

UNITED STATES DEPARTMENT OF JUSTICE  
DRUG ENFORCEMENT ADMINISTRATION

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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 :  
:

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Monday,  
November 18, 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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On Behalf of the Science Policy Counsel,  
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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

|                   |      |      |      |      |
|-------------------|------|------|------|------|
| Joseph Palamar    | 1029 | 1108 | 1120 | 1124 |
| Mario de la       |      |      |      |      |
| Fuente Revenga    | 1128 | 1181 | 1200 | 1209 |
| Theresa Carbonaro | 1219 | 1239 | 1262 | 1263 |

## EXHIBITS MRKD RECD

## Petitioner

|    |                                                                                                            |       |      |
|----|------------------------------------------------------------------------------------------------------------|-------|------|
| 8  | Journal Article. . . . .                                                                                   | .1148 | 1148 |
| 9  | Article attempting to identify<br>therapeutic Responses that emerge<br>from Stimulation of Serotonin 2A. . | .1150 | 1150 |
| 10 | Technical Paper on improving full<br>automated Detection of<br>head-twitch. . . . .                        | .1154 | 1154 |
| 11 | 24-24 SSDP/Ramos Exhibit 11. . . . .                                                                       | .1207 | 1207 |
| 19 | Journal Article 2. . . . .                                                                                 | .1192 | 1192 |
| 82 | CV of Mario de la Fuente Revenga . .                                                                       | .1138 | 1138 |
| 84 | 24-24 SSDP/Ramos Exhibit 84. . . . .                                                                       | .1045 | 1045 |
| 85 | 24-24 SSDP/Ramos Exhibit 85. . . . .                                                                       | .1061 | 1061 |
| 90 | Subpoena . . . . .                                                                                         | .1026 | --   |

## Government

|    |                                                                         |       |      |
|----|-------------------------------------------------------------------------|-------|------|
| 18 | HHS's Evaluation or Assessment of<br>Abuse Potential of Drugs . . . . . | .1219 | 1219 |
|----|-------------------------------------------------------------------------|-------|------|

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

2 9:07 a.m.

3 JUDGE SOEFFING: Good morning everyone.  
4 Welcome back. Before we get started, I do have  
5 from the Petitioners, a request for a subpoena.

6 Mr. Phelps, you filed that yesterday?

7 MR. PHELPS: Yes. That's correct,  
8 Your Honor. In speaking with Dr. de la Fuente  
9 Revenga, it does look like he's worked things out  
10 with his employer. He should be able to be with  
11 us this afternoon.

12 So, it's not as necessary as we  
13 thought it maybe would be. If the Court's  
14 inclined, we would still accept that, he could  
15 have to provide to HR. But, it looks like it's  
16 not going to be the issue we thought it might.

17 (Whereupon, the above-referred to  
18 document was marked for identification as  
19 Petitioners Exhibit No. 90.)

20 JUDGE SOEFFING: Okay. I don't see if  
21 you've got service on it. Government, did you  
22 receive a copy of that subpoena?

23 MR. MANN: We received a copy by  
24 email, I think, it was yesterday, yes.

25 JUDGE SOEFFING: Okay. Well, Mr.

1       Phelps, there needs to be good cause. If it's no  
2       longer needed, it is, of course the subpoena  
3       deadline was set by the prehearing ruling that  
4       was October 28th for the subpoena deadline.

5               If there's good cause for me to issue  
6       it, if there's no objection from the Government,  
7       I'll issue it.

8               But, it doesn't sound like there's  
9       good cause if he doesn't need it for his  
10      employer.

11              MR. PHELPS: I mean, the good -- the  
12      good cause was just essentially we had  
13      anticipated him being able to testify Friday.

14              Because of the technical issues that  
15      he wasn't able to -- and that just changed the  
16      circumstances.

17              So, we'll leave that to your  
18      discretion, Your Honor.

19              JUDGE SOEFFING: Okay. Well, I think  
20      I won't issue it unless there's some sort of  
21      issue with him being able to appear.

22              In which case, I'll let you address  
23      that again to the court. And, I can make a  
24      ruling as to whether there's good cause and  
25      whether I will issue it.

1 But, it sounds right now it's not,  
2 like, it's not needed.

3 MR. PHELPS: That's correct. We did  
4 speak with him this morning and he was able to  
5 get that worked out, we think, so.

6 JUDGE SOEFFING: Okay. All right.  
7 Very good. All right, Mr. Phelps, then you may  
8 call your next witness.

9 MR. PHELPS: Petitioners call Dr.  
10 Joseph Palamar.

11 JUDGE SOEFFING: Okay. Dr. Palamar,  
12 can you hear me?

13 DR. PALAMAR: Yes. Can you hear me?

14 JUDGE SOEFFING: Yes. Okay. So, Dr.  
15 Palamar is on the VTC. Dr. Palamar, please raise  
16 your right hand.

17 WHEREUPON,

18 DR. JOSEPH PALAMAR  
19 was called for examination by Counsel for the  
20 Petitioner, having been first duly sworn, assumed  
21 the witness stand, was examined, and testified as  
22 follows:

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

1 DR. PALAMAR: Joseph Palamar. My last  
2 name is spelled P-A-L-A-M-A-R.

3 JUDGE SOEFFING: Okay. And first name  
4 spelled?

5 DR. PALAMAR: Joseph, J-O-S-E-P-H.

6 JUDGE SOEFFING: Thank you. Doctor,  
7 during your testimony, you should not look at any  
8 materials or documents except exhibits you are  
9 directed to look at by counsel or me.

10 Do you understand?

11 DR. PALAMAR: Yes.

12 JUDGE SOEFFING: Okay. Counsel, you  
13 may inquire.

14 DIRECT EXAMINATION

15 BY MR. PHELPS:

16 Q Thank you, Your Honor. Good morning,  
17 Dr. Palamar. How are you doing today?

18 A All right. How are you?

19 Q Good, good. Dr. Palamar, what are  
20 some of the agencies where you receive the data  
21 you use for the work that you do?

22 A Well --

23 MR. MANN: Objection, Your Honor.  
24 Vague.

25 JUDGE SOEFFING: Overruled.

1 MR. PHELPS: You may answer.

2 DR. PALAMAR: There's different ways  
3 of receiving. I mean, a lot of the data I  
4 receive are publicly available.

5 For example, national data stacks  
6 like, NSDUH, Monitoring the Future, and others.  
7 You can request it or, if you know somebody, you  
8 could possibly obtain the data.

9 For example, DEA data, you could sign  
10 up for a public query system and obtain NFLIS  
11 data.

12 BY MR. PHELPS:

13 Q And -- have you been contacted by the  
14 DEA about the data that you've requested from  
15 them in the past?

16 A Yes. I have requested Freedom of  
17 Information Act requests before. A couple of  
18 times in the past where they didn't fulfill it,  
19 once earlier this year they did fulfill it.

20 And a couple of weeks ago they  
21 appeared to deny one. It was very similar to a  
22 previous one, although, I think they might have  
23 just denied the fact that it was being expedited.  
24 I'm not sure.

25 And I was also contacted by a DEA

1 agent last week actually, about one of my papers.

2 Q I'd like to draw your attention to  
3 that last contact that you just mentioned. Do  
4 you have that available?

5 A That last email from last week? I do.

6 Q And do you recognize that --

7 MR. MANN: Objection, Your Honor.

8 First of all, can we lay some foundation for what  
9 data we're talking about?

10 And secondly, the witness was  
11 instructed not to look at any notes. And there  
12 has in front of him, notes in violation of the  
13 Court's order.

14 I would move that this witness be  
15 stricken for violating your own orders.

16 MR. PHELPS: And Your Honor, we  
17 haven't been able to actually have this admitted  
18 to have an exhibit for him to refer to. I have  
19 them here.

20 But because of the timing of this, we  
21 have not been able to admit it. So, I don't have  
22 an exhibit number for him to refer to, to be able  
23 to look at that.

24 And that's --

25 JUDGE SOEFFING: Well, I -- you know,

1       you're asking him to look at something that's not  
2       been presented to me to look at.

3               And, it sounds like opposing counsel  
4       hasn't seen it either.

5               MR. PHELPS:  Opposing --

6               JUDGE SOEFFING:  Is that right?

7               MR. MANN:  Your Honor, we have two  
8       pages of an email.  But, again, I don't know what  
9       we're talking about here.

10              He's talking about data and talking  
11      about things being refused and trying to get  
12      data.  There's been no foundation at all.

13              We're just going down some long road,  
14      and we have no idea what the subject matter of  
15      this even is.  This exhibit, supposed exhibit, is  
16      a hearsay statement.

17              JUDGE SOEFFING:  Well, hold on.  Let  
18      me see what, let me see the document that we're  
19      talking about?

20              MR. PHELPS:  May I approach, Your  
21      Honor?

22              JUDGE SOEFFING:  Yes.  You may give a  
23      copy to the law clerk.

24              Mr. Phelps, this is an email.  It  
25      appears dated from Wednesday of last week,

1 November 13th.

2 MR. PHELPS: That's correct, Your  
3 Honor.

4 JUDGE SOEFFING: Okay. So, this is  
5 being presented for the first time here. You  
6 have to give me some sort of good cause as to why  
7 you want to have this late exhibit referenced.

8 MR. PHELPS: Well, we would have --  
9 it's late because this is -- this is  
10 communication that our witness received from the  
11 DEA during the pendency of this hearing, while  
12 this hearing has been going on.

13 And so, in candor to the Tribunal, I  
14 think it is important to know that that  
15 communication is there. That's the reason that  
16 we're bringing this up now.

17 And it was just brought to our  
18 attention. So, that's the reason, Your Honor.

19 JUDGE SOEFFING: Well, this is a  
20 document that was created after the hearing  
21 started. So, I'm -- you know, it was certainly  
22 not able to be disclosed to the Government.

23 I think I'm seeing it for the first  
24 time. I think the Government's seeing it for the  
25 first time. It's obviously not covered in the

1 prehearing statement summary for this witness.

