not met the

1 requirements for either DOI nor DOC to be added
2 to Schedule I classification.

3 Through the expert testimony presented
4 today we'll demonstrate that, from our variety of
5 them, that these compounds hold tremendous
6 promise for therapeutic potential, that they pose
7 a minimal risk of abuse, and are indispensable in
8 ongoing federally funded scientific research.

9 Dr. Joseph Palamar, a leading drug
10 epidemiologist, will testify that these
11 substances lack the abuse patterns seen in
12 Schedule I substances.

13 He will demonstrate that DOI and DOC
14 are virtually absent in national drug use
15 statistics, underscoring their low abuse
16 potential.

17 Furthermore, Dr. David Nutt will
18 contextualize these findings with an
19 international framework, noting that DOI has not
20 been listed as a Schedule I substance in other
21 countries, or by the United Nations Commission on
22 Narcotic Drugs.

23 Our testimony will show the immense
24 therapeutic potential that DOI and DOC hold. Dr.
25 Lindsay Cameron from Stanford University will

1 testify on DOI's role in promoting
2 neuroplasticity, which is vital in treating
3 neuro-psychiatric conditions like depression and
4 PTSD.

5 Dr. Ramos and Dr. Harrison Elder will
6 discuss DOI's analgesic properties, highlighting
7 its non-addictive nature, and its importance in
8 research and treatments for chronic and
9 neuropathic pain.

10 Dr. Pasha Davoudian will testify as an
11 expert on the use of psychedelic drugs for the
12 treatment of some of the most challenging mental
13 health issues facing this country.

14 Dr. Santiago Jaramillo will discuss
15 cutting edge research into audio -- auditory
16 neuroscience requiring the use specifically of
17 DOI to accomplish this research.

18 Dr. Lockery will testify as an expert
19 in a study of neuronal and genetic underpinnings
20 of behavior requiring the use of DOI to further
21 this knowledge.

22 Dr. Jason Younkin will testify on
23 complex issues of crosstalk regarding dopamine
24 and serotonin receptors.

25 Scheduling DOI and DOC under Schedule

1 I would severely limit researchers' access to
2 these vital compounds, hindering critical
3 research funded by NIH and other federal
4 agencies.

5 Tanner Anderson and Dr. Mario de la
6 Fuente Revenga will testify that these compounds
7 are essential for studying serotonin receptors, a
8 key area in neuro-psychiatric disorder research.

9 Dr. Alaina M. Jaster, who has
10 extensively researched psychedelics in substance
11 use and neuro-psychiatric models will provide
12 testimony about DOI's unique role in
13 understanding addiction circuits and therapeutic
14 potential.

15 Her research will demonstrate DOI's
16 negligible abuse potential, as shown in animal
17 models where it does not induce
18 self-administration behaviors typical of
19 addictive substances. She will also analyze the
20 methodology utilized in drug discrimination
21 studies, and limitations there.

22 Dr. Jaster will further explain how
23 DOI's induction of rapid tachyphylaxis and cross
24 tolerance with other psychedelics discourage
25 repetitive use, further reducing its potential

1 for abuse.

2 She will also highlight the
3 irreplaceable nature of DOI in her studies on
4 addiction and pain, and that, showing that
5 Schedule I restrictions would disrupt her ongoing
6 research, funded by institutions such as NIDA.

7 Joseph Hennessey will address DOI's
8 high selectivity for the 5-HT2A receptor,
9 underscoring its value for pharmacological
10 research, and limited abuse potential in
11 pre-clinical models.

12 Dr. David Nichols will discuss DOI's
13 pharmacological safety profile, showing it
14 enables in depth study of serotonin receptors
15 without the complex receptor binding seen with
16 other psychedelics.

17 Conclusion, the CSA was designed not
18 to be a blunt instrument regarding adding
19 substances to Schedules. There's a multitude of
20 analysis that's required, and a multitude of
21 tests that are required be performed, such as the
22 Eight Factor Test, and others to schedule a
23 substance.

24 We will provide testimony from top
25 researchers and scholars, presenting objective,

1 verifiable evidence.

2 In conclusion our evidence will show
3 proposed Schedule I classification for DOI and
4 DOC is unsupported by substantial evidence, and
5 inconsistent with Congress' intent to preserve
6 scientific access.

7 We'll also demonstrate that there is
8 a threat to public safety and public health if we
9 remove these substances and inhibit research. We
10 are attempting to solve some of the most
11 pressing, difficult challenges facing the nation.
12 And DOI very well may be critical to solving some
13 of these.

14 The testimonies we present will
15 illustrate that DOI and DOC do not meet Schedule
16 I criteria for high abuse potential, and are
17 crucial to ongoing research. It holds immense
18 promise for addressing -- for advancing mental
19 health treatments.

20 At the conclusion of presentation of
21 our evidence we'll ask that the tribunal
22 recommend DOI and DOC not be placed on Schedule I
23 of the CSA. Thank you, Your Honor.

24 JUDGE SOEFFING: Thank you, Mr. Rush.
25 Who will be calling the first witness? Mr.

1 Phelps.

2 MR. PHELPS: Yes, Your Honor. SSDP
3 and Dr. Ramos would call Dr. Alaina Jaster.

4 JUDGE SOEFFING: All right. Dr.
5 Jaster, would you please raise your right hand?
6 WHEREUPON,

7 ALAINA JASTER
8 was called for examination by Counsel for the
9 Petitioner, and having first been duly sworn,
10 assumed the witness stand, was examined and
11 testified as follows.

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

15 THE WITNESS: First name Alaina,
16 A-L-A-I-N-A. Last name Jaster, J-A-S-T-E-R.

17 JUDGE SOEFFING: Thank you. Counsel,
18 you may inquire.

19 DIRECT EXAMINATION

20 MR. PHELPS: Thank you, Your Honor.
21 Good afternoon, Dr. Jaster. I'd like to start by
22 having you take a look at what's been marked for
23 identification purposes as SSDP Ramos Exhibit
24 number 77.

25 Just wanted to make sure the Court had

1 what they needed in front of them before we get
2 started.

3 JUDGE SOEFFING: Yes.

4 MR. PHELPS: Thank you. So, Dr.
5 Jaster, do you recognize what's been handed to
6 you?

7 THE WITNESS: Yes.

8 BY MR. PHELPS:

9 Q And what is that?

10 A It is a copy of my curriculum vitae.

11 Q And is that an accurate representation
12 of the curriculum vitae that you provided through
13 the discovery process in this case?

14 A Yes.

15 MR. PHELPS: Your Honor, we would move
16 to admit Exhibit 77.

17 JUDGE SOEFFING: Any objection?

18 MR. MANN: No objection.

19 JUDGE SOEFFING: Okay. Petitioner
20 Exhibit marked for identification number 77 has
21 been offered. In the absence of objection it is
22 received in the record as Petitioner Exhibit 77.
23 It's in. You may use it.

24 (Whereupon, the above-referred to
25 document was received into evidence as

1 Petitioner Exhibit No. 77.)

2 MR. PHELPS: Thank you. Dr. Jaster?

3 THE WITNESS: Jaster.

4 BY MR. PHELPS:

5 Q Jaster. What degrees do you hold?

6 A I have a Bachelor's of Science in
7 Neuroscience and a doctoral degree in
8 Pharmacology and Toxicology.

9 Q And where did you pursue your
10 undergraduate education?

11 A Central Michigan University in Mt.
12 Pleasant, Michigan.

13 Q What did you study as an
14 undergraduate?

15 A As an undergraduate I studied
16 neuroscience and specifically had a focus on
17 substance use, intervention, prevention, and
18 treatment.

19 Q And where did you pursue your PhD?

20 A Virginia Commonwealth University in
21 Richmond, Virginia.

22 Q And what do you hold your PhD in?

23 A Pharmacology and toxicology.

24 Q Can you please talk a little bit about
25 your PhD course work curriculum for obtaining

1 those degrees, that degree?

2 A Yes. So during my PhD we are required
3 to take a variety of core courses, which included
4 basic concepts of pharmacology, principles of
5 pharmacology, toxicology, and as well as
6 behavioral pharmacology, and some courses related
7 to neuro-pharmacology, as well as different
8 statistical -- a course on different various
9 statistical methods.

10 Q In addition to that curriculum you
11 described, what else did your PhD program consist
12 of?

13 A It also -- so it consisted of those
14 core courses in the first two years. But it also
15 in those first two years consisted of three
16 laboratory rotations in a variety of labs, as
17 well as directed research, a seminar program and
18 the last two and a half, three years included
19 directed research project, of which was my PhD
20 dissertation, which was an independent project
21 designed and done by myself.

22 Q And can you talk a little bit more
23 about your dissertation research?

24 A Yes. So the main focus of my
25 dissertation work was to assess DOI and

1 psilocybin in rodent models of substance use
2 disorders, specifically opioid use.

3 Q What were those, what were the results
4 of your dissertation studies?

5 A Yes. The results of my studies
6 included kind of two parts. So the first part
7 was establishing that both DOI and psilocybin
8 were able to effectively reduce oxycodone place
9 preference in a model called conditioned place
10 preference.

11 And it was also determined that these
12 findings were attributed to involvement of the
13 serotonin 2A receptor.

14 Q What can you infer from that data?

15 A One of the conclusions that we can
16 infer is that both DOI and psilocybin could be
17 potentially useful for developing novel
18 therapeutics for opioid use disorder.

19 Q What scale of biology does your
20 neuroscience research occur over, has it in the
21 course of your research?

22 A Yes. So I have done a variety of
23 research. And I actually started working in
24 cells and tissues on a research in ketamine. And
25 then I've worked up using live animal systems, as

1 I just mentioned, in my PhD work. And I've also
2 now studied clinical trials and work in humans.
3 And I've also studied post mortem human genetics.

4 Q How many peer reviewed journal
5 articles have you published?

6 A I believe the number is between like
7 12 and 13.

8 Q And where have you published that
9 research?

10 A In a variety of publications or
11 journals, including Molecular Psychiatry, Drug
12 and Alcohol Dependence, ACS Chemical
13 Neuroscience, and I believe Nature, News and
14 Views, among others.

15 Q And Drug and Alcohol Dependence,
16 that's the peer reviewed journal that the
17 Government's witness, Dr. Carbonaro has also
18 published in as well, correct?

19 A Yes.

20 Q Have you published any peer review
21 journal articles based on your DOI research
22 specifically?

23 A I have published, I believe -- do you
24 want an exact number? Do you want me to go and
25 count? Or --

1 Q Sure. If you can take a quick scan
2 through there. We have the papers in front of
3 us.

4 A Okay. One second. Seven publications
5 on my CV have included studies on DOI. And I
6 have two that are currently in preparation.

7 Q Can you explain what in preparation
8 means in this context?

9 A Yes. So in preparation just means
10 that the experiments have been done and the
11 manuscript is being written, and is going to be
12 submitted for peer review in a scientific
13 journal. So we're aiming to submit by the end of
14 the year.

15 Q In addition to the curriculum of your
16 PhD program, and your dissertation research, do
17 you have any other relevant educational
18 experience?

19 A Yes. So I would say two things stand
20 out in my head. So the first refers to
21 experience during my undergrad, which I was
22 trained as a substance use counselor in course
23 work.

24 I didn't complete, like, the hours.
25 But I do have that course work training, as well

1 as during my PhD I worked on a variety of
2 projects and received training in a variety of
3 models, substance use not related to my PhD. So
4 also self-administration and drug discrimination.

5 And I also have worked on various
6 projects looking at minor alterations in
7 chemistry and how that affects behavioral
8 pharmacology outcomes with psychedelic compounds.

9 Q And what is your current title or
10 position?

11 A My current position is a post-doctoral
12 research fellow at Wayne State University.

13 Q And do you have any other relevant
14 work experience previous to that position?

15 A Yes. In between my bachelors and my
16 PhD I worked as a research assistant, also at
17 Wayne State University, in which I had a kind of
18 a two-fold job.

19 One was collecting post mortem tissue
20 for analysis. And the other was reviewing
21 toxicological data in the entirety of Wayne
22 County, Michigan.

23 Q What is the current focus of your
24 research?

25 A The current focus of my research is

1 looking at pharmacology related to
2 endocannabinoids and adolescents, and also
3 identifying patterns of use in risk perceptions
4 of psychedelics among adolescents.

5 Q Can you sort of break down what that
6 means in more of a layman's term of the research
7 you're currently working on?

8 A Yes. So the two projects, one is
9 focused on neuroscience, brain health. And then
10 the second one is focused on substance use among
11 youth in Detroit.

12 Q And have you previously served as an
13 expert witness for any other relevant testimony?

14 A Yes. I have served as an expert
15 witness for a Virginia Subcommittee House
16 hearing.

17 Q And what was the nature of your
18 testimony at that hearing?

19 A Yes. I was invited to talk as a
20 witness and address the Subcommittee on the
21 potential therapeutic effects of psychedelics.
22 Specifically in this case for this bill, it was
23 psilocybin.

24 MR. PHELPS: Your Honor, at this time
25 we would move to have Dr. Jaster admitted as, or

1 established as an expert in neuroscience and
2 substance use disorders.