2 So, I'm inclined not to, you know,  
3 receive this as evidence.

4 MR. PHELPS: I guess, Your Honor, we  
5 -- and, the sub -- the bottom line is, our  
6 concern is that there's been multiple contacts  
7 from the Agency of our witness, while this  
8 proceeding has been going on.

9 That's our concern. It's not the  
10 substance of what's in there. It's the timing  
11 that we thought was important to bring to this  
12 Court's attention.

13 I'm fairly confident that if we were  
14 trying to contact the Government's expert  
15 witnesses in the middle of the hearing, that that  
16 may be something that they thought was worth  
17 addressing.

18 JUDGE SOEFFING: Are you saying that  
19 the subject matter has to do with this hearing?

20 MR. PHELPS: Not -- not maybe  
21 directly. But it is a critique of the data  
22 analysis and his methods of analysis, which is  
23 absolutely the subject of his testimony.

24 He's an expert in drug use  
25 epidemiology. His prehearing statement does

1 describe how his methodology and things that he  
2 uses, and this is a questioning or criticism of  
3 that methodology.

4 If this is something that had been  
5 received prior to the hearing, we certainly would  
6 have introduced it and used it to, you know, to  
7 establish his methodology and, you know, avoid  
8 potentially this being brought up as a criticism  
9 on cross.

10 JUDGE SOEFFING: Mr. Mann?

11 MR. MANN: Well, first of all Judge,  
12 Dr. Palamar is not a represented party.  
13 Secondly, there is no way that the DEA can  
14 control the communications between people who  
15 obviously are communicating with each other.

16 Also, this document is dated the 13th  
17 of November. That's five days ago. It's now  
18 just being presented to us now.

19 And again, I don't even have any idea  
20 what the relevance of this data is. I think some  
21 kind of foundation needs to be levied -- laid  
22 before we even discuss whether this should be  
23 admitted.

24 MR. PHELPS: And I'll be frank with  
25 the Court, the next thing -- I understand that it

1 is a large agency and that there is, you know,  
2 there may not be controls within this Orlando  
3 office specifically.

4 But I'll go ahead and let the Court  
5 know the next exhibit that we had that was a  
6 communication Dr. Palamar received on Friday, was  
7 directly from the Office of Chief Counsel.

8 And so, that seems like a part of the  
9 Agency that should be aware of witnesses  
10 testifying in their own building. We can get  
11 into those exhibits next if the Court would like  
12 to see them, but.

13 JUDGE SOEFFING: Well, I don't think  
14 this is particularly relevant to what he was  
15 going to testify to. It is a late document. It  
16 wasn't created until after the hearing was  
17 started.

18 I would just rather hear, you know,  
19 what his testimony was going to be, is going to  
20 be, based on the previous statement. I don't see  
21 how this, I just don't see how this really  
22 applies at this point.

23 So, I'm going to sustain the  
24 Government's objection at this point. And I will  
25 not receive this exhibit.

1 MR. PHELPS: Understood, Your Honor.  
2 Dr. Palamar, I'd like to direct your attention to  
3 what's been marked for identification purposes as  
4 SSDP/Ramos Exhibit 84. It looks like the title  
5 at the top is curriculum Vitae.

6 DR. PALAMAR: Yes. I have my CV.

7 BY MR. PHELPS:

8 Q Do you have that available?

9 A Yes.

10 Q Do you recognize the document in front  
11 of you?

12 A Yes.

13 Q And are you familiar with the contents  
14 of that document?

15 A I'm very familiar.

16 Q Did you create this document?

17 A Yes.

18 Q And -- how many pages is the document  
19 you have in front of you, sir?

20 A I have multiple versions of my -- I  
21 update my CV almost every day. So, my current  
22 version is 54 pages, so.

23 Q So, the -- the document I'm looking at  
24 has a date prepared of 8/29/2024.

25 A Yeah. I update my CV almost every

1 day. If you want me dig up the exact copy that I  
2 emailed to you, I could pull it up right now.

3 Q That would be the document we'll be  
4 referring to.

5 A Okay, yeah. It was prepared on 8/29,  
6 right?

7 Q That's correct, Dr. Palamar.

8 A Okay.

9 MR. MANN: Your Honor, I'm sorry.  
10 What are we doing here?

11 MR. PHELPS: I want to make --

12 JUDGE SOEFFING: So, Mr. Phelps is  
13 trying to make sure that the witness is looking  
14 at his CV that has been presented to the Tribunal  
15 and to the Government.

16 MR. MANN: So, is he looking at  
17 Exhibit Number 84? Or is he looking at something  
18 else?

19 MR. PHELPS: Well, that --

20 JUDGE SOEFFING: Well, he should be  
21 looking at Exhibit 84, Mr. Phelps.

22 MR. PHELPS: So, I mean, it's the --

23 JUDGE SOEFFING: The Tribunal did  
24 instruct the parties that because of the VTC  
25 witnesses and issues with versions control that

1 it would be best to have, the parties have paper  
2 copies of any exhibit that they were being asked  
3 about.

4 If there's an electronic version that  
5 he can access that is appropriately identified as  
6 Petitioners' Exhibit 84 for identification,  
7 that's acceptable.

8 But, we do need to make sure that he's  
9 looking at everything that's the same that we  
10 have.

11 MR. MANN: Again, he's been instructed  
12 not to look at any documents other than the  
13 exhibits. And if he's looking at something else,  
14 again, that's the second time he has violated  
15 your orders.

16 MR. PHELPS: And, Your Honor, we just  
17 want to make sure that he has the correct one.  
18 We know that he's been given that. He has that.

19 I -- it's his CV. I mean, that's not  
20 a --

21 JUDGE SOEFFING: Yes. Well, it's his  
22 CV, we need to make sure he's looking at exactly  
23 what we're looking at if we're going to be  
24 talking about the document.

25 So, I mean, does he have one that's

1 appropriately labeled and identified as, you  
2 know, SSDP/Ramos Exhibit 84?

3 DR. PALAMAR: I have the exact CV.

4 MR. PHELPS: What?

5 DR. PALAMAR: I have the exact CV I  
6 sent to Mr. Phelps. I found that version.

7 MR. PHELPS: Can you tell us the  
8 number of pages on that, Dr. Palamar?

9 DR. PALAMAR: Yeah. This is 63 pages.

10 MR. MANN: Your Honor, I want to ask  
11 that you -- if you could ask the witness, what is  
12 at the top of that document, please?

13 JUDGE SOEFFING: What's at the top of  
14 the document, Mr. Palamar?

15 DR. PALAMAR: It's the date it was  
16 prepared. Date prepared 8/29/2024.

17 JUDGE SOEFFING: Okay.

18 MR. MANN: And is there any other  
19 markings that --

20 JUDGE SOEFFING: Hold on. Hold on.  
21 I'll let you --

22 MR. MANN: All right. Sure.

23 JUDGE SOEFFING: I'll let you ask  
24 about the document after Mr. Phelps attempts to  
25 lay a foundation. Mr. Phelps?

1 MR. PHELPS: Yes. Thank you. I just  
2 want to make sure we handle this the right way,  
3 Your Honor.

4 So, I guess, Your Honor, here's my  
5 concern. It is the document. It is the same  
6 document. It is the CV.

7 I don't want to get hung up on the  
8 labeling at the top. I also don't want to be,  
9 you know, doing anything inappropriate.

10 If he was here in person, I'd be  
11 handing him a paper copy of this. Would it -- if  
12 it's identical to what he has right now, and we  
13 can establish that, would the Court object to us  
14 getting him a copy that has the exhibit number at  
15 the top to satisfy any of the State's concern?

16 There's nothing substantively  
17 different, but --

18 JUDGE SOEFFING: How would you get him  
19 the copy that's properly labeled?

20 MR. PHELPS: We could get it emailed  
21 to him instantly.

22 JUDGE SOEFFING: You may do that. In  
23 the future, they need to have ready access to the  
24 properly labeled exhibits that are going to be  
25 presented to be put into evidence.

1 MR. PHELPS: Absolutely. I do  
2 apologize. I think that was just a  
3 miscommunication.

4 But, it is literally the same  
5 document. So, thank you for the Court's  
6 consideration on that.

7 Just one moment. And I apologize for  
8 the inconvenience to the Court, Your Honor.

9 MR. RUSH: Okay. I found it. I'll  
10 email it.

11 MR. PHELPS: And it has the heading  
12 label?

13 MR. RUSH: Let me check one second,  
14 please.

15 JUDGE SOEFFING: We'll go off the  
16 record.

17 (Whereupon, the above-entitled matter  
18 went off the record at 9:27 a.m. and resumed at  
19 9:32 a.m.)

20 JUDGE SOEFFING: All right. And Mr.  
21 Phelps, you may continue with your direct  
22 examination.

23 MR. PHELPS: Okay. Thank you, Your  
24 Honor.

25 DR. PALAMAR: I have not received the

1 documents.

2 MR. PHELPS: What are --

3 MR. RUSH: Yeah, I'm sorry. The  
4 address was his. I mean, --

5 JUDGE SOEFFING: Off the record.

6 (Whereupon, the above-entitled matter  
7 went off the record at 9:33 a.m. and resumed at  
8 9:37 a.m.)

9 JUDGE SOEFFING: All right. We took  
10 a short break here so that the witness could get  
11 the exhibits for identification that are going to  
12 be referred to.

13 Mr. Phelps, you may ask your next  
14 question.

15 MR. PHELPS: Thank you, Your Honor.  
16 Dr. Palamar, do you have in front of you what's  
17 marked as SSDP/Ramos Exhibit 84?

18 DR. PALAMAR: Yes.

19 BY MR. PHELPS:

20 Q And do you recognize that Exhibit?

21 A Yes. It's my CV.

22 Q And are you familiar with its  
23 contents?

24 A Yes.

25 Q Okay. And could you take a quick --

1       could you tell us how many pages are in that  
2       document?

3               A       Yeah.   According to the label up top  
4       it says 63.

5               Q       Okay.   And you don't have to go  
6       through all 63 pages.   But with a quick skim of  
7       it, does that -- is that the same document that  
8       you provided to us and that was disclosed in the  
9       discovery?

10              A       Yes.

11                     MR. PHELPS:   Your Honor, at this time  
12       we would move to admit what's marked for  
13       identification purposes as SSDP/Ramos Exhibit 84.