3 JUDGE SOEFFING: Mr. Mann, any
4 objection?

5 MR. MANN: Voir dire.

6 JUDGE SOEFFING: Very well.

7 VOIR DIRE

8 BY MR. MANN:

9 Q Good afternoon, Dr. Jaster.

10 A Good afternoon.

11 Q Is your dissertation being offered as
12 an exhibit here?

13 A A figure from my dissertation is.
14 It's currently, like, not -- it's under embargo
15 by the university. Like as a whole --

16 Q So you're not offering your
17 dissertation?

18 A We have a figure from the
19 dissertation.

20 Q A figure?

21 A Yes.

22 Q And how many pages is that?

23 A One.

24 Q Would that be Government, I mean
25 Petitioner's Exhibit 17?

1 A Yes. I believe so. I don't have it
2 in front of me.

3 Q May the witness be shown Petitioner's
4 Exhibit 17? Do you have it in front of you? So
5 tell me again, what is your dissertation about?

6 A It is about DOI and psilocybin
7 reducing oxycodone place preference.

8 Q All right. And you're not, you didn't
9 bring that with you here today, did you?

10 A The full dissertation, no.

11 Q Okay. Instead there's just a one page
12 with, looks like eight graphs on it, correct?

13 A Yes.

14 Q Now your current work is in
15 endocannabinoids?

16 A Yes, and psychedelics.

17 Q Does it involve DOI?

18 A Not at this point in time. But later
19 iterations of it are planning to include DOI in
20 the questions.

21 Q And have you performed an analysis of
22 the Eight Part Factor Test for DOI?

23 A I have assisted in compiling data for
24 a publication through ASPET.

25 Q But you've not created one yourself?

1 A No.

2 Q Okay. How about DOC?

3 A No.

4 Q And I'm sorry, you're being offered as
5 an expert in what?

6 JUDGE SOEFFING: Expert in
7 neuroscience and substance use disorders.

8 MR. MANN: Just one second. Okay. We
9 have no objection to that designation.

10 JUDGE SOEFFING: All right. Thank
11 you, Mr. Mann. The Petitioners have offered Dr.
12 Jaster as an expert in neuroscience and substance
13 use disorders.

14 In the absence of any objection by the
15 Government, the tribunal accepts the witness as
16 an expert in neuroscience and substance use
17 disorders.

18 MR. PHELPS: May I continue, Your
19 Honor?

20 JUDGE SOEFFING: Yes, Mr. Phelps.

21 MR. PHELPS: Thank you. Dr. Jaster,
22 as part of your neuroscience and substance abuse
23 research, were you trained in drug
24 discrimination?

25 THE WITNESS: Yes. Although I did not

1 end up using it for my dissertation project. But
2 I was trained in how to run the assay.

3 BY MR. PHELPS:

4 Q And why didn't you use that in your
5 dissertation research?

6 A I did not use it due to some of the
7 issues of it being able to address the questions
8 that I was asking. So within my committee
9 members, which is the people that help tailor
10 your project and give advice, they recommended
11 using conditioned place preference instead.

12 Q Okay. I'd like to now turn your
13 attention to what's been marked for
14 identification purposes as SSDP Ramos Exhibit 37.

15 A Thank you.

16 Q Dr. Jaster, do you recognize this
17 document?

18 A Yes.

19 Q And can you tell the Court what it is?

20 A It is an article published in Drug and
21 Alcohol Dependence titled The Rise and Fall of
22 Drug Discrimination Research.

23 Q And are you familiar with the contents
24 of this document?

25 A Yes.

1 Q And from what you see in front of you,
2 is this an accurate representation of the article
3 as it appeared in Drug and Alcohol Dependence?

4 A Yes.

5 MR. PHELPS: Your Honor, at this time
6 we would move to admit Exhibit 37.

7 JUDGE SOEFFING: Mr. Mann, any
8 objection?

9 MR. MANN: Your Honor, this is not
10 written by the witness. So we would object to
11 its admission.

12 MR. PHELPS: There's no requirement
13 that they can only refer to documents that have
14 been written by this witness. It's whether
15 they're familiar with the contents of the
16 document, to be able to discuss it.

17 MR. MANN: I also believe that this
18 document is not referred to in the pre-hearing
19 statement.

20 MR. PHELPS: And in response to that,
21 if we take a look at the Court's order on the
22 motion in limine, this article was specifically
23 allowed to be included as part of our exhibits.
24 So that's in the Court's order.

25 JUDGE SOEFFING: Well what is the

1 subject of the Court Order on the Government's
2 motion in limine?

3 MR. PHELPS: The Government tried to
4 get this excluded. And Your Honor specifically
5 said that this was allowed to be included.

6 JUDGE SOEFFING: So I didn't exclude
7 it at the time. I did allow the Government to
8 raise a new objection at the hearing. I know one
9 of the problems was that, alleged by the
10 Government was that it wasn't mentioned who would
11 testify to it.

12 I think you clarified it was going to
13 be Dr. Jaster. And she is testifying to it
14 today. I don't find that the fact that she
15 didn't author it raises any impediment to it
16 being offered as an exhibit under her testimony.

17 Mr. Mann, was there anything else you
18 wanted to say in support of your objection?

19 MR. MANN: Well, I guess simply, Your
20 Honor, that I think the Government has faced this
21 hurdle over and over again, is that the
22 Government is really pretty much in the dark
23 about what any of these documents are being used
24 for, and how they're being cited.

25 You know, we've found certain cites,

1 for instance in Dr. Jaster's testimony it will
2 say Jaster 2024. And I'm just learning now, for
3 instance, that Jaster 2024 dissertation is not a
4 dissertation. It's a piece of paper with eight
5 graphs on it.

6 Accordingly, there's no mention of
7 Exhibit 37 anywhere in the testimony offered by
8 anyone. And there's no mention of this
9 particular article anywhere.

10 So I think the Government is
11 substantially prejudiced by the fact that it's
12 just being offered and now they're giving us a
13 reason as to what the relevance is.

14 MR. PHELPS: Your Honor, the
15 Government's had ample time to review these and
16 make appropriate challenges. And at this point
17 there's no material prejudice here.

18 They've had this document. They're
19 aware of it. And so we believe it's fully
20 appropriate for Dr. Jaster to be able to testify
21 about it.

22 JUDGE SOEFFING: I tend to agree.
23 This was timely submitted. The Government's had
24 it for a while. It was the subject of the motion
25 in limine.

1 I think the question of who was going
2 to testify about it was resolved in the briefing
3 on the motion in limine. So I'm going to
4 overrule the Government's objection.

5 Petitioner's Exhibit, marked for
6 identification, Number 37 has been offered. Over
7 the Government's objection it is received in the
8 record as Petitioner's Exhibit 37. It's in, you
9 may use it.

10 (Whereupon, the above-referred to
11 document was received into evidence as
12 Petitioner's Exhibit No. 37.)

13 MR. PHELPS: Thank you, Your Honor.
14 Dr. Jaster, can you tell us the title of this
15 paper?

16 THE WITNESS: Yes. The title is The
17 Rise (And Fall?) of Drug Discrimination Research.

18 BY MR. PHELPS:

19 Q And where was this article published?

20 A Drug and Alcohol Dependence.

21 Q And are you familiar with that
22 journal?

23 A Yes.

24 Q How so?

25 A I've published there previously.

1 Q Okay. Can you summarize what this
2 article is about?

3 A Yes. So this article discusses the
4 history and applications, and various
5 interpretations of drug discrimination, as well
6 as highlights alternatives or adjuncts to drug
7 discrimination such as self-administration, and
8 compares the drug discrimination
9 self-administration paradigms across substance
10 use research.

11 Q If you could take a look at Page 3 of
12 this article. And in the first full paragraph do
13 you see a sentence beginning with, the subjective
14 effects? Oh.

15 A In the first paragraph or the second
16 paragraph?

17 Q The second paragraph. My apologies.
18 If you --

19 A Yes, yes. I see it there.

20 Q Okay. And can you read what that
21 says?

22 A Yes. It says, the subjective effects
23 of drugs are private events that define the human
24 experience of drug use.

25 Unlike external events that can be

1 independently described among human observers,
2 the verbal description of the internal events
3 associated with drug use are based solely on the
4 conditioning history and experience of the
5 individual.

6 An individual who reports euphoria
7 after receiving a dose of cocaine potentially has
8 a very different subjective experience from the
9 individual who reports a virgin after receiving
10 the same dose of cocaine.

11 Despite these markedly different
12 subjective experiences, both individuals can be
13 trained to reliably perform the same operant
14 behavior after receiving a dose of cocaine and
15 the same distinct operant behavior when receiving
16 a vehicle.

17 Both individuals discriminate cocaine
18 as evidenced by unitary responses. But their
19 subjective description of the cocaine experience
20 is markedly different.

21 Do you want me to keep going?

22 Q No, that's good.

23 A Okay.

24 Q Can you explain what all that means?

25 A Yes. So I, in my interpretation, and

1 also based on some of the conclusions in this
2 publication, it is a discussion of how the
3 subjective effects, which are typically referred
4 to as what is involved in drug discrimination.

5 So how the animal is pressing the
6 lever based on the effects of the drug is often
7 referred to as subjective effects.

8 So in this specific paragraph, it's
9 describing how even though the rodent may be
10 having some physiological effect, it cannot be
11 deemed as a subjective effect, similar to what
12 humans may experience following drugs. And they
13 use cocaine as an example.

14 Q Thank you. I'd like you to turn to
15 Page 4 of the article, and take a look at Section
16 5 there.

17 A Okay.

18 Q And can you summarize what that
19 section says?

20 A Yes. So the section titled Use of
21 Drug Self-Administration Versus Drug
22 Discrimination in the Study of Neurobiology?

23 Q Yes.

24 A Yes. So this section basically just
25 discusses how drug self-administration is also a

1 useful screen for abuse liability. But it is
2 also able to investigate the circuitry, or like
3 how the brain responds to various drugs. And how
4 we can target different areas to have new
5 pharmacotherapies for substance use disorders.

6 It also discusses some of the
7 downfalls of both self-administration and drug
8 discrimination. And potential ways that they can
9 be used collectively or separately with
10 modifications.

11 Specifically, the use of food versus
12 drug choice in self-administration, which allows
13 the animal to make a choice between a substance
14 or like a naturally occurring reinforcer, just
15 like humans would.

16 Q So what is the conclusion that the
17 authors of this paper reach?

18 A The main conclusion is that the use of
19 drug discrimination, specifically in neurobiology
20 research and pharmacology research, is on a
21 steady decline and that other methods are now
22 more widely used, or used in conjunction with
23 drug discrimination measures to determine abuse
24 liability.

25 Q So there are other methods that

1 complement drug discrimination for understanding
2 abuse liability?

3 A Yes.

4 Q And what are some of those other
5 methods?

6 A So one of them would be the one
7 mentioned here, which is drug
8 self-administration, which is where an animal has
9 a self selection. So they are able to choose to
10 administer a drug at different rates, at
11 different concentrations. Able to choose between
12 a positive thing like food or social activity.

13 And then there's also one that's not
14 mentioned in this paper. That's called
15 intracranial self-stimulation, in which an animal
16 is hooked up to a probe in their brain that
17 essentially stimulates the reward center of the
18 brain. And they can select, self-select for
19 stimulation of that brain center.

20 Q I'd like to bring your attention to
21 what's been marked for identification purposes as
22 SSDP Ramos Exhibit 18.

23 A Thank you.

24 Q Do you have that in front of you?

25 A Yes.

1 Q And do you recognize this document?

2 A Yes.

3 Q Can you tell the Court what it is?

4 A This is a manuscript that was
5 submitted and accepted to Psychopharmacology, a
6 peer reviewed journal, that I wrote myself. Some
7 experiments I did during my time at my PhD.

8 Q Are you familiar with the contents of
9 this document?

10 A Very much so.

11 MR. PHELPS: Your Honor, we would move
12 to admit what's marked for identification
13 purposes as SSDP Ramos Exhibit 18.

14 JUDGE SOEFFING: Mr. Mann, any
15 objection?

16 MR. MANN: Just one question. I can
17 do it from here. Did you write this document?

18 THE WITNESS: Yes.

19 MR. MANN: No objection.

20 JUDGE SOEFFING: All right.
21 Petitioner's Exhibit, marked for identification,
22 Number 18 has been offered. In the absence of
23 objection it is received in the record as
24 Petitioner's Exhibit 18. It's in. You may use
25 it.

1 (Whereupon, the above-referred to
2 document was received into evidence as
3 Petitioner's Exhibit No. 18.)

4 MR. PHELPS: Thank you. What's the
5 title of this paper?

6 THE WITNESS: The title is Effects of
7 the 5-HT_{2A} Receptor Antagonist Volinanserine on
8 Head-Twitch Response and Intracranial
9 Self-Stimulation Depression Induced by Different
10 Structural Classes of Psychedelics in Rodents.

11 BY MR. PHELPS:

12 Q And where did you say this was
13 published?

14 A Psychopharmacology.

15 Q And can you -- what do you know about
16 that journal?

17 A It's a peer-reviewed journal.

18 Q So can you summarize what this article
19 is about?

20 A Yes. So this article essentially
21 characterizes DOI, mescaline, LSD, psilocybin,
22 and another substance, salvinorin A. And it
23 characterizes it in bold, a measure of acute
24 psychedelic behavior in rodents, and also in rat
25 intracranial self-stimulation. And it also looks

1 at the effects of the 2A receptor in these
2 models.