14                     JUDGE SOEFFING:   Mr. Mann, any  
15       objections?

16                     MR. MANN:   I'd just like to ask one or  
17       two questions.

18                     JUDGE SOEFFING:   Very good.

19                     MR. MANN:   Dr. Palamar -- I'll stay  
20       here.   What's at the top of the document marked  
21       84?

22                     DR. PALAMAR:   It says docket number  
23       24-24 SSDP/Ramos Exhibit 84.   And then, it says  
24       ID in parentheses.

25                     MR. MANN:   Okay.   Thank you.   That's

1 all. No objection.

2 JUDGE SOEFFING: Okay. All right.  
3 Petitioners' Exhibit marked for identification  
4 Number 84 has been offered. In the absence of  
5 objection, it is received in the record as  
6 Petitioners' Exhibit 84.

7 It's in. You may use it.

8 (Whereupon, the above-referred to  
9 document was received into evidence as  
10 Petitioners Exhibit No. 84.)

11 MR. PHELPS: Thank you, Your Honor.  
12 Dr. Palamar, what degrees do you hold?

13 DR. PALAMAR: So, I have my  
14 associate's in criminal justice. I have my BA in  
15 forensic psychology.

16 My MA, my first master's in  
17 educational psychology. Got my second master's  
18 in public health. And my PhD in public health.

19 BY MR. PHELPS:

20 Q And where did you pursue your original  
21 degree? Your associate's?

22 A The associate's was on Long Island.  
23 I was at Nassau Community College.

24 Q And then how about the bachelor's?

25 A The bachelor's was at John Jay College

1 of Criminal Justice in Manhattan.

2 Q And then what about the rest of your  
3 educational career? Where did you pursue those  
4 degrees?

5 A The three graduate degrees were all  
6 from NYU at the Steinhardt School.

7 Q Thank you. And what do you hold your  
8 PhD in?

9 A Public health.

10 Q Was there any kind of specialization  
11 in that? Or is it a general public health?

12 A It was general public health.

13 Q Okay. And can you tell us a little  
14 bit about your PhD course work curriculum?

15 A Yeah. So, it was a long time ago.  
16 But we took a lot of the standard public health,  
17 you know, core classes.

18 But I focused particularly on  
19 statistics. With a focus, my own specific focus  
20 on drug use.

21 So, whenever there was a project, I  
22 tried to focus on drug related data.

23 Q And in addition to that curriculum,  
24 what else did your PhD program consist of?

25 A I think the core classes, I don't

1 remember specifically other -- the main things I  
2 remember were the statistics classes I took.

3 What else, I took a historical  
4 research class. I -- just the standard public  
5 health courses.

6 Q And outside of just the standard  
7 courses, what else was there in the PhD program  
8 besides just course curriculum?

9 What did you have to do to get that  
10 degree?

11 A My dissertation. So dissertation was  
12 a very big part of the last couple of years.

13 Q And can you talk a little bit about  
14 your dissertation research?

15 A Absolutely. I felt there was a lack  
16 of focus on stigma related to drug use. So, I  
17 focused on that.

18 And I personally oversaw the survey of  
19 over a thousand people, young adults in New York  
20 City, focusing on scales that I developed.

21 And so I published, you know, multiple  
22 papers based on that. I published my  
23 dissertation. And I won the dissertation of the  
24 year award given at NYU Steinhardt based on that  
25 work.

1           Q       And can you describe a little bit  
2 about those methods that you referred to there  
3 that you followed or created?

4           A       Yeah. So, again, I was just -- I was  
5 a student essentially. So, it wasn't the most  
6 difficult stuff at the time.

7                   But, what I did was, I found measures  
8 of a similar topic. And I changed the measures.  
9 I modified them to fit more or less what I was  
10 focusing on, like recreational drug use and the  
11 stigma.

12                   And I tested them. I piloted them.  
13 And then I disseminated my survey, and I got a  
14 whole bunch of people to take it.

15                   And, you know, that led to multiple  
16 papers focusing on the prevalence of drug use,  
17 how it relates to stigma, and so on.

18           Q       And how did that dissertation work  
19 that you did relate specifically to epidemiology?

20           A       Yeah. Because I did focus very much  
21 on the prevalence of drug use and correlates of  
22 drug use. So, I figured prevalence and  
23 correlates largely relate to the epidemiology of  
24 drug use behavior.

25           Q       And could you just explain to us, what

1 is epidemiology?

2 A So, epidemiology in like, the most  
3 basic sense, would explain it as being like,  
4 essentially like the study of the distribution of  
5 diseases typically.

6 But, as a drug use epidemiologist, I  
7 think about it instead of diseases, I focus more  
8 on the way drug use is distributed throughout  
9 society.

10 And, you know, predict who's at risk  
11 factors for drug use as well.

12 Q So, if drug use epidemiology -- okay.  
13 And, roughly, how many peer review articles have  
14 you published on the topic of drug use  
15 epidemiology?

16 A So, that depends on whether or not it  
17 has to be research-based, or if you count  
18 letters.

19 But, if you're talking about regular,  
20 like, research papers, well, again, the CV is now  
21 getting old, because as I mentioned earlier, I  
22 update it nearly every day.

23 But at the time that I submitted this  
24 to you, it was 198 peer reviewed research papers.  
25 Now, it's over 200.

1                   And if you count the research letters,  
2                   which are a little bit lower tier, at the time I  
3                   published 21. So, over 20.

4                   If you put them all together, it's  
5                   over 220.

6                   Q       And what's your current title or  
7                   position?

8                   A       An Associate Professor of Population  
9                   Health.

10                  Q       And where do you do that?

11                  A       I'm at the -- we now call ourselves  
12                  NYU Langone Health. But, you know, specifically  
13                  I'm at the NYU Grossman School of Medicine.

14                  Q       And, could you explain a little bit  
15                  about what kind of courses you teach? Or the  
16                  general course work that you teach?

17                  A       Sure. So, I am 100 percent research  
18                  right now for my position at NYU Langone. But, I  
19                  also have another professorship down at  
20                  Washington Square NYU, down in the Village.

21                         And there I've been teaching  
22                  statistics to undergrads for over 15 years.

23                  Q       And, outside of your professorship, do  
24                  you have any other -- outside of that work, do  
25                  you have any other committee assignments that you

1 do with this work?

2 A They're not necessarily assignments.  
3 But I am involved in plenty of other things.  
4 Like, for example, I'm on multiple editorial  
5 boards for journals at different levels.

6 So, like, I'm an associate editor for  
7 multiple journals. Which is like, essentially a  
8 lot of papers that are submitted by researchers  
9 go through me and I find reviewers for peer  
10 review.

11 So, that's a very big side thing that  
12 I've been focusing on for many years.

13 Q And have you won any awards for your  
14 work in the field of epidemiology for drug use?

15 A Yes. So, awards that I've won, you're  
16 not talking about awards like grant awards, I  
17 assume?

18 Q No. Awards that are recognitions,  
19 yes.

20 A Yes. So, yeah. So, one that stands  
21 out, but the whole list is here, I have the  
22 roundtable from the Biden transition. I put that  
23 under awards because it's also honors.

24 But, anyway, the most recent one aside  
25 from that was in 2019, the AMERSA Manuscript of

1 the Year award, about how people have been using  
2 social media in a risky manner while high. I've  
3 been warning against that.

4 And, I have plenty of other awards  
5 listed there as well.

6 MR. PHELPS: Your Honor, at this time  
7 we would move to have Mr. Palamar, excuse me, Dr.  
8 Palamar admitted as an expert in drug use  
9 epidemiology.

10 JUDGE SOEFFING: Mr. Mann, any  
11 objection?

12 MR. MANN: Just one question.

13 JUDGE SOEFFING: Sure.

14 MR. MANN: Dr. Palamar, you're not  
15 teaching drug use epidemiology currently, are  
16 you?

17 DR. PALAMAR: No, I never taught that.  
18 I've given guest lectures about drug use and drug  
19 policy.

20 But no, I only formally teach  
21 statistics.

22 MR. MANN: We have no objection, Your  
23 Honor.

24 JUDGE SOEFFING: Okay.

25 MR. MANN: Well, we have no objection

1 to him being admitted as expert in the field of  
2 drug use epidemiology.

3 JUDGE SOEFFING: All right. Very  
4 good. The Petitioners have offered Dr. Palamar  
5 as an expert in the field of drug use  
6 epidemiology.

7 In the absence of any objection by the  
8 Government, the Tribunal accepts Dr. Palamar as  
9 an expert in the field of drug use epidemiology.

10 MR. PHELPS: Dr. Palamar, could you  
11 explain the work that you do with the National  
12 Drug Early Warning System?

13 DR. PALAMAR: Sure. I am now Deputy  
14 Director of that center. And what we do, we  
15 monitor emerging drug trends, with a focus on  
16 novel psychoactive substances.

17 We did a focus on quote/unquote  
18 traditional drugs such as cocaine and ecstasy.  
19 But, most of what we try and focus on, are novel  
20 drugs and novel drug trends.

21 For example, novel drugs that have  
22 recently been discovered that become problematic,  
23 such as synthetic cannabinoids, these things that  
24 we call bath salts, synthetic cathinones.

25 We focus heavily on fentanyl and its

1 analogues and other novel opioids. And,  
2 psychedelics as well.

3 BY MR. PHELPS:

4 Q And can -- and how is that work  
5 funded?

6 A That work is funded through the  
7 National Institutes of Health, through NIDA,  
8 through the drug branch.

9 Q And what other kind of NIDA funded  
10 grants have you submitted for or been granted?

11 A I have been granted, aside from as a  
12 principal investigator, as a PI, I think I'm up  
13 to five.

14 So first big grant was a training  
15 grant called a K01. So that was focusing on  
16 developing a tool to monitor use of novel  
17 psychoactive drugs and limited trends.

18 And then I've had multiple grants  
19 focusing particularly on the high-risk nightclub  
20 scene. I focus heavily on the nightclub scene  
21 because they're at very high risk for use of  
22 drugs such as party drugs and psychedelics.

23 I also have a new grant focusing on  
24 the ketamine landscape. I have a new grant  
25 focusing on drug use among older people, age 65

1 and older.

2 I focused on a lot of different topics  
3 all related to the epidemiology of drug use.

4 Q And just so we're clear, what is NIDA?

5 A NIDA is the National Institute of  
6 Drug, on Drug Abuse.

7 Q Okay. And -- do you know why NIDA now  
8 refers to, refers to -- well, let me rephrase  
9 this.

10 Does NIDA, outside of their title,  
11 does NIDA use the term drug abuse in the work  
12 they do today?

13 A Not to my knowledge. We, or drug  
14 researchers in general, have largely been trying  
15 to stay away from the term drug abuse.

16 That has a very specific meaning  
17 related to a book called the DSM-IV, which is now  
18 outdated. The DSM-5, it's like a psychiatric  
19 manual.

20 I don't use it that much. That's more  
21 for, like, psychiatry. But drug abuse is more of  
22 a specific, like, psychiatric term.

23 So, abuse has largely been deemed a  
24 more stigmatizing term. It's overused. So, a  
25 lot of people are staying away from it, even

1       though NIDA has abuse in its title.

2               Q       And, how about on any of your -- on  
3       any of the -- within any of the organizations  
4       that you work or hold committee assignments, do  
5       they -- do they use specifically the concept or  
6       term abuse?

7               MR. MANN:  Objection, Your Honor.  I  
8       think this is getting way beyond what's been  
9       disclosed in the prehearing statement.

10              Also, I don't see the relevance in any  
11      of this.

12              JUDGE SOEFFING:  Mr. Phelps?

13              MR. PHELPS:  Well, this, I mean, this  
14      is entirely relevant, because the term abuse is  
15      what's within the -- it's what's within the  
16      four-factor test, or the eight-factor test as  
17      well as within the four-prong analysis.

18              But what Dr. Palamar is getting at, is  
19      that there is a substantial difference --

20              MR. MANN:  Objection, Your Honor.  Dr.  
21      Palamar needs to testify, not counsel.

22              MR. PHELPS:  Well, I'll be happy to  
23      let him flesh that out and explain the relevance  
24      of the terminology.

25              JUDGE SOEFFING:  Well, I'm not seeing

1 in the prehearing statement where he's going to  
2 testify about the factors. Or, you know, the,  
3 you know, this drug abuse term.

4 So, I'm going to sustain the  
5 objection.

6 MR. PHELPS: Dr. Palamar, I'd like us  
7 to -- within your -- within your work as an  
8 epidemiologist, how do you define substance use  
9 disorders?

10 DR. PALAMAR: Substance use disorder  
11 is a DSM-5 term. It's a little bit newer. It --  
12 to my understanding it kind of aggregates  
13 criteria from what we use to call abuse and  
14 dependence.

15 Kind of like what we call addiction.  
16 But addiction may or may not, like, really, very  
17 much overlap with what we used to call abuse.

18 But anyways, to my understanding,  
19 substance use disorder puts them together. And  
20 if a person is diagnosed as having multiple  
21 indicators of what we used to call abuse or  
22 dependence.

23 Then they can be diagnosed with having  
24 substance use disorder, which, loosely, is  
25 addiction.

1 MR. PHELPS: And can you go into a  
2 little more detail about that distinction or  
3 similarities between substance use disorders and  
4 substance addiction?

5 MR. MANN: Objection, Your Honor.  
6 Again, not disclosed in the prehearing statement.  
7 This witness is being offered to discuss  
8 associated effects in poisoning, seizures of  
9 compounds, trends, and drug submissions, testing  
10 positive for DOI and DOC.

11 There is nothing in here about a  
12 discussion of what addiction is, substance abuse  
13 is, or drug abuse.

14 MR. PHELPS: We'll move on.

15 JUDGE SOEFFING: All right.  
16 Sustained.

17 MR. PHELPS: Dr. Palamar, I'd like to  
18 -- I'd like to -- could you tell us about what  
19 your recent and current epidemiological research  
20 has shown regarding DOI and DOC?

21 THE WITNESS: Sure. As -- would you  
22 like me to discuss it in order of the way it's  
23 presented in the exhibit?

24 BY MR. PHELPS:

25 Q I think now would -- yes, would --

1 would be a good time to -- well, for -- could --  
2 could you just talk about it generally, and then  
3 -- and then we can have a foundation --

4 A Sure.

5 Q -- to get into the document?

6 A Sure. So I do this on my own, and I  
7 do this based on -- on my Deputy Director  
8 position through NDEWS, which you mentioned,  
9 National Drug Early Warning System. So I focus  
10 on, as I said, the epidemiology of drug use with  
11 a particular focus on novel drugs and novel drug  
12 trends. And through NDEWS in particular, we  
13 focus on monitoring of emerging trends.

14 Our hope is to catch on to trends  
15 early enough that we could alert scientists and  
16 the public and say, we -- we think this is  
17 becoming a problem; keep your eye on it or  
18 address it. So that -- that's the main thing we  
19 do, focusing on traditional and new drugs.

20 Q Thank -- thank you, Dr. Palamar. I'd  
21 -- I'd like to turn your attention to what's  
22 marked for identification purposes as SSDP/Ramos  
23 Exhibit 85. Do you have -- do you have that  
24 there?

25 A Yes, Docket Number 24-24.

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

3 A Yes.

4 Q And are -- are you familiar with its  
5 contents?

6 A Yes. I created it.

7 Q And in looking at that, is the  
8 document in front of you the same document that  
9 -- that you submitted to us?

10 A Yes.

11 MR. PHELPS: Your -- Your Honor, at  
12 this time, we would move to admit what's been  
13 marked as SSDP/Ramos Exhibit 85.

14 JUDGE SOEFFING: Mr. Mann, any  
15 objection?

16 MR. MANN: Just one question, Your  
17 Honor.

18 Dr. Palamar, you created this  
19 document, correct?

20 THE WITNESS: Yes.

21 MR. MANN: And does this appear in any  
22 of your peer review journals or peer review  
23 articles?

24 THE WITNESS: No. Nothing directly  
25 appears. But one thing I mentioned --

1 MR. MANN: Just -- that's all my  
2 question. This doesn't appear in any peer review  
3 --

4 THE WITNESS: Okay. No, not  
5 specifically.

6 MR. MANN: -- journals or anything?

7 THE WITNESS: No.

8 MR. MANN: Is that correct? Okay.  
9 No objection.

10 JUDGE SOEFFING: Okay. Petitioner's  
11 exhibit marked for identification number 85 has  
12 been offered. In the absence of objection, it is  
13 received in the record as Petitioner's Exhibit  
14 85. It's in. You may use it.

15 (Whereupon, the above-referred to  
16 document was received into evidence as Petitioner  
17 Exhibit 85.)

18 BY MR. PHELPS:

19 Q Dr. Palamar, can you tell us what that  
20 first figure is titled?

21 A Yeah. This is -- Figure 1 is trends  
22 in submissions of substances submitted to the DEA  
23 NFLIS labs testing positive for DOI and DOC.

24 Q And can you -- can you tell us what --  
25 can you tell us what's in that figure? Can you

1 describe the figure for us?

2 A Yeah. So this provides count data.  
3 This is downloaded from the publicly available  
4 DEA NFLIS data query system, as I noted there in  
5 the -- in the document. So data appeared to be  
6 available for 2005 to 2020. Those are the data  
7 that I was able to download. And just so you  
8 know, I extracted these data on September 10th,  
9 2024.

10 So the reason I focused on this is  
11 because NFLIS submission data and fusion data  
12 could indicate availability of drugs. So, just  
13 briefly, the number of submissions testing  
14 positive according to my data query -- the number  
15 of submissions testing positive for DOI remain  
16 stable, ranging from 0 to 12 per year with a peak  
17 of 12 detections in 2012. And there were no  
18 detections between 2019 and 2022.

19 The number of submissions testing  
20 positive for DOC ranged from 1 to 152 per year  
21 with a peak of 152 detections in 2012. Between  
22 2012 and 2025, there were 115 to 152 detections  
23 per year followed by a steep decrease through  
24 about 2020. In 2020 through 2022, there were a  
25 total of six submissions testing positive for

1 DOC. And specifically, there were three in 2022.

2 Q And as -- as an epidemiologist, how do  
3 you -- how do you interpret that data?

4 A My interpretation is that within  
5 roughly the past decade, it appears that neither  
6 of these substances are -- are available, or  
7 illicitly available to the public.

8 Q And what does -- as an epidemiologist,  
9 what do these numbers tell you about actual use  
10 of DOI or DOC?

11 A I don't think they tell us very much  
12 at all. If it does indicate availability, which  
13 I think it does -- availability is associated  
14 with use, but it's not that -- it doesn't mean  
15 that one necessarily predicts the other. But  
16 availability is a pretty good indicator.

17 Like with other studies, we find that,  
18 for example, as fentanyl availability goes up,  
19 overdose deaths go up. So there are certain ways  
20 of looking at that. But with -- with -- with  
21 these DO compounds, it just -- availability is  
22 almost nonexistent, at least according to the DEA  
23 NFLIS submissions.

24 Q Thank you. I'd like you to turn to  
25 page 2 of that document.

1 A Sure.

2 Q And what is --

3 A -- Do you want me to.

4 Q What is that figure there, sir?

5 A So this is high-intensity drug  
6 trafficking area seizures testing positive for  
7 DOI and DOC because, you know, high-intensity  
8 drug trafficking areas -- we call those HIDTA.

9 Q And what -- what is -- what is HIDTA?

10 A HIDTA was enacted by Congress decades  
11 ago to focus on problematic drug areas throughout  
12 the United States. And police departments who  
13 seize drugs, they record information regarding  
14 the drugs that they seize, and they submit it  
15 through a data system. So these are all compiled  
16 nationally, and they're examined to -- to show,  
17 you know, basically, how are police efforts going  
18 with respect to stopping, you know, drug flow  
19 throughout the United States?