3 Q I'd like you to turn to Page 18 of
4 this article.

5 A Okay.

6 Q And specifically what's identified in
7 the paper as Figure 2. Do you see that there?

8 A Yes.

9 Q There's six different graphs. Can you
10 please explain what those figures mean?

11 A Yes. So just briefly, the first
12 three, so A, B, and C are looking at the
13 head-twitch response, which is the acute
14 psychedelic effect in rodents.

15 And then D, E, and F are looking at
16 the rates and number, yes, number of
17 self-stimulations of ICSS in rodents of DOI.

18 Q Can you explain just a little bit more
19 of what the head-twitch response is?

20 A Yes. So the head-twitch response is
21 something that occurs when you give a rodent a
22 psychedelic. So it's been formally tested across
23 many labs, and is considered a very good standard
24 of a read out of psychedelic effects.

25 And so essentially you administer a 2A

1 agonist psychedelic. And the effect is very
2 specific to the psychedelic 2A agonist, not
3 non-psychedelic 2A agonist.

4 So the animals will have an increase
5 in this head-twitch that can be quantified. And
6 then it has a nice dose response that can be
7 measured and compared across different
8 psychedelics, different doses.

9 Q Okay. And taken as a whole, can you
10 kind of explain the significance of these
11 figures, what they mean in context?

12 A Yes. So the main finding of this
13 specific figure is, if you look at the first
14 three panels, the administration with DOI
15 increases that acute head-twitch, which is most
16 notably associated with the hallucination
17 effects, or, like, hallucination-like effects in
18 rodents.

19 And then the last three panels are
20 very specific to the self-stimulation of the
21 reward system in the brain. So you can see that
22 when DOI is administered the self-stimulation
23 that happens without any drug onboard actually
24 decreases.

25 So this is just essentially suggesting

1 that DOI does not produce the same reward based
2 effects in the brain.

3 Q And what is, what does that mean in
4 terms of abuse liability of the substance?

5 A Yes. So this assay is commonly used
6 to, it's like an adjunct, like I mentioned, to
7 assess abuse liability in pre-clinical work.

8 And so there's been papers that have
9 been published on both stimulants like cocaine,
10 amphetamines, and even on opioids where those
11 types of drugs will increase self-stimulation
12 very reliably and robustly.

13 And so here we're showing that DOI
14 actually does the opposite. So that is just, the
15 overall conclusion that can be made there is that
16 it does not produce the same type of abuse
17 liability measured by this assay.

18 Q So when you say it does not produce
19 the same substance abuse liability, is that
20 greater or less than?

21 A So compared to those other substances
22 I mentioned, stimulants and opioids, it produces
23 no abuse liability in this measure.

24 Q I'd like to now turn your attention to
25 the next page, what's marked there as Figure 3.

1 And then on the following page we also have
2 Figure 4. So starting with Figure 3, can you
3 describe the findings shown in these figures?

4 A Yes. So they're very similar to the
5 previous figure with DOI. But instead of looking
6 at DOI, it's looking at LSD in Figure 3. So the
7 same pattern did occur with LSD. So when
8 administered, the animals did not self-stimulate,
9 but they did have a head-twitch response.

10 And then this effect in LSD was not
11 fully blocked by the 2A antagonist, whereas in
12 the previous figure with DOI it was fully blocked
13 with a 2A antagonist. So it's suggesting a
14 different mechanism of its involvement in the
15 reward pathway.

16 Q So what is, what does it mean when you
17 observe a head-twitch response, but not
18 self-administration?

19 A So in these models it would be
20 suggestive that the dose that is given is enough
21 to produce potential psychedelic effects. But at
22 that same dose, it does not produce reliable or
23 similar self-stimulation as other drugs would do.

24 Q Okay. And you said as a whole
25 psychedelics, psychedelic drugs and the other

1 ones that you studied, show a -- What type of
2 affinity do they show for self-administration?

3 A So in previous studies looking at
4 psychedelics and self-administration there's
5 been, I believe, one or two in non-human primates
6 and then maybe one or two in rodents.

7 But they've both showed that
8 psychedelics do not produce self-administration.
9 So animals will not self-select to take
10 psychedelics, at least in a way that is a similar
11 pattern, like related to human consumption.

12 Q And so, within the broader range of
13 psychedelics, where does DOI fit in, in regards
14 to self-administration, comparatively?

15 A So given the evidence that was
16 presented previously that DOI substitutes in
17 self, or in drug discrimination assays, it, by
18 that measure, it's pharmacologically and
19 chemically similar to drug discrimination.

20 But it does not produce
21 self-administration or ICSS. So that would just
22 suggest that similar to other, to the studies
23 with other psychedelics it would not produce
24 self-administration.

25 Q And, so this research shows that,

1 actually let me -- In your opinion, would DOI be
2 -- Let me rephrase that.

3 Despite the substances having similar
4 pharmacological properties via substitution in
5 drug discrimination, are there different
6 pharmacological effects in other assays?

7 A Based on my research and others', yes.

8 Q And can you expand on a little bit of
9 what that means?

10 A Yes. So it essentially means that
11 despite the fact that they substitute for each
12 other in drug discrimination, that -- so based on
13 my findings in the exhibit before us, we found
14 that they may all produce head-twitch, but it's
15 at different potencies that they produce their
16 maximal effects. So that's one behavioral
17 difference.

18 There's also a difference in the way
19 that they potentially block or produce -- not
20 block -- but also a difference in the way that
21 they can represent in this ICSS study, as
22 characterized by the involvement of the serotonin
23 2A receptor.

24 So just because they're alike in one
25 assay doesn't mean they're going to be alike in

1 another. But it's also possible they are.

2 Q And so what does that say about using
3 drug discrimination studies alone in regard to
4 evaluating a substance's potential for abuse?

5 A On my expert opinion, I believe that
6 it is not solely enough on its own to determine
7 abuse liability and should be used in conjunction
8 with other assays to assess abuse liability.

9 Q I'd like you to know turn to what's
10 been marked for identification purposes as SSDP
11 Ramos Exhibit 17.

12 A Okay.

13 Q And, sorry, just before we get into
14 that, one last question about the
15 psychopharmacology paper. Could you sort of
16 summarize in broad terms what your ultimate
17 conclusions of that paper were and the relevance
18 of that to today's proceeding?

19 A Yes. So the general conclusion from
20 that study is that while psychedelics do produce
21 potential psychedelic effects, as measured
22 through head-twitch, that the abuse liability is
23 actually quite low in this measure of
24 intracranial self-stimulation.

25 Q In your expert opinion, and based on

1 your research that you conducted, why do you
2 think that drugs don't self-administer but do
3 discriminate?

4 A That's a great question. So they can
5 substitute in discrimination, because that's more
6 of a measure of the pharmacology, so what
7 receptors are involved in, like, these behaviors.
8 And then so that is basically a pharmacological
9 effect.

10 But the effects of, like, that are
11 measured in these other measures of abuse
12 liability have to do with a lot more than just
13 the single receptor. It has to do with the whole
14 reward system which can be further targeted with
15 these more developed measures.

16 Q And what does that mean for behavior?

17 A I would say that that means that just
18 because something produces some psychedelic-like
19 effects doesn't mean that it produces negative,
20 or what is deemed, a negative behavior. So it
21 doesn't produce something like
22 self-administration or self-stimulation just
23 because it's a psychedelic.

24 Q Okay. And so in that paper you --
25 could you just break down again what other

1 elements of testing you use besides drug
2 discrimination research, besides drug
3 discrimination?

4 A In what paper?

5 Q In the one we're just going over.

6 A I do not -- that one uses intracranial
7 self-stimulation and head-twitch response, not
8 drug discrimination.

9 Q Okay. Can you explain the IC --

10 A ICSS?

11 Q ICSS, yes, please.

12 A Yes. So intracranial self-stimulation
13 is essentially a way to look at the reward
14 circuitry in the brain, so basically what brain
15 regions are involved in producing the drug
16 craving or the self-selection.

17 And it's measured in rodents by
18 inserting a cannula into the brain that provides
19 stimulation to that specific brain region and
20 those neurons which is just like a natural way
21 without a drug to, like, stimulate that part of
22 the brain.

23 And then when drugs are given, they
24 also stimulate potentially that part of the
25 brain, depending on the drug class. So for,

1 like, the example I said earlier, the stimulants
2 in some opioids produce an increase in
3 self-stimulation on top of what the animals are
4 already just naturally doing. But psychedelics
5 reduce that self-stimulation.

6 Q In your expert opinion, why do you
7 think, why might drugs like psychedelics, and
8 specifically DOI, not produce self-stimulation or
9 self-administration?

10 A Yes. So there is -- we've mentioned
11 throughout the last day or two that the serotonin
12 2A receptor and the serotonin 2C receptor are the
13 main targets of DOI.

14 And so these receptors are also,
15 they're expressed in these brain regions that I
16 mentioned, this reward circuitry, in differing
17 patterns. And they also have opposing effects
18 based on the brain region that they're in. I
19 don't want to get too into the weeds about it.

20 So essentially what that means is that
21 when activated, depending on the dose in any
22 specific areas, they actually produce signaling
23 that is adaptive for behavior instead of
24 maladaptive. So instead of producing those,
25 like, drug craving effects, it actually produces

1 the opposite.

2 Q Okay. And what might that mean in a
3 broader -- this was all done on rodents, right?

4 A Yes.

5 Q And potentially what might that mean
6 in a broader context?

7 A Yes. It's a great first step to
8 developing a potential target and mechanism for
9 developing novel medications for drug craving and
10 substance use disorders.

11 Q Thank you. I'd now like to turn your
12 attention to what's been marked for
13 identification purposes as Exhibit 17.

14 A Okay.

15 Q Do you recognize this document?

16 A Yes.

17 Q Can you tell the Court what it is?

18 A Yes. So this is a figure from my
19 dissertation work which shows the change in
20 preference of oxycodone before and after
21 administration of DOI in both male and female
22 rodents, mice.

23 Q So you're familiar with the contents
24 of this document?

25 A Yes.

1 Q And you, in fact, wrote this?

2 A Yes. Well, I analyzed, wrote it, and
3 -- yes.

4 Q You did the writing that led to the
5 production of these figures?

6 A Yes.

7 Q Thank you.

8 MR. PHELPS: We would move to admit
9 what's been marked for identification purposes as
10 SSDP/Ramos Exhibit 17.

11 JUDGE SOEFFING: Mr. Mann, any
12 objection?

13 MR. MANN: Your Honor, this is just
14 one page of a larger document. And I guess if
15 it's just being offered as a drawing by Dr.
16 Jaster, we have no objection.

17 JUDGE SOEFFING: Okay.

18 MR. MANN: But there's no context
19 here.

20 JUDGE SOEFFING: Well, I'll allow you
21 to explore that on cross examination if you wish.

22 Petitioner's Exhibit marked for
23 identification Number 17 has been offered. In
24 the absence of objection, it is received in the
25 record as Petitioner's Exhibit 17.

1 (Whereupon, the above-referred to
2 document was received into evidence as
3 Petitioner's Exhibit No. 17.)

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

6 MR. PHELPS: Thank you, Your Honor.

7 I guess just to start, Dr. Jaster, can
8 you explain why there's only one page of your
9 dissertation here?

10 THE WITNESS: Yes. So the
11 dissertation is currently in preparation to be
12 published. And also through the university the
13 full document is under embargo but, as it is
14 partially my intellectual property, I'm able to
15 show the figure but not the whole, entire
16 document.

17 MR. PHELPS: Thank you.

18 JUDGE SOEFFING: Can you explain to me
19 what you mean by embargo, what's under embargo?

20 THE WITNESS: Yes. So the university,
21 when you submit your dissertation, some
22 university's require that they hold it in their
23 system before it gets released to the public.
24 And that gives you time to publish it yourself
25 before it becomes a public document.

1 JUDGE SOEFFING: Okay. But that
2 doesn't affect your ability to release portions
3 of it, like has been done here?

4 THE WITNESS: I don't believe so.
5 Because the data is still my intellectual
6 property. So to my understanding, I'm still able
7 to show this portion, just not the entire
8 document.

9 JUDGE SOEFFING: Thank you.

10 THE WITNESS: Thank you.

11 MR. PHELPS: Can you walk us through
12 what these figures mean, please?

13 THE WITNESS: Yes, so just a general
14 overview, so I was doing conditioned place
15 preference which essentially is another measure
16 of abuse liability but is mainly considered a way
17 to look at context involvement in drug use.

18 So in the animal model they are placed
19 in one side of a chamber when they're given
20 oxycodone, in my case, and on another side of a
21 chamber when they're given just saline. And they
22 are trained to go to the side where they received
23 oxycodone over a period of days.

24 And then on the test day they are in
25 a drug-free state and placed back in a neutral

1 part of the chamber and allowed to explore. And
2 upon exploring they choose to go to the side
3 where they received oxycodone pretty reliably.

4 And so in this figure, I'm showing the
5 pre and the post on each graph. So the pre is
6 their oxycodone preference before given DOI. And
7 the post is their preference after getting DOI.

8 And so A through, or A, C, E, and G
9 are those administered saline after oxycodone
10 conditioning. And then in B, D, F, and H, it's
11 those who received DOI after oxycodone
12 conditioning.