20 Q And what does -- what does this data  
21 tell you about that drug flow?

22 A So HIDTA law enforcement seizure data  
23 -- this is for all -- data from all 50 U.S.  
24 states -- indicate that between 2017 and 2022,  
25 only three seizures were reported as testing

1 positive for DOC. All three seizures were in the  
2 state of Washington. And the recorded number of  
3 dosing units seized in 2017, 2020, and 2021  
4 respectively were 55, 34, and 8. There were no  
5 recorded seizures of DOI within that time frame.

6 Q And can -- can you explain a little  
7 bit about dosing units, what that means?

8 A Sure. So I'm -- I'm very familiar  
9 with the HIDTA system. I'm the first one to ever  
10 publish HIDTA data, to my knowledge. And dosing  
11 units typically indicates that a seizure was in  
12 -- in pill form. But I would think that in this  
13 case, it was probably in tab form because dosing  
14 units are an actual unit, like a pre-specified  
15 unit, such as a pill.

16 So, to me, it makes sense that these  
17 were reported in dosing units, probably tabs, as  
18 opposed to a weight, which -- a weight usually --  
19 not always, but usually, suggests powder form.

20 Q And --

21 JUDGE SOEFFING: Let me ask, doctor,  
22 when you say tabs, are you referring to tablets?

23 THE WITNESS: No. Thank you for that  
24 question. No. Tabs -- it's kind of like -- a --  
25 a lot of psychedelics, especially the old-school

1        psychedelics, were on either blotter or tabs. So  
2        blotter is like a tiny little piece of paper that  
3        somebody puts in their mouth, like if you think  
4        of LSD.

5                    A tab is like that but bigger. It's  
6        like a thicker piece of paper that someone puts  
7        in their mouth. So that is the general -- we  
8        call them tabs.

9                    JUDGE SOEFFING: Okay.

10                   THE WITNESS: Not tablets as in, like,  
11        a pill.

12                   JUDGE SOEFFING: So it's a piece of  
13        paper with the drug compound on it?

14                   THE WITNESS: Yes.

15                   JUDGE SOEFFING: Okay. Thank you.

16                   BY MR. PHELPS:

17                   Q        And what does this data tell you, if  
18        -- if anything, about widespread or problematic  
19        use of -- of DOI and DOC?

20                   A        From this, I mean -- and remember, I  
21        -- when I -- when I talk about seizures, I'm  
22        essentially talking about what I think is  
23        availability or illicit availability. It appears  
24        that these drugs are, you know, not really  
25        available. I mean, as I said, there have been a

1 couple of instances of the DOC appearing, there  
2 are no recorded instances of DOI appearing. But  
3 either one is very rare.

4 If you've seen, like, any of the  
5 papers mentioned on my CV focusing on drug  
6 seizures, what I'm publishing about, for example,  
7 trends in fentanyl seizures, we're talking about  
8 tens of thousands of seizures. That's what's  
9 going on. This is almost nonexistent compared to  
10 other drugs such as fentanyl or cocaine or  
11 methamphetamine.

12 Q Thank you. I'd like you to turn to  
13 page 3 of the document.

14 A Sure.

15 Q And what's -- what is the title of  
16 that figure there?

17 A So this is the number of instances of  
18 -- of report of lifetime use of DOI and DOC in  
19 the National Survey on Drug Use and Health. We  
20 -- we refer to this -- it's spelled out  
21 N-S-D-U-H. We usually just call it NSDUH. So,  
22 if I refer to NSDUH, I'm referring to this  
23 survey.

24 Q And can -- can you tell us what --  
25 what NSDUH is?

1           A       This is, like, in my opinion, the,  
2       like, leading drug survey in the United --  
3       national drug survey in the United States. This  
4       has been going on in one form or another since  
5       the 1970s, and this is used to track drug  
6       prevalence and correlates throughout the -- the  
7       United States.

8           Q       And how -- how is that survey  
9       conducted?

10          A       It has changed. So it -- it used to  
11       be specifically a household survey. In fact, the  
12       house -- household used to be in the survey name,  
13       and that changed in -- I think it was the late  
14       '90s or early 2000s. Then it became the National  
15       Survey on Drug Use and Health. And then it  
16       spread out beyond households because we -- you  
17       don't have to live in a house to use drugs. We  
18       wanted to expand.

19                 So now it focuses on what we call --  
20       what we refer to as non-institutionalized  
21       individuals. So this would include homeless or  
22       specific -- homeless who obviously use shelters.  
23       It would focus on various other transient  
24       individuals who temporarily have a home that  
25       might not be their actual proper household.

1 Q And who -- who conducts this survey?

2 A This is funded by SAMHSA, which is the  
3 Substance Abuse -- I'm not even sure what it  
4 stands for, but it's SAMHSA.

5 Q It -- if -- if you don't know exactly  
6 what the acronym is, what -- what is SAMHSA?

7 A SAMHSA -- it's -- it's another  
8 drug-focused government organization. It's very  
9 important. It focuses on drug epidemiology, but  
10 from what I see, it focuses particularly with  
11 respect -- on -- on drug treatment. So, a lot of  
12 times, I will see studies about treating  
13 individuals who use drugs. A lot of times, those  
14 are funded by SAMHSA.

15 Q Okay. And --

16 A Not -- not as much epidemiology, other  
17 than this survey, to my knowledge.

18 Q And how exactly is this survey data  
19 collected?

20 A So, currently -- well, things have  
21 changed since COVID, as you can probably imagine.  
22 So, before COVID hit in 2020, the surveys were  
23 always done in person. They would contact -- I  
24 -- I -- I think the proper term is dwellings.  
25 They don't call them households anymore. They

1 would contact dwellings, and they would see if  
2 people are eligible. You have to be at least age  
3 12 to be eligible for the study.

4 And they screen people, and if people  
5 remain eligible and interested after the -- after  
6 the screener, then they are offered the full  
7 survey on a computer. I believe somebody from  
8 SAMHSA would bring a laptop into a dwelling and  
9 -- and give it to them then. Now, since COVID,  
10 since 2020, roughly half of these are done  
11 online, so roughly half via the web and roughly  
12 half via in-person survey.

13 Q So -- so, if somebody sits down to do  
14 that survey, what does -- what does it look like?  
15 What is -- how is the surveying done?

16 A I have never taken it myself. I have  
17 seen PDFs of the -- the documents that -- that  
18 are publicly available to inform how to interpret  
19 the results. So I've never seen the actual  
20 survey on a computer, like if it was given to me.  
21 But it -- it looks like just a regular survey,  
22 like if you've taken anything sent to you, for --  
23 for example, business or university-related.

24 You answer a question. And if you  
25 say, yes, I've used marijuana, there's going to

1 be a bunch of follow-up questions about marijuana  
2 use. If you say, no, I've never used marijuana,  
3 it's going to move on and ask about another drug.

4 Q And does this survey specifically list  
5 all drugs?

6 A No. No. It -- it -- it primarily  
7 focuses on -- I call it -- what I refer to as  
8 the, quote unquote, traditional drugs, like  
9 cocaine, marijuana, methamphetamine, LSD. But  
10 there's also an option where -- there are  
11 multiple options where people can type in names  
12 of drugs they've used that they were not  
13 specifically asked about because there are  
14 thousands of -- of drugs.

15 Q And why -- why wouldn't they include  
16 -- why would they choose to include some and not  
17 others?

18 A That's a great question. I think that  
19 -- well, for -- the main reason is that if they  
20 think a drug is not very prevalent, there's no  
21 need to ask 50 or 60 thousand people about it if  
22 pretty much everybody's going to say no. And I  
23 -- I deal with that in my own surveys as well.  
24 But if a drug is used by very few people, they  
25 don't want to waste a precious minute on that

1 question. They'd rather ask it on a different  
2 drug or a different topic.

3 Q And do you know what psychedelic drugs  
4 specifically are included in this survey?

5 MR. MANN: Objection, Your Honor.  
6 Again, we're outside the scope of the prehearing  
7 statement discussing how surveys are created and  
8 formed.

9 MR. PHELPS: Your Honor, I think it  
10 provides context to understanding specifically  
11 what -- how DOI relates to this -- this survey.  
12 It -- it's important if -- if no psychedelics are  
13 -- are included, that's something different than  
14 if some are and -- and DOI is or isn't.

15 JUDGE SOEFFING: I'll overrule the  
16 objection.

17 MR. PHELPS: Do -- do you know what --  
18 (Simultaneous speaking.)

19 BY MR. PHELPS:

20 Q Yes. Do you know what -- what  
21 psychedelics are included?

22 A Off the top of my head, it's only a  
23 handful. There's a couple of very big  
24 psychedelics that a lot of people are aware of,  
25 so psilocybin -- I believe it asks about

1 mescaline, although I've never focused on that.  
2 It definitely focuses more heavily on LSD.

3 And there -- there's a question about  
4 a couple of somewhat rare drugs, but tryptamines  
5 combined together. They combine three different  
6 types of tryptamines, which are psychedelics,  
7 into one single question. And I focused on that  
8 also. But other than, like, a handful, they  
9 don't ask specifically about other psychedelics.

10 Q What -- what drugs within the -- the  
11 DOx family are included in that survey?

12 A They, to my knowledge, have never been  
13 included. They definitely have not been included  
14 for a few decades.

15 Q And that would include DOI and DOC?

16 A Yes. I -- I have never seen any DOx  
17 included.

18 Q So how -- how would -- how would DOI  
19 or -- or DOC end up being reported through this  
20 survey?

21 A So, as I mentioned, there are a couple  
22 of areas on -- on the survey where NSDUH will  
23 ask, are there any drugs you have used in your  
24 lifetime that we have not asked you about,  
25 essentially? And that -- that gives people the

1 opportunity to type in the names of drugs they've  
2 used in their lifetime that they have not been  
3 asked about.

4 And that is where you start finding,  
5 like -- when you get the code book for that year,  
6 that's where you get the raw data of how many  
7 people said that they have used a particular drug  
8 compound. And it's usually very few. That's why  
9 it's just a type-in response.

10 Q And can -- can you explain what --  
11 what they mean by -- by lifetime use?

12 A Yes. So -- well -- well, they ask if  
13 you have used in your lifetime --

14 MR. MANN: Objection, Your Honor.

15 JUDGE SOEFFING: Hold on.

16 MR. MANN: Speculation.

17 MR. PHELPS: Your Honor, he's  
18 published peer-reviewed articles on this.

19 JUDGE SOEFFING: Overruled.

20 BY MR. PHELPS:

21 Q Can you explain what they mean by  
22 lifetime use?

23 A So -- well, they don't say -- we say  
24 lifetime use, but that's how -- what we're  
25 defining it as. It's lifetime use, which means

1 if somebody has ever used in their lifetime as  
2 per self-report. I -- they don't specifically  
3 say, have you engaged in lifetime use? No one  
4 would say that on a survey.

5 But they ask, have you ever used  
6 others? Like, when you ask have you ever used,  
7 to us, we interpret that as a lifetime use, ever.  
8 It doesn't mean you've been using your whole  
9 lifetime, as some people think, but have you ever  
10 used?

11 Q And does -- does that -- would that  
12 survey data tell you anything about current use?

13 A No, you cannot differentiate between  
14 current versus -- current use versus, like, use  
15 that occurred many years ago. It -- it would be  
16 more relevant for someone who started young.  
17 Like if you ask a teenager about lifetime use,  
18 they're pretty young, so it's probably relatively  
19 recent.

20 But I mean, a big problem is a lot of  
21 psychedelics like this were -- I consider them  
22 more old school, like -- like DOX compounds. If  
23 they were popular at all, they were more popular  
24 in -- in the 1960s. So you might get someone  
25 who's, like, 70 years old who says, yes, I used

1 this drug. But it might have been half a century  
2 ago.

3 Q And what did -- on your review of the  
4 -- the survey data over the years, what did it  
5 tell you about DOI and DOC?

6 A Yes. So let me see what it was. So,  
7 with respect to the lifetime use, NSDUH received  
8 a total of nine mentions of lifetime DOI use and  
9 32 mentions of DOC use between 2005 and 2022.

10 JUDGE SOEFFING: Dr. Palamar, you're  
11 looking at the Exhibit 85?

12 THE WITNESS: Yes.

13 JUDGE SOEFFING: When you're looking  
14 at it, what page specifically are you looking at?

15 THE WITNESS: Figure 3, which I think  
16 is the third page.

17 JUDGE SOEFFING: Thank you.

18 THE WITNESS: Yeah. And I'm literally  
19 just reading for you what I wrote.

20 BY MR. PHELPS:

21 Q And so what do those -- what do those  
22 numbers of lifetime use of DOI and DOC tell you  
23 as an epidemiologist about these drugs' risk to  
24 public health?

25 A I -- I mean, I don't know if I

1 personally would directly equate prevalence to  
2 risk. But if some -- it seems extremely rare,  
3 especially in more recent years, and if it is  
4 very rare, it just -- it seems like fewer people  
5 are using it, which would probably equate to a  
6 lower likelihood of adverse outcomes. But it  
7 very -- it looks like very few people have been  
8 using these compounds.

9 Q And -- and if so, specifically, what  
10 does -- what does that mean to you, as an expert,  
11 about -- about these -- actually, you -- you  
12 mention here that you published a -- an article  
13 based on this data?

14 A Part of these data are included in  
15 that, and that's why I specifically put the  
16 citation that after 2005 to 2017 -- this article  
17 focused on dozens of drugs, and the DOXes were in  
18 the mix. So they're in there. So that's why I  
19 clearly noted the citation. But for this, I  
20 added the extra years to make it as current as  
21 possible.

22 Q And can -- can you give a -- a summary  
23 of what that paper was about?

24 A Yes. That is a paper that focused on  
25 type-in mentions, like we've been discussing, of

1 various novel drugs with a focus on, like,  
2 stimulants and psychedelics in particular,  
3 anything that is synthetic, because I've been  
4 more interested in the synthetic drugs.

5 And what we found was various  
6 phenethylamines, which are stimulants -- those  
7 tended to be more prevalent compared to a lot of  
8 these other drugs. These are -- the DOCs are  
9 phenethylamines, but I don't know if you would  
10 call it a sister or a cousin category. The 2C  
11 category was, if I recall correctly, the most  
12 common category typed in. Drugs like 2C-B -- I  
13 call them 2C-Xes -- much more prevalent than the  
14 DOXes.

15 Q And do -- do you recall what -- and  
16 when you were -- when you were working on that  
17 paper, do you recall what its conclusions were  
18 about the DOx class of drugs?

19 A I don't recall specifically discussing  
20 it because it was -- the mentions were almost  
21 nonexistent. We might have briefly discussed it,  
22 but it didn't seem as important as a lot of the  
23 other findings, particularly the 2C drugs.

24 Q And -- and when was that article  
25 published?

1           A       Let's see. The publication date,  
2       according to PubMed, is 2019. I don't know what  
3       month that was, but typically, an article is  
4       accepted and put in press months before. So it  
5       might have actually come out in 2018, but the  
6       official publication date is listed as 2019.

7           Q       So that was research done wholly  
8       outside of the scope of these proceedings here,  
9       the scheduling -- relating to the scheduling of  
10      DOI and DOC?

11                   MR. MANN: Objection. Leading.

12                   JUDGE SOEFFING: Sustained.

13                   BY MR. PHELPS:

14           Q       Dr. Palamar, I'd like you to turn to  
15      page 4 of your report.

16           A       Okay.

17           Q       Do you see Figure -- what's -- what's  
18      the title there of Figure 4?

19           A       It is percentage of New York City  
20      nightclub and festival attendees reporting  
21      past-year use of DOC and willingness to use if  
22      offered.

23           Q       Can -- can you explain what -- what  
24      this data -- where was -- where was this data  
25      collected?

1           A       Yes. So these data were collected  
2 through two -- multiple -- wait, 2022 -- either  
3 two or three of my -- my NIH-funded studies to  
4 focus on the nightclub scene. And what we do is  
5 we survey people entering nightclubs throughout  
6 New York City, and we ask them about use of close  
7 to 100 drugs to try and monitor the prevalence of  
8 use.

9                   And we were also hair-testing people  
10 at the time, and now we saliva test. But here,  
11 I'm just focusing on the self-report on the  
12 survey.

13           Q       And why -- why would NIDA be  
14 interested in -- in giving grants for this kind  
15 of research?

16           A       So they are particularly interested in  
17 monitoring the use of the novel or new  
18 psychoactive substances because these drugs --  
19 they're very hard to track. A lot of people  
20 don't know how to ask about them properly. And  
21 that is what I wanted to specialize in.

22                   So they gave me that training grant to  
23 essentially develop a tool to ask about them in a  
24 way that -- that the normal -- your average  
25 person would understand how they answered it. So

1 I developed this tool. We ask about them, and we  
2 include a few of the DOC -- the DOs in the mix.  
3 But we ask about common drugs, such as cocaine,  
4 and we ask about a lot of other drugs, less  
5 common drugs.

6 Q And what's -- what's the relevance of  
7 hair testing that you mentioned?

8 A So the hair testing is valuable  
9 because -- well, there are different uses for  
10 biospecimen testing. My main interest in  
11 biospecimen testing is to detect what we call  
12 unreported or underreported use. This is when  
13 somebody says that they did not use a drug, but  
14 then their hair tests positive for the drug,  
15 suggesting that they have used it. They could  
16 have been unknowingly exposed, so if the drug was  
17 an adulterant -- and think about the fentanyl  
18 crisis. A lot of fentanyl eight, nine, ten years  
19 ago were people unknowingly exposed, until people  
20 started using it on purpose.

21 So we try and pick up mainly on  
22 unknown exposure, but it's also a good way of  
23 confirming reliability of responses.

24 Q And if -- if you recall, how many  
25 times did DOI show up in hair testing?

1           A       We have never detected that in hair.

2           Q       And DOC?

3           A       No DO compound ever.

4           Q       And what specifically is the first  
5 chart in Figure 4 showing?

6           A       So that is the percentage, meaning the  
7 prevalence, of past-year self-reported use. And  
8 that's specifically of DOC. We did not ask about  
9 DOI in all of these years. So what it shows is  
10 the -- well, first of all, you see that the line  
11 is very close to zero across years. So, between  
12 2016 and 2022, the unweighted prevalence ranged  
13 from 0 percent to 0.4 percent. So it's --  
14 essentially nobody reported using this compound  
15 within that time frame.

16          Q       And can -- can you explain why that Y  
17 axis is a percentage -- what -- what's the  
18 significance of the percentage there?

19          A       We tried to focus on percentage so we  
20 could -- because sample size could change per  
21 year. So, you know, some years, we have over  
22 1,000 people. Other years, we have maybe 500  
23 people. So, if you focus on a percentage, you  
24 could easily compare across. Like -- like, it's  
25 the same thing as proportion. You compare across

1 use.

2 Q And how does the proportion of people  
3 willing to use DOx-type drugs compare to some of  
4 the other drugs you -- you tested for in that --  
5 in that survey?

6 MR. MANN: Objection, Your Honor.

7 THE WITNESS: So, briefly, as I noted  
8 --

9 JUDGE SOEFFING: Hold on.

10 Mr. Mann?

11 MR. MANN: This survey concerns only  
12 DOC. He's trying to expand it to something else.

13 JUDGE SOEFFING: Mr. Phelps, are you  
14 can you ask about DOx --

15 MR. PHELPS: Absolutely. Yes. You  
16 said that DOI is --

17 JUDGE SOEFFING: Hold on. Mr. Phelps,  
18 did you have a response to that?

19 MR. PHELPS: Yes. I -- I was trying  
20 to -- to broaden the scope of this to all DOx  
21 because he said DOI was -- was nonexistent on  
22 here. So we can get into that specifically, but  
23 this is a graph specifically related to the DOx  
24 class of drugs. I can ask a clarifying question.

25 JUDGE SOEFFING: We're talking about

1 the figures on page 4, right?