13 And so what we see here is that those
14 that received DOI in B, which would be the male
15 mice, have a statistically significant reduction
16 in their preference score 24 hours after DOI was
17 given.

18 BY MR. PHELPS:

19 Q So can you just go to a little bit
20 more of how they were behaving, behaviorally
21 pre-administration of DOI and
22 post-administration?

23 A Yes. So when you condition them with
24 oxycodone, like I mentioned, they prefer to spend
25 their time in the chamber on the side that they

1 receive this drug. And so they'll seek out the
2 area in which they received it. They're
3 otherwise normally behaving animals.

4 And then we take them out of that
5 context fully to administer the psychedelic, in
6 this case is it was DOI. So they received that
7 drug, and they do have that, like, head twitch
8 response in the acute administration phase which
9 only lasts for four hours.

10 And then we put them back in the
11 chamber 24 hours later to see the long-term
12 potential intervention effect of DOI. And in the
13 aftermath, they do not seek out that oxy side.

14 Q And there's been some discussion
15 previously about the long lasting effects of DOI
16 in humans. How are you able to determine that it
17 lasts for the amount of time it does in the
18 rodents?

19 A Oh, we use head twitch response for
20 that. So as I mentioned earlier, when you give
21 the psychedelics, it increases this head movement
22 in the mice. And you can measure the duration
23 that that lasts with different psychedelics.

24 So it's actually interesting that --
25 so head twitch is really reliable and consistent

1 across species. There was a paper published that
2 actually looked at it in terms of its
3 correspondence with human data and, like, the
4 long lasting effects pharmacologically in humans.

5 And so DOI lasting four hours compared
6 to something else in rodents where something like
7 psilocybin only lasts, like, an hour, and that's
8 consistent with how psilocybin's shorter acting
9 in humans, but DOI is longer.

10 Q So you mentioned a variety of
11 conditioned place preferences. Can you explain
12 what those various steps -- that's different
13 types of testing you've been describing, right?

14 A So conditioned place preference is the
15 model overall, and it just -- the title is very
16 nice, because it says kind of what it is. So
17 you're just conditioning the animal to associate
18 a place with a drug.

19 Q Okay. So what was the role of -- was
20 drug discrimination an element of this study?

21 A When initially designing my studies,
22 I was interested in looking at drug
23 discrimination. But ultimately I was really
24 interested in environmental influence in drug
25 seeking. And so I chose to use conditioned place

1 preference. I was also going to add in the
2 adjunct of self-administration to my project but
3 just didn't have the time, honestly, in the PhD
4 to get that far.

5 Q So can you, looking back at these
6 figures, can you explain sort of in broad,
7 general terms what this shows about your
8 subjects' propensity for taking oxycodone?

9 A Yes. So in this they didn't take it,
10 just to clarify, but they were administered it
11 and were seeking out the environment that they
12 received it.

13 So generally this would suggest that
14 animals who do not receive the DOI intervention
15 did not have a reduction in their drug-seeking
16 behavior. But those that received DOI did have a
17 reduction in drug-seeking behavior. And I just
18 wanted to clarify that.

19 The A and B, and E and F are not the
20 individual mice but the group collapse. But the
21 C and D, and the G and H show each individual
22 mouse's change over time.

23 Q Okay. So can you explain then how DOI
24 effects oxycodone condition placed preference?

25 A Yes. So the first part of my

1 dissertation was looking at this behavior. But
2 the second part was actually characterizing a
3 potential target and mechanism to explain what's
4 going on here.

5 So in that part of my work, we used
6 genetic techniques to identify a specific
7 serotonin 2A receptor population in brain regions
8 that send signals to the nucleus accumbens, which
9 is a brain region that is primarily involved in
10 reward and drug seeking.

11 And so what we found there,
12 essentially, is that DOI activation of these
13 serotonin 2A receptors in the cortex are
14 influencing behavior that causes the animals to
15 have this decrease in their preference.

16 Q And this was the preference for
17 opioids specifically, oxycodone and --

18 A Yes.

19 Q Okay. And you've been in the building
20 here the last couple days. Did you see the Faces
21 of Fentanyl on the wall when you came into the
22 building?

23 A I did, yes.

24 Q Okay. And so you're familiar with the
25 DEA's mission or goals to prevent deaths via

1 overdose, specifically of opioids?

2 A Yes.

3 Q So what do you think that this data
4 that you show, that you produced in your
5 research, what does that data mean in the context
6 of the DEA's mission to prevent overdose deaths?

7 MR. MANN: Objection, Your Honor, I
8 don't see any of this in pre-hearing statement.
9 There's no mention of fentanyl in here.

10 MR. PHELPS: She's been specifically
11 recognized as an expert in substance abuse. I
12 believe the Faces of Fentanyl wall decoration is
13 directly relevant to substance abuse.

14 JUDGE SOEFFING: Mr. Phelps, do you
15 agree that it's not in the pre-hearing
16 statements?

17 MR. PHELPS: Well, we would say that
18 this falls under what is listed as the expertise
19 in substance abuse.

20 JUDGE SOEFFING: I'll give some
21 latitude here, and I'll overrule the objection.

22 MR. MANN: Well, Judge, I just say she
23 may be an expert in substance abuse, but she's
24 not here to testify about any other drugs, except
25 DOI or DOC.

1 JUDGE SOEFFING: I'll give it a little
2 latitude.

3 MR. MANN: It's not here anywhere in
4 the pre-hearing statement?

5 JUDGE SOEFFING: I understand, sir,
6 and I'll give a little latitude here, but it's
7 not going to be an extensive examination of this.

8 MR. PHELPS: Absolutely, Your Honor,
9 just a simple question --

10 JUDGE SOEFFING: So the objection is
11 overruled.

12 MR. PHELPS: Thank you. What do the
13 findings in your paper mean in the context of the
14 DEA's mission to prevent overdose deaths?

15 THE WITNESS: Are you referring to the
16 exhibit in front of us or the previous paper?

17 BY MR. PHELPS:

18 Q Well, we'll start with this one.

19 A Okay.

20 Q The one in front of you.

21 A Okay. So this specific project
22 doesn't have to do with overdose specifically,
23 but it can lend some information to how DOI could
24 specifically reduce drug craving. And drug
25 craving is a key aspect of substance use

1 disorders which people with substance use
2 disorders often do overdose.

3 Q Did any of the findings in your other
4 research that we've discussed, could you explain
5 to me their relevance in this same context?

6 A I would say generally kind of the same
7 statement. While I never looked at overdose
8 specifically in my models, that I can't speak to
9 DOI's effect there. But I know that my work, so
10 I would say --

11 MR. MANN: Judge, she's answering a
12 question that hasn't been asked. She's already
13 said twice that she's not assessing any overdose.
14 And that was the question.

15 MR. PHELPS: So I can lay a --

16 JUDGE SOEFFING: Yes, I think the
17 question is a little vague. I was not exactly
18 sure what the question was referring to. So if
19 you could be a little more specific --

20 MR. PHELPS: Yes, not a problem. So
21 how could reducing potential drug cravings, how
22 is that relevant in, or how does that relate to
23 potentially preventing overdose deaths?

24 THE WITNESS: Yes, so increased drug
25 craving is typically a hallmark of substance

1 abuse disorders. And so when people are sober,
2 or abstinent from drug use, they will still have
3 cravings associated with the drug, and so
4 specifically based on environment that they are
5 in.

6 And so if they return to an
7 environment where they used drugs previously and
8 decide to use again, they may have an overdose
9 based on environment, new or different.

10 So I would say that the research is
11 relevant, because DOI could be used to reduce
12 drug craving and thus reduce returning to an
13 environment where you previously used the drug.

14 BY MR. PHELPS:

15 Q I'd just like to go back to a couple
16 questions about your broader methodology or the
17 different methodologies that you use. Could you
18 go through again, briefly, just listing off types
19 of addiction models that we've discussed, the
20 ICSS and so on?

21 A Just name them?

22 Q Yes.

23 A Okay. So intracranial
24 self-stimulation, self-administration, food
25 versus drug choice, drug discrimination, and

1 conditioned place preference.

2 Q Okay. And those are all various
3 methods to -- are those methods used
4 interchangeably, or do they work differently?

5 A They all work differently to assess
6 different aspects of abuse liability.

7 Q Okay. And the Government's witness
8 testified previously that drug discrimination is
9 the gold standard for testing abuse liability.
10 Do you have any opinions on that?

11 A I would say in my recent training in
12 pharmacology and toxicology that we were told
13 the, and it is my own opinion, that the drug
14 discrimination model alone is not sufficient to
15 determine abuse liability and that it needs to be
16 used in conjunction with something more robust
17 such as food versus drug choice, or intracranial
18 self-stimulation, but cannot be relied upon by
19 itself.

20 Q And is that also supported by the
21 article we first talked about, about the rise and
22 fall of drug discrimination research?

23 A Yes, I would say it is.

24 Q So as a researcher in these fields,
25 what would you describe as the gold standard for

1 assessing abuse liability?

2 A I would say, at least in pre-clinical
3 models, a combination of multiple assays, so
4 specifically something like, I imagine, a
5 combination of drug discrimination to understand
6 pharmacological effects, but also potentially
7 self-administration with a drug versus food
8 choice or a drug versus any other reward choice,
9 just to determine whether or not the animal would
10 self-select if given another option like we do
11 see in humans.

12 Q And you said this is an opinion shared
13 by yourself and other researchers who you trained
14 under?

15 A Yes.

16 Q And who were those folks and what are
17 their qualifications to make that assessment?

18 A So specifically in my training on
19 these assays, one of the, or two of the major
20 folks that I trained with are in the pharmacology
21 department, and are co-authors on this paper, and
22 another paper which I evaluated a dual vaccine
23 for fentanyl and heroin for self-administration.
24 And so that was Dr. Steve Negus and Dr. Matthew
25 Banks who are considered experts in these models,

1 as well as determining abuse liability in
2 pre-clinical studies.

3 Q And your own research also reflected
4 that position?

5 A Yes.

6 Q Thank you. No further questions for
7 this Witness, Your Honor.

8 THE WITNESS: Thank you.

9 JUDGE SOEFFING: Mr. Mann, are you
10 conducting a cross examination?

11 MR. MANN: Yes.

12 JUDGE SOEFFING: Do you want to do
13 that now or take an afternoon break?

14 MR. MANN: Let's take our break.

15 JUDGE SOEFFING: Okay. We'll take a
16 15 minute break. We're off the record.

17 (Whereupon, the above-entitled matter
18 went off the record at 3:15 p.m. and resumed at
19 3:35 p.m.)

20 JUDGE SOEFFING: All right, we are
21 back on the record.

22 Dr. Jaster, remember you are still
23 under oath.

24 THE WITNESS: Yes.

25 JUDGE SOEFFING: And, Mr. Mann, you

1 may conduct your cross examination.

2 MR. MANN: Dr. Jaster, could you take
3 a look at your Exhibit 37, please.

4 THE WITNESS: Okay.

5 CROSS EXAMINATION

6 BY MR. MANN:

7 Q I believe you testified that there is
8 substitution for DOI in drug discrimination
9 studies with other hallucinogens, correct?

10 A Yes.

11 Q Okay. First of all, Exhibit 37 does
12 not discuss or mention DOI or DOC in any way,
13 does it?

14 A No.

15 Q And you concur with the findings of
16 this article, is that correct?

17 A Yes.

18 Q All right. I want to read you some
19 excerpts from the article.

20 In non-humans, this is on Page 2, in
21 non-humans, as in humans, some drug classes are
22 not robustly self-administered. Hallucinogens
23 such as lysergic acid diethylamide, or LSD, and
24 DOM are not typically self-administered by
25 non-human species.

1 Drug discrimination has provided an
2 excellent alternative for classifying these and
3 other drugs on the basis of hallucinogenic
4 activity mediated by 5-HT_{2A} Receptors.

5 You agree with that, correct?

6 A Yes.

7 Q Further down I'm going to read,
8 moreover, drug discrimination has been a valuable
9 resource for assessing the in vivo pharmacology
10 of drugs with unique physiochemical properties.
11 Do you agree with that?

12 A Yes.

13 Q Looking at Page 4, at the bottom of
14 the middle column, simply put, a sufficient
15 quantity of anything will decrease operant
16 responding for any reinforcer, including a drug
17 reinforcer.

18 A reduction in self administration is
19 often misinterpreted as a decrease in reinforcing
20 effects without first eliminating simpler
21 interpretations, i.e. general suppression of all
22 operant behavior that can only be rejected by
23 gathering additional controlled data.

24 Do you agree with that?

25 A Yes.

1 Q And finally, at the last paragraph,
2 drug discrimination has many applications, some
3 tried and true, and others more novel and unique.
4 Most importantly, drug discrimination continues
5 to be among the best, if not the best, option for
6 classification and characterization of the
7 mechanism of actions of CNS acting drugs in whole
8 animals.

9 And you agree with that?

10 A Yes.

11 Q All right, I believe that in Exhibit
12 17, if you could look at Exhibit 17, the one page
13 from your dissertation that you brought here --

14 A Okay.

15 Q -- and this concerns a conditioned
16 place preference study, is that correct?

17 A Yes.

18 Q All right. Would you agree there's a
19 difference between rewarding effects and craving?

20 A I would say that craving is part of
21 the overall rewarding effects of substances.

22 Q But they are not the same, is that
23 correct?

24 A Rewarding effects is a broad term, and
25 craving is a specific behavior.

1 Q Now your dissertation here, or this
2 chart, deals with how DOI relates to the use of
3 oxycodone, is that correct?

4 A The conditioned place preference of
5 oxycodone.

6 Q An opioid?

7 A Yes.

8 Q A completely different class of drugs
9 than hallucinogens?

10 A Yes.

11 Q Correct? And you don't have any
12 relation here between DOI and any other
13 hallucinogens in this report at all. Is that
14 correct?

15 A Not in this figure.

16 Q Okay. And would you agree that
17 conditioned place preference is not favored by
18 the FDA in assessing abuse liability?

19 A I have seen presentations that have
20 said that it can be used in conjunction with
21 other assays but alone cannot be used.

22 Q I'm sorry?

23 A But alone cannot be used.

24 Q I'm going to read from the document
25 that was at one point your Exhibit 6, the

1 assessment of abuse potential drugs guidance for
2 industry published by the FDA.

3 Quote, "Condition placed preference,
4 this study evaluates whether a test drug produces
5 rewarding effects that are demonstrated by an
6 animal's preference to be on the side of a cage
7 where it received the test drug as opposed to the
8 side where it received vehicle.

9 "Notably, CPP differs from
10 self-administration in that it does not measure
11 whether the rewarding effects of the drug produce
12 reinforcement. It is also not considered to be a
13 sensitive or reliable as self-administration."

14 Do you dispute that statement?

15 A No.

16 Q I want to read this. Certain classes
17 of drugs with hallucinogenic properties do not
18 typically produce animal self-administration or
19 are only self-administered by animals under
20 limited conditions, even when they are known to
21 be taken by humans for their rewarding effects.

22 Sponsors may propose that a
23 self-administration study is not appropriate
24 based on similarity and mechanism of action or
25 behavioral effects for these classes of drugs.

1 Do you dispute anything about that
2 statement?

3 A Can you repeat the statement, please?

4 JUDGE SOEFFING: Mr. Mann, is this
5 what was Petitioner's Exhibit 6?

6 MR. MANN: It was Exhibit 6.

7 JUDGE SOEFFING: And what page are you
8 reading from?

9 MR. MANN: Eighteen.

10 JUDGE SOEFFING: Okay.

11 MR. PHELPS: Just a point of
12 clarification, has the Witness been provided a
13 copy of that?

14 JUDGE SOEFFING: No. Mr. Mann, would
15 you like to provide the Witness with a copy of it
16 or just continue to read?

17 MR. MANN: I could let her take a look
18 at the copy. I only have one copy with me. They
19 have a copy.

20 JUDGE SOEFFING: We have a copy.
21 Would you like to show the Witness? My clerk can
22 show her a copy if you'd like.

23 MR. MANN: I would rather you do that.
24 Mine is highlighted, there's notes all over it.

25 JUDGE SOEFFING: Okay. So the record

1 will reflect that the Witness is being shown what
2 had previously been identified as SSDP and Dr.
3 Ramos' exhibit for identification Number 6.

4 MR. MANN: Do you have that before
5 you?

6 THE WITNESS: Yes, what page are you
7 on?

8 MR. MANN: So we're looking at Page 18
9 at the bottom. Certain classes of drugs with
10 hallucinogenic properties do not typically
11 produce animal self-administration or are only
12 self-administered by animals under limited
13 conditions, even when they are known to be taken
14 by humans for the rewarding effects.

15 Sponsors may propose that a
16 self-administration study is not appropriate
17 based on similarity and mechanism of action, or
18 behavioral effects to those classes of drugs.

19 Do you dispute that statement?

20 THE WITNESS: I apologize, I'm just
21 trying to locate it. Is this Page 18 of the
22 document or 18 labeled through the --

23 MR. MANN: I only see one page number
24 on my copy, 18. I'm not sure how that was
25 labeled.

1 JUDGE SOEFFING: So when it was filed
2 with the tribunal, it was re-labeled. I think
3 that we are looking at 21. Does it go on to Page
4 19, Mr. Mann, on your copy?

5 MR. MANN: I guess you had three --
6 yes, it would be 21.

7 JUDGE SOEFFING: All right, so bottom
8 of Page 21 to the top of Page 22.

9 MR. MANN: Right.

10 THE WITNESS: Okay, yes, I see it now.

11 MR. MANN: My question was do you
12 dispute this statement?

13 THE WITNESS: I do not dispute the
14 first paragraph, or the sentence, but I'm unclear
15 as to the second sentence based on similarity and
16 mechanism of action or behavioral effects of
17 these classes of drugs.

18 MR. MANN: Okay, if the Witness could
19 please see Exhibit Number 18.

20 Could I have one moment, Your Honor?

21 JUDGE SOEFFING: Certainly.

22 MR. MANN: Okay, first of all, we
23 talked about this ICSS, correct?

24 THE WITNESS: Yes.

25 BY MR. MANN:

1 Q All right. And you would agree that
2 ICSS affects in DOI are similar to other
3 psychedelics, is that correct?

4 A Yes.

5 Q And when I talk about other
6 psychedelics, I'm talking about LSD, correct?

7 A Okay.

8 Would you agree that's
9 another psychedelic?

10 A Yes.

11 Q It would be similar in effect under
12 this ICSS test.

13 A Yes.

14 Q All right. And LSD is a drug with a
15 high abuse liability, is it not?

16 A I don't agree with that statement.

17 Q Do you agree that psilocybin is a drug
18 with high abuse liability?

19 A I do not agree with that statement.

20 Q And do you disagree, or do you agree
21 that DOM is a drug of high abuse liability?

22 A I do not agree with that statement.

23 Q So you don't believe that any three of
24 those Schedule I psychedelics have a high abuse
25 liability, do you?

1 A No.

2 Q Do they have an abuse liability at
3 all?

4 A I would say very minimal.

5 Q All right, if you could look at the
6 first page of Exhibit 18 for me.

7 A Okay.

8 Q Now what is this again? This is
9 something you wrote, correct?

10 A Yes.

11 Q Okay. And what are you trying to
12 determine here?

13 A The study was to determine the
14 behavioral pharmacology of structurally distinct
15 psychedelics in paradigms associated with 2A
16 receptor activation and behavioral disruption in
17 two rodent models.

18 Q And what drugs did you use?

19 A LSD, psilocybin, DOI, mescaline, and
20 Salvinorin A.

21 Q Okay. It sounds like you named a
22 couple of Schedule I drugs, correct?

23 A Correct.

24 Q So in your research someone had a
25 Schedule I registration, did they not?

1 A Yes.

2 Q Okay. Now I'd like you to look at
3 Page 2 of this document --

4 A Okay.

5 Q -- where it says, the second paragraph
6 in the introduction, although serotonergic
7 psychedelics are not currently approved for
8 clinical use, several lines of evidence has
9 suggested that this class of psychoactive
10 compounds may be useful for treatment of certain
11 psychiatric conditions such as mood disorders.
12 Do you agree with that?

13 A Yes.

14 Q And then further down it says, in the
15 middle of the paragraph, even with growing
16 evidence for their therapeutic potential, the
17 behavioral disruptive effects associated with the
18 use of these drugs may limit their future success
19 in clinical practice.

20 Do you agree with that?

21 A Yes.

22 Q So you acknowledge that there are
23 behavioral disruptive effects from psychedelic
24 drugs?

25 A Yes.

1 Q Now is ICSS a tool used by FDA for
2 evaluating rewarding drug effects?

3 A Not that I'm aware of.

4 Q Just one second.

5 Dr. Jaster, you don't believe that any
6 drugs should be scheduled, do you?

7 A No, I do not.

8 Q In fact, you wrote on Twitter that no
9 drugs should be decriminalized.

10 A Can you repeat that?

11 Q You wrote on Twitter that no drugs
12 should be -- or should be criminalized. Is that
13 correct.

14 A Correct.

15 Q So any drug that is scheduled is
16 criminalized?

17 A Is that a question or a statement?

18 Q Yes, is that true?

19 A Yes, according to the CSA.

20 Q You also acknowledge that there are
21 such things as having bad trips on psychedelic
22 drugs, correct?

23 A Correct.

24 Q And that is a very adverse effect of
25 a psychedelic drug, is it not?

1 A To some individuals, but to some it is
2 considered also helpful.

3 Q So from where you stand today, your
4 position is no drugs should be scheduled at all.

5 A Correct.

6 Q Correct? And you realize this is a
7 scheduling action, and that the CSA is founded on
8 scheduling certain drugs.

9 A Yes, but I am here to oppose
10 scheduling of two psychedelics, DOI and DOC.

11 Q And you're even opposed to scheduling
12 of every single drug, are you not?

13 A No.

14 Q You just said that no drug should be
15 scheduled, correct?

16 A Correct.

17 Q Okay. That's all I have, thank you.

18 JUDGE SOEFFING: Thank you, Mr. Mann.
19 Mr. Phelps, would you like to redirect?

20 MR. PHELPS: Yes, please, Your Honor.

21 (Pause.)

22 MR. PHELPS: Dr. Jaster, I'd like to
23 point your attention to what's marked as Exhibit
24 37, the article, Rise and Fall of Drug
25 Discrimination Research.

1 THE WITNESS: Okay.

2 REDIRECT EXAMINATION

3 BY MR. PHELPS:

4 Q So the Government's Attorney
5 questioned you about language in this article
6 about drug discrimination being the best for
7 mechanisms of action. Can you explain what
8 that's referring to? Is mechanisms of action
9 something specific unrelated to abuse liability
10 potential?

11 A Yes. So my mechanism of action just
12 refers to the way that the drug targets in the
13 brain and how it produces its effects in the
14 brain. Just generally a mechanism of action is
15 how a drug produces its effects.

16 Q It's just how a drug works in your
17 brain?

18 A Yes.

19 Q And in regards to DOI and some of the
20 similar substances we've been talking about, the
21 mechanism of action is, what is the mechanism of
22 action there?

23 A So for the DOI and DOC, it's mainly a
24 serotonin 2 receptor activation. So for DOI it's
25 2A and 2C very specifically.

1 Q Okay. And so you wouldn't dispute
2 that drug discrimination is one of, if not the
3 best ways of testing specifically mechanism of
4 action?

5 A I would agree with that statement.

6 Q Okay. Is that the same as, is testing
7 for mechanism of action the same as testing for
8 abuse liability potential?

9 A No, it is not.

10 Q What are the differences?

11 A So testing for abuse liability
12 potential would include looking specifically at
13 behaviors related to substance use, including
14 some of the ones I mentioned, as well as looking
15 at the specific rewarding, the rewarding effects
16 in the brain and the circuitry that's specific to
17 reward, which includes, like, dopamine-related
18 function.

19 Q Would you agree that using only drug
20 discrimination provides an incomplete picture of
21 abuse liability?

22 A Yes.

23 Q And why is that?

24 A Because it's only assessing the
25 specific pharmacological effect of a single class

1 of drugs or comparing it to a class of drugs that
2 is known to not be similar, so just
3 characterizing the mechanism of action of those
4 drugs to substitute for a drug with a similar
5 mechanism of action.

6 Q So mechanism of action is much
7 narrower than the broader abuse liability that's
8 the subject of this test?

9 A Yes.

10 Q And so it wouldn't necessarily be
11 inconsistent that drug discrimination is maybe
12 the best, one of the best methods for testing
13 mechanisms of action but not the best or gold
14 standard for determining abuse liability
15 potential?

16 A That is correct.

17 Q And what were the methods that you
18 used again in that, or that you used in your
19 research?

20 A So I've used self administration, food
21 versus choice models with various types of, like,
22 reinforcement rates. And then I've also used the
23 intracranial self stimulation which is written in
24 that paper. And then I've used conditioned place
25 preference and was also trained on drug

1 discrimination but did not end up using the
2 assay.

3 Q And why did you choose to use so many
4 different methods?

5 A To determine the best method to answer
6 my specific research question.

7 Q And what was that specific research
8 question?

9 A How psychedelics can reduce drug
10 context paring, specific to oxycodone.

11 Q And have you presented any, given any
12 public presentations about your use of these
13 different methods?

14 A Yes.

15 Q Could you tell us about some of those?

16 A Yes. So I have presented all my data
17 at a variety of different professional
18 conferences, including psychedelic conferences,
19 the European Behavioral and Pharmacology
20 conference. I just recently went to -- I
21 presented at the American College of
22 Neuropsychopharmacology, ACNP. I've presented at
23 -- I don't have my CV in front of me, but yes,
24 several.

25 Q Okay. And are you invited to present

1 at those are do you submit your own application?
2 How does that work?

3 THE WITNESS: It depends on the
4 conference.

5 MR. MANN: Objection, you know, this
6 goes beyond the scope of cross.

7 JUDGE SOEFFING: Mr. Phelps?

8 MR. PHELPS: Well, I guess the point
9 I was getting at is the Government was really
10 insistent on hammering home the point of this one
11 particular research method being the best. And I
12 wanted to see the consensus of the broader
13 scientific community where Ms. Jaster has
14 presented this research --

15 JUDGE SOEFFING: Okay.

16 MR. MANN: She's not an expert in the
17 broader sense of the scientific community. She's
18 an expert on substance use, and I believe it was
19 pharmacology.