2 MR. PHELPS: Correct, Your Honor.

3 JUDGE SOEFFING: Which is labeled as  
4 DOC.

5 MR. PHELPS: You're -- you're --  
6 you're right. I apologize.

7 JUDGE SOEFFING: I'll -- I'll sustain  
8 the objection. You can ask your next question.

9 MR. PHELPS: Certainly. Certainly.

10 BY MR. PHELPS:

11 Q So -- so this is specifically relating  
12 to DOI. Why don't you have these numbers --

13 MR. MANN: Objection.

14 MR. PHELPS: Or -- excuse me. Excuse  
15 me. I -- I misspoke.

16 JUDGE SOEFFING: DOC.

17 BY MR. PHELPS:

18 Q DOC. This is specifically relating to  
19 DOC. Why don't you have this similar type of  
20 data for DOI?

21 A I did not ask about it. I -- if I  
22 recall correctly, I -- I think I asked about it  
23 one year, and we had zero responses. So I  
24 removed it. I've done that often with drugs.  
25 There's a bunch of DO -- DOXes. And so I --

1 since one, maybe two, people reported using over  
2 the years, I left it on. So that's why I have  
3 the -- the data across. You know, it's  
4 essentially close to zero percent.

5 So, if I asked about use, I also asked  
6 about willingness to use if offered. And as you  
7 see, as is duly noted here, it's -- it's less  
8 than one percent.

9 Q So can -- can you explain what -- what  
10 the -- the willingness to use means?

11 A So that can be interpreted differently  
12 from -- from, you know, different readers. So we  
13 ask something along the lines of, if you are  
14 offered this drug in the -- in the next 30 days  
15 by a friend, would you be willing to -- to use  
16 it? I'm not sure if that's the exact wording,  
17 but it's something along those lines.

18 So you can take -- to try to pick up  
19 on, like, if it were offered, would you use it,  
20 so if it were available?

21 Q And how do these graphs for DOC  
22 compare to other -- other substances that were  
23 included in this survey?

24 A Much longer -- I mean, not than all  
25 substances. For example, when you ask about a

1 drug like fentanyl, most people are very scared  
2 of that drug -- would not use it. So fentanyl is  
3 probably just as low. I -- I don't have the data  
4 in front of me, though.

5 But a drug like cocaine or MDMA --  
6 like, prevalence would be much, much higher. I  
7 -- I don't know the numbers offhand, but much  
8 higher.

9 Q And -- and I -- you were -- just to be  
10 clear, you were specifically referring to the  
11 second draft there of the willingness to use?

12 A Yes.

13 Q Okay. And how does the -- how does  
14 the top graph above there compare to other  
15 past-year-use graphs for drugs that were also  
16 tested for?

17 A Well, that were -- that people were  
18 asked about and that self-report. So there are  
19 some -- if you look into my reports, which -- I  
20 think some of which are -- I think the most  
21 recent one is now available for free through  
22 PubMed Central, but if you look at other things  
23 that I've published recently, you'll see that  
24 most drugs are more highly prevalent across time.

25 There are a few drugs that are of very

1 low prevalence. For example, one of the -- I'll  
2 -- I'll call it cousin drug to the DOXes. It's  
3 called NBOMe, N-B-O-M with a lowercase E. That  
4 was a -- that's a very dangerous psychedelic  
5 phenethylamine. And that we still ask about, and  
6 that is -- that, I think, is even more prevalent  
7 than the DOs. And that's a drug that people are  
8 very scared of, for the most part.

9 But other than a handful of other rare  
10 drugs, most drugs we ask about, at least as per  
11 what the specific class of drugs, tend to be much  
12 more prevalent than the DOXes.

13 Q I'd like you to turn to page 5 of the  
14 exhibit, please.

15 A Mm-hmm.

16 Q And this says additional data. What  
17 -- is this -- where is this additional data from?

18 A So each -- I'll call it a bullet  
19 point. But each -- each paragraph or bullet  
20 focuses on a different source or a different type  
21 of survey. I just wanted to provide as much data  
22 as I could come up with to be as objective as  
23 possible. So these, in my opinion, weren't  
24 really able to be put in a -- a figure in a clean  
25 manner, so I figured, let me just jot this down

1 to present it in a short paragraph.

2 Q And what is -- what is the -- the  
3 first -- the first bullet point there about?

4 A Sure. So -- and I'm reading these  
5 word for word. So the New York City night club  
6 and festival attendees were also asked about DOI  
7 in 2016 and 2017, but the question was dropped  
8 due to low or no reported use. In 2016, .5  
9 percent reported past-year use, and in 2017,  
10 there was no reported use.

11 I believe I even mentioned that a  
12 couple minutes ago, or I alluded to that when  
13 discussing the previous figure.

14 Q Sure. And what does -- what does the  
15 -- the next part tell us?

16 A In -- in 2024, New York City nightclub  
17 and festival attendees were asked about DOx  
18 overall, not specifically DOC, for example. And  
19 .1 percent reported use. If -- if I may add, the  
20 reason I started asking about just DOx in general  
21 was because prevalence of the others was just so  
22 low. So I figured, instead of asking people  
23 about multiple drugs and wasting survey space, I  
24 asked, have you ever used, for example, DOM, DOI,  
25 DOC, in one single question. And as you can see,

1 prevalence was still, like, almost nonexistent.

2 Q And when -- when did you conduct your  
3 2024 survey?

4 A In 2024.

5 Q Well, I -- I guess what I -- I -- was  
6 -- was that survey conducted in any way in  
7 relation to your -- your involvement in these  
8 proceedings or your testimony here?

9 A No. These -- okay. So these were the  
10 most up-to-date results of 2024 until I sent you  
11 this document. I don't remember the exact date.  
12 I'm not sure if it's on here. But these were all  
13 the data collected up until, yeah, I created this  
14 document. It's nothing after. So I don't  
15 remember what month that was. Was that in  
16 August? I'm -- I'm not sure.

17 Q And that's okay. And it wasn't -- it  
18 -- it wasn't -- the data wasn't collected or --  
19 or prepared in connection with -- with your  
20 testimony here in any way?

21 A No. No.

22 Q Okay. And this is specifically about  
23 New York City nightclub and -- and festival  
24 attendees. In -- in your expert opinion, how are  
25 -- how are these findings representative of

1 nationwide use of DOI and DOC?

2 A I would assume that they're higher  
3 because this population is at much higher risk  
4 for use of drugs like this than the general  
5 population. So, for example, if five percent of  
6 this population used a drug like ecstasy, I would  
7 expect that that's exponentially higher than what  
8 the general population prevalence is.

9 And here, it's, you know, 0.1 percent,  
10 which is probably much higher than the general  
11 population. So now we're getting into, like, you  
12 know -- add zeros before that, and that's  
13 probably how it relates to the general  
14 population.

15 Q And the next -- the -- the next bullet  
16 point there is some NDEWS reporting. Can you  
17 explain what -- first, can you explain what that  
18 is? And then we can talk about the -- the  
19 numbers there.

20 A Yes. So I -- I explained this  
21 earlier. So NDEWS is the National Drug Early  
22 Warning System. It's a NIDA-funded center to --  
23 to monitor the use and trends of -- of various  
24 drugs, with a particular focus on novel drugs.  
25 And we do this in order to pick up on trends as

1 they're starting, to quickly alert scientists and  
2 the public.

3           So we try and stay on date. So most  
4 -- most organizations that track drug use tend to  
5 be labs, meaning that if they publish their  
6 results, the results are oftentimes already over  
7 a year old. We don't like doing that. We want  
8 results out as close to -- to -- we -- we want  
9 them to be released as immediate as -- as  
10 possible to alert the public.

11           Q       So do you -- do -- do you collect data  
12 for NDEWS?

13           A       I help oversee the majority of our  
14 data collection initiatives. There -- there are  
15 many.

16           Q       So I -- I'm -- what -- what's your  
17 relationship with NDEWS?

18           A       So I am the Deputy Director, so I help  
19 oversee most aspects of this -- of this system.

20           Q       And what -- what kinds of information  
21 sources do you use to do this rapid street  
22 reporting survey?

23           A       That is actually based on my survey I  
24 discussed a few minutes ago that I developed  
25 through the -- the NIDA funding. We introduced

1 my developed survey to this as the Rapid Street  
2 Reporting Initiative. So, roughly every month,  
3 we send a group of recruiters to a various city,  
4 typically a city of concern that might have high  
5 rates of drug use.

6 And we -- we send them there for the  
7 weekend to survey typically a couple hundred  
8 people throughout various venues to pick up on  
9 possible emerging drug trends.

10 Q And based on -- on NDEWS' data, have  
11 you released any warnings about DOI?

12 A We have not released warnings. We  
13 issued one question in a briefing, which I'm sure  
14 you'll ask me about in a minute. But no, we have  
15 not issued any alerts about use.

16 Q And what did the -- what did the --  
17 the numbers in 2022 and 2023 tell you about DOC  
18 in those rapid reporting surveys?

19 A And I'm -- I'm discussing DOC because  
20 that was specifically asked about, because that  
21 is -- it's very similar to the survey of mine we  
22 just discussed. So yeah. We asked about one --  
23 one of the DOs specifically. But anyway, between  
24 2022 and 2023 -- so .02 percent of participants,  
25 of over 6,000, reported past-year use of DOC.

1           Q       And can -- can you explain a little  
2 bit about your -- your weekly email briefing,  
3 just in -- in general, how that -- how that  
4 works?

5           A       Yeah. So -- so, as I mentioned a  
6 couple times, one of the main purposes of our  
7 center is to rapidly alert scientists and the  
8 public about, you know, things that we think are  
9 important, you know, or alerts with respect to  
10 drug use, with a particular focus on novel drugs.

11                   And so, every Friday morning, we issue  
12 an alert, an email alert, to our subscribers with  
13 a bunch of updated information. We publish our  
14 own results on that email, and we try our hardest  
15 to keep up to date with other publications in the  
16 area and disseminate important information that  
17 our readers could, you know, obtain information  
18 on.

19           Q       And who are your readers?

20           A       We don't specifically know everybody.  
21 A lot of times, we look at, like, the end of the  
22 email to try and get a sense of where -- where  
23 they are, like government or university. I don't  
24 know the specific proportions, but we have a lot  
25 of subscribers from universities -- so that would

1 be professors and staff, probably -- a lot of  
2 government employees. I don't know how many  
3 would be federal government, but we have a lot of  
4 Department of Health employees, and that's  
5 considered government also.