20 MR. PHELPS: And she's only going to
21 be speaking about her own actual experience that
22 she has personal knowledge of.

23 JUDGE SOEFFING: Overruled, but I
24 think wrap it up.

25 MR. PHELPS: Yes. How was that

1 research received by the broader scientific
2 community at those presentations.

3 THE WITNESS: Very well, it stimulated
4 a lot of productive conversations on which models
5 should be the gold standard, which ones can be
6 used in conjunction with others, and just helped
7 better formulate the research questions that me
8 and my colleagues were focused on.

9 BY MR. PHELPS:

10 Q So in your expert opinion, where would
11 you say the, in this field, testing is going,
12 what direction is it moving?

13 A I would say it's moving in a direction
14 that's multi-faceted. So like I mentioned
15 earlier, just relying on not just one study of
16 mechanism of action but looking at the broader
17 neurobiology of substance use in a variety of
18 models including, some of the ones I've mentioned
19 today, but not related to those.

20 Q Okay. I'd like to know point you back
21 to Exhibit 18.

22 A Okay.

23 Q This is your paper, right?

24 A Yes.

25 Q And in this paper you used a variety

1 of substances in your testing as mentioned in
2 cross, right?

3 A Yes.

4 Q And what were those substances again?

5 A DOI, LSD, psilocybin, mescaline, and
6 Salvinorin A.

7 Q And some of those -- why did you use
8 DOI for this particular part of your testing?

9 A It was for two reasons, one it's very
10 commonly published on, so we wanted to be
11 consistent with literature. And this paper was
12 building off of a previous publication from the
13 Negus Lab that showed that DOI did not produce
14 self stimulation. It decreased self stimulation.

15 So we wanted to look at mechanism of
16 action of DOI compared to other psychedelics like
17 tryptamine psychedelics and then a control which
18 is the Salvinorin A. It's a different drug
19 class.

20 Q Okay. And some of those substances
21 you were able to use because the -- what was your
22 lab again, I'm sorry, where you did this?

23 A So this was a collaboration across the
24 lab that I was in, which is the Gonz lez-Maeso
25 Lab at VCU, and then Steve Negus' Lab at VCU.

1 Q Okay. And some of the substances you
2 were able to use were in Schedule I, right.

3 A Yes.

4 Q And how would your research process,
5 is it changed if DOI was in Schedule I?

6 A So specifically, for this project, it
7 would have been slightly altered. Specifically
8 the experiments with DOI would have to have been
9 halted while we re-submit our applications to the
10 Institutional Review Board, or not Institutional
11 Review Board, the IACUC, which is a rodent review
12 board.

13 And so we would have to submit new
14 protocols with the updated DEA application to add
15 DOI to the drug scheduling and then would also
16 have to resubmit for just the state, and update
17 all of our just inline protocols, and make sure
18 personnel that would be using DOI would also
19 become trained under the institution in state and
20 federal requirements for the CSA.

21 Q So when you're conducting testing that
22 uses both Schedule I and non-scheduled
23 substances, you have to treat those differently
24 in how they're used in the testing?

25 A The storage and the, like, safety

1 protocols are pretty similar. There's just some
2 added safety blocks as per the CSA Schedule I
3 requirements for schedule of drugs.

4 Q And so there would have been
5 additional hurdles for you to use DOI in that
6 way.

7 MR. MANN: Objection, leading.

8 THE WITNESS: Yes.

9 JUDGE SOEFFING: Overruled, it was
10 answered.

11 MR. PHELPS: Okay, so still in Exhibit
12 18, the Government asked you about behavioral
13 disruptive effects. What are those?

14 THE WITNESS: So, behavioral
15 disruptive effects just mean any changes in
16 normal-behaving animals.

17 BY MR. PHELPS:

18 Q So could you give some examples, to
19 put that in the context, of different types of
20 behavioral disruptive effects?

21 A Yeah. So, broadly, the term could
22 mean any disruption to any normal animal
23 behavior, so any drug administration can disrupt
24 normal animal behavior. Sometimes, in the
25 context of other assays, like, in this case, we

1 were measuring the self-stimulation, so the
2 animals will normally self-stimulate with
3 increasing frequency.

4 So, while other substances, such as
5 the stimulants and some opioids that I mentioned,
6 they increase that self-stimulation, the DOI and
7 these other psychedelics decrease it, which is
8 considered a behavioral disruption because it's
9 decreasing. But, technically, the increase would
10 also disrupt normal behavior, as well.

11 Q So is a behavioral disruptive effect
12 inherently bad or negative?

13 A I don't think it can be inferred as
14 good or bad. It just depends on the context.

15 Q Okay. So a behavioral disruptive
16 effect is a neutral term just meaning any change?

17 A It could be inferred that way, yes.

18 Q Okay. In the case of your research,
19 how would you contextualize the behavioral
20 disruptive effects that you found?

21 A I would contextualize that as these
22 psychedelics were able to disrupt behaviors that
23 are associated with reward circuitry that are
24 implicated in substance use disorders.

25 Q I'm sorry, could you just break that

1 down a little bit more for me?

2 A Yeah. So, essentially, these
3 substances are able to reduce the -- I'm trying
4 to think of a good word -- reduce the way that
5 the brain functions with rewarding effects. It's
6 able to alter that to reduce behaviors associated
7 with rewarding function.

8 Q And are behavioral disruptive effects
9 as a -- just taken on their own, pulled out of
10 context like this, is that part of the test
11 within the CSA for abuse liability?

12 A Not to my knowledge.

13 Q Now, the Government attorney asked you
14 about what he referred to as a bad trip. Would
15 you -- would you say that "bad trip" is
16 scientific terminology?

17 A No.

18 Q Why not?

19 A I would say it's a very subjective
20 term that depends on the individual's experience
21 with the psychedelic compound.

22 Q And can you give us a little maybe
23 broader historical context of this concept of a
24 bad trip? Where does that come from, in your
25 understanding of substance abuse as an expert in

1 that field?

2 A Yeah. So, I think bad trip
3 historically just comes from any potential
4 challenging experience with psychedelics, or is
5 something that people just presume less than
6 favorable. But there is also some historical
7 reports or writings in, like what was mentioned,
8 like a PiHKAL, where something was potentially
9 challenging or a bad trip, but it -- and also in
10 scientific papers that have recently been
11 published -- that challenging experiences or bad
12 trips, quote/unquote, can produce positive
13 effects in the individual experiencing them.

14 Q Okay, so I guess -- or do you have any
15 knowledge of where the concept of this bad trip
16 came about in historical popular culture?

17 A I don't know, like, any specific,
18 like, citation, I guess, for the term, but --

19 Q In general, any general history or
20 context of where that maybe originated?

21 A Like, the 1970s movement.

22 Q And how so? Can you just explain a
23 little bit more about that?

24 A I would just say popularized use in
25 1970s. More people were talking about their

1 psychedelic experiences, so it just became more
2 popular to talk about the different types of
3 experiences, which some would deem,
4 quote/unquote, bad.

5 Q And would you say that this concept of
6 the bad trip was used to stigmatize these
7 substances across popular culture?

8 A Yes.

9 Q How so?

10 A There was a lot of media tactics
11 surrounding negative or challenging experiences
12 of psychedelics that just deemed them bad to use
13 or to ingest, despite multiple people not having,
14 quote/unquote, bad trips.

15 Q Okay. And is the term "bad trip"
16 something that's used in the scientific study of
17 these substances today?

18 A Typically, the terminology is
19 challenging experience or, like, something along
20 those lines. Not "bad trip."

21 Q Do you see any scientists, other than
22 the Government's expert, describing these
23 experiences as bad trips?

24 A Not my immediate knowledge.

25 Q Why do you think science has moved

1 away from that understanding of these
2 experiences?

3 A Because it stigmatizes substance use
4 in a broad sense.

5 Q And what are the potential negative
6 impacts of the stigmatization of drug use?

7 A So just overall, generally?

8 Q Yes.

9 A So not specific to psychedelics, but
10 all drug use?

11 Q Yes. In general.

12 A So, I would say that it influences the
13 -- if somebody is struggling with a substance use
14 disorder, I would say that the stigmatization
15 causes them to not want to seek out treatment or
16 talk about their substance use or their
17 experiences, and potentially self-isolate,
18 furthering their substance use.

19 Q Okay. In the context of psychedelics,
20 how might the characterization of these
21 experiences as challenging rather than a bad trip
22 be beneficial?

23 A It would allow people to discuss their
24 experiences more without being given a, like,
25 good versus bad quality, and instead, like, you

1 can have a challenging experience, like, on a day
2 to day; it doesn't necessarily mean that it's
3 good or bad, it just might be something you have
4 to, like, deal with. So I think it just helps in
5 the discussion of substance use and outcomes, and
6 understanding those.

7 Q And you said there's actually
8 literature out there about potentially positive
9 benefits of challenging experiences with
10 psychedelics?

11 A Yes.

12 Q Could you expand on that a little bit?

13 A There's been several studies in a
14 variety of institutions, including Johns Hopkins,
15 including, I believe, some from some places in
16 the UK, as well as some in California, just
17 focusing on different outcomes in clinical
18 trials, some deemed challenging, some deemed more
19 favorable, and how they influence the potential
20 therapeutic effect or the outcomes.

21 Q Could you give me some possible
22 examples out of that of challenging experiences
23 that people had that ended up benefiting them?

24 A I don't know any, like, specifics, so
25 I don't want to speak to those papers if I don't

1 have them in front me.

2 Q Could you -- this is something -- this
3 is a concept that you're familiar with outside of
4 the context of publications on this particular
5 topic, right?

6 A Yes.

7 Q You have an understanding of a bad
8 trip versus a challenging psychedelic experience
9 beyond just what you've read in academia?

10 A Yes, I have knowledge of the concepts.

11 Q Okay, so could you give us an example
12 of a concept of -- yeah, of how that -- an
13 example of how that concept may work?

14 A Yeah. So, for example, a person could
15 be consuming a psychedelic and be sitting
16 thinking about -- so, either at home or in the
17 context of a clinical trial -- and they could be
18 thinking about a traumatic experience that they
19 had, and that could cause some emotional -- acute
20 emotional discomfort, which would be deemed as
21 something that was challenging. But they may
22 come out of that discomfort within the
23 psychedelic duration, or after the psychedelic
24 duration, and may be able to have worked through
25 some of that traumatic memory experience.

1 Q So in -- and back to this -- well, the
2 Government asked you about your opinions about
3 drug criminalization in general.

4 A Yes.

5 Q And you said that you did not believe
6 that drugs should be criminalized.

7 A Correct.

8 Q Could you explain why you feel that
9 way?

10 A Yes. So, just generally, I have seen
11 what criminalization can do to families and to
12 those suffering from substance use. There's
13 often not very many treatment options available
14 to those who are imprisoned because of substance
15 possession or use. Families get separated.
16 There's more increased stigma associated if you
17 have a criminal record, on top of if somebody is
18 suffering from substance use disorder. And so,
19 just generally, I think that criminalization can
20 pose a threat in that sense.

21 But even more so in terms of just the
22 substances that are available. When substances
23 become criminalized there are more opportunities
24 for people in the black market and that are
25 trafficking substances to cut these substances

1 with more potentially dangerous things. And
2 people will not be aware of what they're taking,
3 and thus increasing overdose, or potential for
4 overdose, because there's just a lack of
5 knowledge of what they're taking versus something
6 that's legally available.

7 Q Throughout recorded human history, how
8 long have humans used drugs?

9 A Thousands of years, if not more.

10 Q Has criminalizing a drug ever stopped
11 people from using it?

12 A Not to my knowledge.

13 MR. MANN: Objection, Your Honor.
14 This has gone way beyond the scope of cross.

15 MR. PHELPS: Your Honor, he opened the
16 door to her positions on drug criminalization.

17 JUDGE SOEFFING: I think he did open
18 the door, so I'll overrule the objection.

19 BY MR. PHELPS:

20 Q So, just to repeat the question, you
21 said that criminalization, in your experience as
22 an expert on substance abuse, has not stopped
23 people from using drugs?

24 A No.

25 Q What has it done?

1 A It's increased drug overdose. It's
2 imprisoned people for possession or use of
3 substance. It's removed families -- or separated
4 families through imprisonment, et cetera.

5 Q Is this something that's personally
6 affected you?

7 A Yes.

8 Q If you're comfortable, would you want
9 to expand a little more on that? You can go into
10 as much or little detail as you're comfortable
11 with.

12 A Yeah, I can just briefly. So I have
13 a -- like, my family has a history of substance
14 use disorders. So, my father is a recovering --
15 he deems himself as a recovering addict, so I'm
16 going to use that terminology, because that's
17 what he uses; I know not everybody uses that
18 terminology. So, him and my grandfather. And so
19 my -- half of my life, I would say, that my
20 father was not present in my life due to
21 substance use, both legal substances, alcohol,
22 but also due to crack cocaine.

23 And so he had been put in jail, he was
24 absent from the family, and it wasn't until he
25 was able to be released from the system,

1 essentially, that he was able to find adequate
2 treatment, in which he's now, I believe, 15
3 years, around -- somewhere around 15 years
4 abstinent from substances.

5 Q Okay. And you also mentioned that
6 criminalization of drugs can lead to
7 contamination or unsafe -- can you explain that?

8 A Yeah. So, in general, so, the reason
9 -- I'll use fentanyl for an example since it's
10 the most prominent. So, the recent fentanyl
11 overdose crisis has actually seen in -- we've
12 seen an increase in overdoses over the last four
13 to five years, which many research organizations
14 have found it to be linked specifically to the
15 adulteration of supply of, say, heroin, for
16 example, with things like fentanyl, or other more
17 potent fentanyl analogues, in which can cause
18 these increases in overdose.

19 And we've seen that, despite efforts
20 from law enforcement or lawmaking to increase
21 penalties for fentanyl trafficking, that this has
22 not stopped. So, this is just an example of how
23 increased laws and increased criminalization
24 actually can lead to more overdoses, because
25 these supplies that were once used safely are now

1 taken away and replaced with something that's
2 adulterated.

3 Q To your knowledge, do psychedelics
4 frequently get adulterated with fentanyl?

5 A Not to my knowledge.

6 Q Okay. And so, just to be clear, it's
7 that that lack of controlled supply that can
8 ultimately lead to that adulteration?

9 A That's one component, yes.

10 Q What are what are some other
11 components?

12 A That can lead to adulteration?

13 Q Yes.

14 MR. MANN: Judge, again, the point of
15 bringing up her opposition to criminalization of
16 drugs is to show bias, not to make a political
17 statement about the war on drugs, or the DEA, or
18 anything else. This has gone far too far.

19 MR. PHELPS: And, Your Honor, we're --
20 yes, we're here to -- the point of this
21 questioning is to show that it's not biased in
22 the fact of -- it's not to bias, it's actually
23 just to show a big difference in perspective and
24 understanding of what the Government seems to --
25 or the Agency seems to mostly be taking as a

1 given. And so it's providing broader context to
2 the opinions and position that the Government
3 opened the door to.

4 JUDGE SOEFFING: Well, I think that
5 you explored the reasoning behind her position
6 being against the criminalization of drugs.

7 MR. PHELPS: Okay. We can move on.

8 JUDGE SOEFFING: So I think the area's
9 been covered.

10 MR. PHELPS: No problem.

11 JUDGE SOEFFING: So I'll sustain the
12 objection and allow you to move on.

13 BY MR. PHELPS:

14 Q The Government said that you were here
15 to testify against scheduling of any drugs. Do
16 you remember that?

17 A Yes, I recall that.

18 Q Is that what you're here to testify
19 for?

20 A No.

21 Q What is the purpose of you being here
22 to testify today?

23 A I'm here to testify to oppose the
24 scheduling of psychedelic DOI and DOC.

25 Q And that's a -- your opposition to

1 scheduling of DOI and DOC specifically arises
2 from your context as an academic researcher,
3 correct?

4 A Correct.

5 MR. PHELPS: No further questions.

6 JUDGE SOEFFING: Okay. Mr. Mann,
7 would you like to recross?

8 MR. MANN: Yes, please.

9 RECROSS EXAMINATION

10 BY MR. MANN:

11 Q Dr. Jaster, on redirect, there was
12 some discussion about the behavioral disruption.
13 Wouldn't a head-twitch response be considered a
14 behavioral disruption?

15 A Yes.

16 Q And I believe you testified that the
17 -- was it, rodents had head twitches for up to
18 four hours?

19 A Under DOI, yes.

20 Q That's pretty disruptive, isn't it?

21 A Correct.

22 Q Now, you talked about an organization
23 called IACUC?

24 A Yes.

25 Q Right? And did you write the

1 protocols that IACUC approved in your research?

2 A I have been involved in the IACUC
3 inspections for the laboratory that I was in and
4 helped write some of the protocols, but not all
5 the protocols.

6 Q All right, so wouldn't IACUC have to
7 approve the use of DOI in this particular study
8 that you discussed?

9 A Yes.

10 Q All right. Now, you talked about bad
11 trips.

12 A Yes.

13 Q And how stigmatizing that word is in
14 your opinion. Bad trips can produce lingering
15 effects, can they not?

16 A Correct.

17 Q That can last for weeks?

18 A In some individuals.

19 Q Months?

20 A In some individuals.

21 Q Years?

22 A Maybe.

23 Q And bad trips in your view is
24 tantamount to suffering, is it not?

25 A I would not say so.

1 Q All right. If I could?

2 JUDGE SOEFFING: Yes.

3 MR. PHELPS: No, that's fine.

4 MR. MANN: Is it upside down?

5 JUDGE SOEFFING: No.

6 MR. MANN: Okay. Do you see that on
7 the screen?

8 THE WITNESS: Yes.

9 MR. MANN: Okay.

10 MR. PHELPS: Could we get a copy of
11 that? I cannot see that screen.

12 MR. MANN: Oh, here we go.

13 JUDGE SOEFFING: Mr. Mann, how many
14 copies do you have of that?

15 MR. MANN: I have plenty.

16 JUDGE SOEFFING: Okay, would you pass
17 them up to the court, please?

18 MR. MANN: Oh, I just have one more.

19 JUDGE SOEFFING: Just one extra, I'll
20 take that one.

21 BY MR. MANN:

22 Q So I'm representing this is from the
23 website X, also known as Twitter. Is this
24 something that you wrote?

25 A Yes.

1 Q And it says the no such thing as a bad
2 trip rhetoric is so irritating and harmful. Bad
3 trips exist. Suffering does not equal growth.
4 If you had what you consider a bad trip, don't
5 let someone discount your experience. Did you
6 write that?

7 A Yes.

8 Q Okay.

9 MR. MANN: Judge, at this point, I'd
10 like to mark this as Government Exhibit 16.

11 JUDGE SOEFFING: I think we're up to
12 17.

13 MR. MANN: Oh I'm sorry, 17.

14 JUDGE SOEFFING: Go ahead, 17. The
15 clerk will mark it as Government Exhibit 17.

16 MR. MANN: And offer this into the
17 record.

18 JUDGE SOEFFING: Okay. As an exhibit?

19 MR. MANN: Yes.

20 JUDGE SOEFFING: Okay. Any objection,
21 Mr. Phelps?

22 MR. PHELPS: Yes, this is something
23 that was not disclosed. I think it can be used
24 potentially for impeachment purposes, but not to
25 be entered into the record as substantive

1 evidence.

2 JUDGE SOEFFING: Well, it's going to
3 be entered into the record. It's been talked
4 about and it needs to be made part of the record
5 just like the other documents that have been
6 discussed, so it'll be marked for identification
7 as Government Exhibit 17. I think she's admitted
8 that it's accurate and that she wrote it, so we
9 will go ahead and make it Government Exhibit 17
10 and put it into evidence.

11 (Whereupon, the above-referred to
12 document was marked as Government Exhibit No. 17
13 for identification.)

14 (Whereupon, the above-referred to
15 document was received into evidence as Government
16 Exhibit No. 17.)

17 MR. MANN: Thank you, Your Honor.

18 BY MR. MANN:

19 Q There was discussion about abuse
20 liability and mechanisms of action, did I get
21 that correct?

22 A Correct.

23 Q Okay, and mechanisms of action is not
24 the same as abuse liability?

25 A I would not say so.

1 Q Are they similar?

2 A There are mechanisms of action that
3 are in -- that have to do with abuse liability,
4 but I wouldn't say that those two terms are so,
5 like, the same.

6 Q But measuring mechanisms of action is
7 also measuring abuse liabilities, is it not?

8 A It depends on the mechanism that
9 you're referring to.

10 Q Do you believe that hallucinogenics
11 cause no harm?

12 A I wouldn't say no harm.

13 Q Do you believe they are safe?

14 A Generally speaking, yes.

15 Q How can something that causes harm be
16 safe?

17 A I think that depends how you qualify
18 harm and qualify safe, and it fully depends on
19 the individual's experience on what they deem a
20 harmful or a safe experience.

21 Q Well, I believe you testified that
22 they could cause harm, o how can they be safe?

23 A I don't know how to answer that
24 question.

25 Q All right, that's all I have. Thank

1 you.

2 JUDGE SOEFFING: Thank you, Mr. Mann.
3 Thank you for your testimony, Dr. Jaster, you are
4 excused. I direct you not to discuss your
5 testimony with anyone except your counsel until
6 the conclusion of the hearing.

7 THE WITNESS: Thank you, Your Honor.

8 JUDGE SOEFFING: We have about another
9 half an hour. Mr. Phelps, you can go ahead and
10 call your next witness.

11 MR. PHELPS: Certainly. Petitioners
12 call Dr. Raul Ramos.

13 JUDGE SOEFFING: All right, Dr. Ramos,
14 would you please raise your right hand?
15 WHEREUPON,

16 RAUL RAMOS
17 was called for examination by Counsel for the
18 Petitioners, having been first duly sworn,
19 assumed the witness stand, was examined and
20 testified as follows:

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

24 THE WITNESS: My name is Raul Ramos.
25 And my name is spelled R-A-U-L R-A-M-O-S.

1 JUDGE SOEFFING: Thank you. Counsel,
2 you may inquire.

3 MR. PHELPS: Thank you, Your Honor.
4 Good afternoon, Dr. Ramos. I'd like to begin by
5 pointing your attention to what's been marked as
6 -- for identification purposes as SSDP Ramos
7 Exhibit 81.

8 THE WITNESS: Thank you.

9 DIRECT EXAMINATION

10 BY MR. PHELPS:

11 Q Are you -- do you recognize this
12 document?

13 A Yes, it's my CV.

14 Q And did you write this?

15 A Yes, I've authored the whole document.

16 Q And would you say that this document
17 as it's presented to you today is an accurate
18 representation?

19 A Yes. It is only missing a
20 presentation I gave recently at a symposium for
21 rising stars in neuroscience research.

22 Q Okay, but it's an accurate
23 representation of your CV as it was when you
24 provided it through the discovery process?

25 A Yes.

1 Q Okay.

2 MR. PHELPS: Your Honor, we would move
3 to admit Exhibit 81.

4 JUDGE SOEFFING: Okay, Mr. Mann, any
5 objection?

6 MR. MANN: No objection.

7 JUDGE SOEFFING: Okay. Petitioner's
8 exhibit marked for identification Number 81 has
9 been offered. In the absence of objection, it is
10 received in the record as Petitioner's Exhibit
11 81. It's in, you may use it.

12 (Whereupon, the above-referred to
13 document was received into evidence as Petitioner
14 Exhibit No. 81.)

15 BY MR. PHELPS:

16 Q Dr. Ramos, what degrees do you hold?

17 A I have a bachelor of arts and a PhD.

18 Q Where did pursue your undergraduate
19 education?

20 A I pursued my undergraduate education
21 at Texas A&M International University located in
22 Laredo, Texas.

23 Q That's an affiliate of the Texas A&M
24 University based in College Station?

25 A Yes. They would call it a sister

1 school.

2 Q What did you study as an
3 undergraduate?

4 A As an undergraduate I majored in
5 psychology and I minored in biology. I also took
6 enough chemistry courses to qualify for a major
7 in chemistry. My curriculum as an undergraduate
8 included classes in cell and molecular biology,
9 biological psychology, chemistry, inorganic
10 chemistry, organic chemistry, statistics, and it
11 was a very broad scientific curriculum.

12 Q And where did you pursue your PhD?

13 A I pursued my PhD at Brandeis
14 University in Waltham, Massachusetts.

15 What do you hold your PhD in?

16 A My PhD is granted in neuroscience.

17 Q And can you talk to us about your PhD
18 coursework curriculum?

19 A Yes. During the duration of my PhD
20 the curriculum included a course on general
21 principles in neuroscience, as well as more
22 advanced courses that cover sound molecular
23 concepts of neuroscience including neuronal
24 excitability and synaptic plasticity, as well as
25 systems neuroscience. I also took courses on

1 advanced optics, advanced statistics, and I think
2 that covers the majority of my PhD curriculum.

3 Q In addition to your curriculum, what
4 else did your PhD program consist of?

5 A In addition to the course curriculum,
6 my PhD program consisted of four rotations
7 through different laboratories at Brandeis that
8 allowed me to gain a wide breadth of experimental
9 neuroscience research, and it also included my
10 dissertation research which I pursued for
11 approximately four to five years.

12 And the four different labs
13 that you did the rotation on, were those
14 specifically related to psychedelics in any way?

15 A Those rotations were not related to
16 psychedelics.

17 Q Okay. Can you tell me about your
18 dissertation research?

19 A Yes. For my dissertation I studied
20 the synaptic plasticity mechanisms that are
21 important for learning and memory. So what that
22 means is I studied how our brain changes and the
23 cells in our brains change at the molecular level
24 to empower animals to learn and alter and change
25 their behavior as a consequence of having

1 learned.

2 Q And can you explain just a little bit
3 of the testing or the research protocols or
4 methods that you used for that dissertation?

5 A Certainly. My dissertation research
6 included many methods in neuroscience that are
7 really important for modern experimental
8 neuroscience. So I did -- I used techniques that
9 could be considered cell and molecular
10 neuroscience techniques, so at the smaller scale.
11 I also used physiology techniques that allowed us
12 to -- that allow us to understand how changes in
13 cells drive changes in animal behavior.

14 I performed several behavioral
15 experiments and I'm -- also have a wide expertise
16 in animal behavior experiments. And so cell
17 molecular experiments, physiology experiments,
18 behavioral experiments, it really is -- expands
19 the gamut of experimental neuroscience.

20 Q So what scale of biology has your
21 neuroscience research occurred over?

22 A Yeah, so my neuroscience research has
23 occurred over a broad scale of biology. So
24 biology can take place at many different distinct
25 levels. And so you could imagine doing

1 experiments at the cell molecular level, you can
2 imagine doing experiments focusing on specific
3 tissues or organs, or experiments in the entire
4 animal while it's awake and behaving.

5 My experiments have basically gone
6 from cells and molecules all the way up to awake
7 and behaving animals, and I have done experiments
8 in vitro, in vivo, and ex vivo, which means I
9 have done them in cells on a glass, in living
10 animals, and in isolated tissues from animals
11 that were recently alive, and in tissues that
12 have been fixed and prepared for further
13 examination.

14 Q And as a scientific researcher what is
15 the significance of working across these scales?

16 A It gives us the opportunity to ask
17 questions more deeply and determine more deeply a
18 mechanistic insight into how the biology is
19 working, so when we want to understand how
20 something is working we really want a
21 comprehensive picture of what's going on, and by
22 having this broad expertise it allows me to
23 determine a more comprehensive picture.

24 Q Dr. Ramos, where has your research
25 been published?

1 A My research has been published in
2 Nature Neuroscience, Current Biology, and
3 Frontiers in Cellular Neuroscience.

4 Q And can you tell me a little bit more
5 about what those publications are?

6 A Yes. These publications I would argue
7 are highly esteemed peer-reviewed journals that
8 are well respected in the neuroscience community.

9 Q And in addition to the curriculum of
10 your PhD program and your dissertation research,
11 do you have any other relevant educational
12 experience?

13 A Yes, I trained in the neurobiology
14 course at the Marine Biological Laboratory in
15 Woods Hole, Massachusetts. This course is a
16 premier, world-renowned course for training
17 advanced experimental neuroscience techniques.
18 The course actually has a history of training
19 many people who went on to become Nobel
20 laureates. And after I participated in the
21 course as a student, I was invited to teach in
22 the course and teach advanced physiology
23 techniques.

24 Q What does it take to get accepted into
25 that program?

1 A It's incredibly competitive.

2 Q And what, do you apply, are you
3 selected, how do you --

4 A Yeah, you have to apply and be
5 selected. I am not aware of the criteria of
6 selection as I was not a part of the selection
7 committee, but it's a highly competitive process,
8 and many researchers from all over the world
9 apply every year.

10 Q And then you said after you completed
11 that, you actually went back to teach in that
12 program?

13 A Yes, I was a student in 2018, and then
14 I was invited back to teach in 2019 and 2021.
15 And then I actually was invited to help manage
16 the entire course in 2022 and 2023.

17 Q How many other students from your 2018
18 cohort, if you're aware, return to teach in the
19 following years? Sorry, real quick, how big was
20 the cohort in that class? How many people do
21 they accept for this program?

22 A If I remember correctly, it was
23 approximately like 20 students that year. And if
24 memory serves I think that no one who was a
25 fellow student got invited to teach the following

1 year.

2 Q None that you're aware of?

3 A None that I'm aware of.

4 Q Okay. And this was at something known
5 as the Marine Biological Laboratory, does that --
6 is that related to marine biology?

7 A The Marine Biological Laboratory is an
8 institute that has a history of studying marine
9 biology, but it is also an institute where many
10 other disciplines of science gather to advance
11 their experimental approaches, and it has a long,
12 rich history in the field of neuroscience, but
13 the work with respect to neuroscience now, and
14 the course, is not necessarily related to marine
15 biology. In other words it's just a name.

16 Q And we in our supplemental pre-hearing
17 statement, we had you listed as an expert in the
18 study of the effects of psychedelics on
19 somatosensory perception, or touch, itch, and
20 pain. Can -- do you have any other experiences
21 from when you were pursuing your PhD that are
22 relevant to your expertise in pain?

23 A Yes, when I was pursuing my PhD, I was
24 awarded the Brandeis University Prize
25 Instructorship, and this is also a very

1 competitive award. It's only awarded to one or
2 two students in the department every year, and
3 what this award did was it gave me the
4 opportunity to design from scratch and teach an
5 advanced course on the neurobiology of
6 somatosensation, and specifically that means it
7 was an advanced course on the neuroscience of
8 touch, itch, and pain.

9 Q Okay, can you can you give a little
10 bit more detail about what somatosensory
11 perception means?

12 A Yes, so, soma is the Greek word for
13 body, so somato, body sensation. Somatosensation
14 refers to all of the rich senses that we
15 experience throughout our body, and so that
16 includes touch, itch, and pain but it's not
17 limited to those sensations either. It includes
18 thermal sensations such as hot and cold, and
19 proprioception, so where our limbs are in space.
20 It can involve soft pressure, deep pressure
21 vibration, and the list goes on. It's a very
22 rich umbrella of sensations.

23 Q So it's the scientific way of saying
24 feelings sensations?

25 A Through our body.

1 Q Through your body, yes. How is that
2 different? You had it specifically in your
3 feeling sensations in your body, how is that
4 different than other ways you may feel
5 sensations?

6 A What I mean is that it's specifically
7 tied to -- the reason I say in our body is
8 because it's specifically tied to sensory neurons
9 that innervate our body, and the distinction that
10 I'm trying to draw is for example, perceiving
11 vision through our eyes or perceiving sound
12 through our ears, this is perceiving sensation
13 through our -- through basically the entirety of
14 our body. It actually includes the exterior of
15 our body, so when something touches our skin, and
16 the interiors of our body such as feeling our
17 stomach stretch when we're bloated.

18 And does that include feeling
19 things in your mind?

20 A No.

21 Q Is that different? How is that
22 different?

23 A Feeling things in your mind does not
24 activate sensory neurons, and somatosensation is
25 the study of the perception evoked by the

1 activation of the somatosensory neurons. Feeling
2 something in your mind is a cognitive process
3 that takes place largely in the brain.

4 Q And what is your current title or
5 position?

6 A My current title and position, so, I
7 currently hold two titles and two affiliations,
8 so I am a Miller postdoc fellow with the Miller
9 Institute for Basic Research in Science at UC
10 Berkeley, and I am also a Hanna Gray Fellow with
11 the Howard Hughes Medical Institute, abbreviated
12 often as HHMI.

13 And for those of us who may
14 not be familiar with those, what is your
15 post-doctoral fellowship? Could you just kind of
16 describe broadly what that position entails?

17 A Yes. So people who become post-doc
18 fellows often are on the academic career path,
19 and so, being a post-doc fellow is usually the
20 stage that you are at before you become the
21 principal investigator of your own lab. It's
22 kind of the last stepping stone to becoming an
23 independent investigator at a university.

24 Q Okay. And what about the Hanna Gray
25 fellow -- can -- fellowship. Can you describe in

1 general how that works, and then we'll -- we can
2 get into your specific program, but what is that
3 program as a whole?

4 A So, the Hanna Gray fellowship is a --
5 it is not -- the Hanna Gray fellowship is one of
6 the most competitive post-doctoral fellowships in
7 the entire country, if not the most coveted of
8 fellowships for biomedical researchers. The
9 reason is it is as such is because it provides
10 funding for eight years. It provides four years
11 of funding while you're a post-doc and then four
12 years of funding as a principal investigator, but
13 it gives you this funding before you become a
14 principal investigator, so people call it a
15 transition award.

16 And so the rate of this awards is that
17 HHMI is investing in you early because they think
18 that your research is on the path to be highly
19 influential and highly successful.

20 Q And what is HHMI?

21 A HHMI, or the Howard Hughes Medical
22 Institute is a biomedical philanthropy that funds
23 a significant amount of research across the
24 United States. Many scientists across the U.S.
25 want to be affiliated with HHMI because they

1 provide a lot of funding in parallel to funding
2 that other scientists receive from other sources,
3 such as the federal government.

4 Q Do you know, or are you aware of how
5 many people are awarded that fellowship yearly?

6 A I -- the HHMI keeps the details for
7 the most part private, but around every year
8 there are 20 applicants that are selected for the
9 award, and I've heard that the amount of
10 applications that they receive is deep into the
11 hundreds.

12 Q And so you said this fellowship, they
13 take people on in this because they believe in
14 their long-term research projects?

15 A Yes, because they're investing all of
16 this money in you, and they're doing that because
17 they think that what you're doing is going to go
18 somewhere.

19 Q How much money?

20 A \$1,500,000.

21 Q That's for a period of eight years?

22 A Yes.

23 Q And just to be clear, that's -- how is
24 that \$1,500,000 spent? Is that just a salary?

25 A It changes throughout different cycles

1 of the grant. As a post-doctoral fellow the
2 first four years includes salary, as well as
3 additional funds for me to support my research,
4 so these are funds that I can use to purchase
5 anything that I might need. And then when you
6 transition to being a faculty at a research
7 institute, the funds change as well, and at this
8 moment I don't recall the exact nature of them.

9 Q Okay, but it's money to be spent
10 supporting the research itself, not just --

11 A It's money that goes directly to my
12 research and nothing else, it's all for my
13 research.

14 Q So what was your research that HHMI
15 awarded you this grant for?

16 A The research proposal that I wrote for
17 HHMI was in its entirety about studying DOI in
18 the context of pain.

19 Q Can you explain a little bit more in
20 detail what that -- yeah?

21 A Yeah, so for every grant, you have to
22 write a research proposal, and in my proposal I
23 wrote about studying how DOI alters our
24 perception of -- and sorry, I misspoke earlier --
25 how DOI alters our perception of touch and pain.

1 Q And --

2 JUDGE SOEFFING: Mr. Phelps, we are
3 closing in rapidly on 5:00, which is our hard
4 stop time, so if you have a couple more questions
5 that you want to get out, that'd be fine, but
6 then we're going to have to stop for the day.

7 MR. PHELPS: Oh --

8 JUDGE SOEFFING: Whenever's a good
9 time in the next two or three questions.

10 BY MR. PHELPS:

11 Q Okay. Certainly. So how would you
12 describe the current focus of your research then?

13 A Currently at UC Berkeley I study how
14 DOI changes our perception of touch and pain.

15 Q And how are you studying that?

16 A I'm studying that in animal models,
17 and so what I do is I can both isolate pain
18 neurons from an animal and wash on DOI onto these
19 neurons and ask how DOI changes the functional
20 properties of these neurons, but I can also
21 inject DOI into animals and measure behaviors
22 that are related to pain.

23 Q And why did you choose to use DOI in
24 this project?

25 Because it's not a scheduled

1 substance.

2 Q Were there other substances that you
3 were considering for this -- are there other
4 substances that could be used to do this type of
5 research?

6 A Yes. Before I started at Berkeley I
7 received a three-year grant to pursue a research
8 plan that involves studying what I'm studying now
9 but with -- in the context of MDMA.

10 And so I wrote this three-year
11 proposal and was funded a quarter of \$1,000,000
12 to go start my research at Berkeley, but when I
13 got there, because the lab that I am in does not
14 have a Schedule I license, I would have to go
15 through the process, and in conferring with
16 scientists at Berkeley, some of which are in labs
17 that have Schedule I license, it seemed like the
18 the number -- the amount of time that most people
19 had to -- the amount of time that it took to get
20 a Schedule I license -- and it usually ended up
21 being around a year -- and because a year was one
22 third of the entire funding period that was not
23 going to be conducive to me accomplishing my
24 research goals, and so I needed to come up with
25 an alternative plan that would allow me to pursue

1 my research in a timeframe that made sense. And
2 so I began working with DOI.

3 Q Okay. And looking at your
4 publications, do you have any published research
5 using DOI?

6 A No.

7 Q And why is that?

8 A Because I'm currently doing that
9 research right now.

10 Q And what is the projected timeline for
11 that research?

12 A I've been doing this research for two
13 years now, and I think that to have a suitable
14 amount of work for publication I need two more
15 years.

16 JUDGE SOEFFING: Is that a good
17 stopping point for you, Mr. Phelps?

18 MR. PHELPS: Yes, Your Honor, I was
19 just going to conclude by moving to admit Dr.
20 Ramos as an expert in the study of the effects of
21 psychedelics on somatosensory perception.

22 JUDGE SOEFFING: Okay. Mr. Mann, any
23 objection?

24 MR. MANN: Yeah, I would like to do
25 voir dire.

1 JUDGE SOEFFING: Okay. So we'll pick
2 up with that tomorrow, then. Dr. Ramos, you're
3 excused for the day.

4 THE WITNESS: Thank you.

5 JUDGE SOEFFING: You are still on the
6 witness stand so I direct you not to discuss your
7 testimony with anybody until we get back tomorrow
8 and pick up your testimony again. We are off the
9 record.

10 (Whereupon, the above-entitled matter
11 went off the record at 5:00 p.m.)
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This is to certify that the foregoing transcript

In the matter of: Schedules of Controlled Substances

Before: US Drug Enforcement Administration

Date: 11-13-24

Place: Arlington, Virginia

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