6 We have other people, teachers. We  
7 have reporters. We have just general people. We  
8 have people who use drugs, I assume, who are --  
9 you know, who are -- who are -- who want, you  
10 know, up-to-date information. Pretty much  
11 everyone you can think of is probably covered.  
12 We're trying to expand as much as we can. And at  
13 the time I sent you this, we had almost 5,000  
14 subscribers. And, you know --

15 Q Is --

16 A -- we're getting more and more  
17 subscribers every week.

18 Q Do you know if there's individuals in  
19 the field of law enforcement that subscribe to  
20 this briefing?

21 A Oh, yes. Yes, absolutely. And we  
22 work closely with HIDTA, too. That's a  
23 high-intensity drug trafficking organization.  
24 They're funded by the White House ONDCP. We work  
25 closely with them, and that's where I obtain my

1 drug seizure data. And I suspect we have a lot  
2 of HIDTA people in the mix, and law enforcers.  
3 And we have something called sentinel  
4 surveillance sites, which are sites that we reach  
5 out to on at least a monthly basis and ask about  
6 local drug trends throughout their cities.

7 I believe we have 16 sites now, and at  
8 least one of them is led by a law enforcer. And  
9 that is -- I believe that's in -- is that  
10 Florida? I'm not sure, but it's down south,  
11 southern.

12 Q And what did you do on your email  
13 briefing when you became aware of the DEA's  
14 proposal to place DOI and DOC into Schedule I?

15 MR. MANN: Objection, Your Honor.  
16 Outside the scope of the prehearing statement.

17 JUDGE SOEFFING: Sustained.

18 MR. PHELPS: Can he refer to what's in  
19 his document?

20 JUDGE SOEFFING: Well, the document  
21 speaks for itself.

22 BY MR. PHELPS:

23 Q Dr. Palamar, is social media one of  
24 the sources you use to collect your data on  
25 emerging drug use? Or how do you, excuse me --

1           A       Yes.

2                   MR. MANN:  Objection.  It's not in the  
3 prehearing statement.

4                   JUDGE SOEFFING:  Overruled.

5                   THE WITNESS:  Can I answer?

6                   JUDGE SOEFFING:  Yes, you may answer.

7                   THE WITNESS:  Okay.  Yes, we focus on  
8 social media, with a particular focus on Reddit.

9                   MR. PHELPS:  And, Your Honor, we're at  
10 10:48 now.  I don't know if it might be -- if we  
11 want to go down that -- we have a -- another -- a  
12 bit of a ways to go still with Dr. Palamar.  I  
13 don't know if now might be an okay time to --

14                   JUDGE SOEFFING:  Okay.

15                   MR. PHELPS:  -- take a break.

16                   JUDGE SOEFFING:  Let's take a  
17 15-minute break.  We're off the record.

18                   MR. PHELPS:  So, Dr. Palamar, just to  
19 --

20                   JUDGE SOEFFING:  Oh, let me -- back on  
21 the record.

22                   MR. PHELPS:  Dr. Palamar --

23                   JUDGE SOEFFING:  You are still on the  
24 witness stand while we take our break.  I'm  
25 directing you to not look at anything regarding

1 this case while we're on our 15-minute break.

2 Thank you. We'll break for 15 minutes.

3 THE WITNESS: I -- sure. Can I step  
4 away briefly?

5 JUDGE SOEFFING: Yes, you may.

6 THE WITNESS: Okay.

7 (Whereupon, the above-entitled matter  
8 went off the record at 10:48 a.m. and resumed at  
9 11:10 a.m.)

10 JUDGE SOEFFING: Dr. Palamar, I will  
11 remind you you're still under oath. And Mr.  
12 Phelps, you may continue your direct examination.

13 MR. PHELPS: Thank you, Your Honor.

14 BY MR. PHELPS:

15 Q Dr. Palamar, you mentioned earlier  
16 when we were going through your CV that you had  
17 received an award for a manuscript of the year.  
18 Can you tell us about that article?

19 A Yes. That was the AMERSA paper of the  
20 year award. That was about a paper we got a lot  
21 of media attention for. What we did was we  
22 looked at some of my nightclub survey data. And  
23 aside from use of drugs, we asked the people that  
24 year if they have ever posted on social media or  
25 texted people while high on a drug. And if they

1 did report affirmatively, then we asked if they  
2 regretted it.

3 So it was very straightforward. And  
4 we published like prevalence estimates of that.  
5 And we found that a lot of people not only use  
6 drugs, but use social media while high. And  
7 that's of concern.

8 Q And why is that of concern?

9 A Because it could be dangerous while  
10 using a drug. I mean, you know, each drug has  
11 some level of dangerousness. But when you  
12 introduce social media, that's why I consider it  
13 a social risk because if you're high on a drug  
14 and you post something on social that could be  
15 complete nonsense. It could be -- maybe you put  
16 a picture of yourself and you were high or drunk  
17 and then people could see it. That photo of you  
18 might live online forward.

19 You could say something you don't  
20 mean. Or maybe it doesn't really matter if your  
21 friends see that you say something that's kind of  
22 dumb. But if you have a boss or somebody else or  
23 a family member that sees it, you could get in  
24 trouble. So I consider it social risk. And it  
25 could stay there forever. It's a social danger.

1           Q       And you -- what's your familiarity  
2 with the website Reddit?

3           A       Reddit --

4           MR. MANN: Judge, again, we are way  
5 outside the parameters of the prehearing  
6 statement here. The information regarding social  
7 media posts is well-known to the Petitioners. It  
8 was in Dr. Carbonaro's report. There is nothing  
9 in this prehearing statement where he is going to  
10 comment or criticize or make any judgment about  
11 the reliability of social media.

12           JUDGE SOEFFING: So I am going to  
13 overrule the objection. He did refer to Reddit  
14 in earlier testimony. But I would ask Mr. Phelps  
15 to keep it as brief as he can.

16           MR. PHELPS: Certainly, certainly.

17           BY MR. PHELPS:

18           Q       Could you just explain a little bit of  
19 what is the website Reddit?

20           A       Yes. So Reddit is a social media  
21 site. I consider it more of a message board.  
22 It's not necessarily -- it's not like Twitter  
23 where you're just posting photos or saying, you  
24 know, things to get attention. Typically, it's a  
25 deeper discussion that people are seeking on

1 various topics.

2 I personally don't use it that much.  
3 I mean, I look up like heart surgery information  
4 on Reddit for myself. But my colleagues at  
5 NDEWS, every week, they scrape Reddit for  
6 drug-related information to try to certain --  
7 monitor emerging trends. And this is a very  
8 unique and novel way of us, you know, picking up  
9 on new discussion of drugs, drugs sometimes we  
10 had never heard of.

11 And if somebody starts talking about  
12 it on Reddit, we see. Does it seem like -- first  
13 of all, is this a real drug? Like what are they  
14 talking about? Because a lot of people have no  
15 idea what they are using, especially when it  
16 comes to what we call these alphabet soup names.  
17 A lot of these names, all you need to do is  
18 misspell a couple of letters or numbers, and it's  
19 a totally different compound.

20 But it is an indicator. We have a lot  
21 of people talking about it. And then we think,  
22 okay, if we have a lot of people talking about  
23 it, this might lead to use, and it might led to  
24 poisonings.

25 Q And how do you weigh the reliability

1 of the information found on Reddit versus other  
2 methods of data collection you use?

3 MR. MANN: Objection. Outside the  
4 scope of the prehearing statement.

5 JUDGE SOEFFING: Overruled.

6 THE WITNESS: So to my knowledge, we  
7 don't look at the reliability of the content.  
8 But what we focus primarily on is counts of  
9 mentions of drugs.

10 So when you use webs scraping  
11 technology -- I'm not advanced in this matter. I  
12 just look at the results. But when we have the  
13 web scraping people scraping the data, they have  
14 a way of reporting how many mentions there are of  
15 specific drugs or how many posts. And they are  
16 tracking that on a daily basis for example.

17 So we've been focusing on this almost  
18 every week for between four and five years  
19 scraping Reddit and looking at trends in  
20 mentions.

21 Lately, we've been looking at content.  
22 But it's more -- I think the web scraping, the  
23 machinery or AI, I think, has been summarizing  
24 what people are saying about the drugs. But,  
25 again, we mainly focus on counts of how many

1 mentions of the drugs there are.

2 BY MR. PHELPS:

3 Q And you mentioned before, a lot of  
4 people have no idea what drugs they are using.  
5 Can you kind of explain that?

6 MR. MANN: Objection.

7 THE WITNESS: Yeah, so.

8 JUDGE SOEFFING: Hold on.

9 MR. MANN: Outside the scope.

10 JUDGE SOEFFING: As the scope?

11 MR. MANN: Outside the scope.

12 JUDGE SOEFFING: Outside the scope?

13 MR. MANN: Outside the scope of the  
14 prehearing statement.

15 JUDGE SOEFFING: Overruled.

16 THE WITNESS: So there are different  
17 ways that people don't know what they're using.  
18 So my big concern, as I mentioned earlier, was  
19 unknown or unintentional exposure. And then it  
20 was the big problem with fentanyl years ago. I  
21 mean, it's still a huge problem, but particularly  
22 the people who are unknowingly exposed.

23 So this goes with other drugs, too,  
24 whether it's a psychedelic or stimulant or  
25 opioid. A lot of people don't know what they are

1 using. You are buying drugs illegally. It's not  
2 like you are going to a store where hopefully the  
3 product you are buying is regulated. It's not  
4 like that with illegal drugs.

5 And when it comes to these, you know,  
6 compounds, a lot of people don't know what they  
7 are using. Somebody might think that they are  
8 using a particular stimulant because somebody  
9 said, hey, this is drug X. But maybe it's Drug  
10 Y, and it looks the same and might even feel the  
11 same. But that doesn't mean -- you can't always  
12 rely on somebody you just gave \$50 to on the  
13 street for what it is. You don't know. A lot of  
14 these drugs are similar.

15 BY MR. PHELPS:

16 Q I'd like to point your attention now  
17 to what's been marked as Government's Exhibit 10.  
18 Do you have a copy of that?

19 A Do I have 10?

20 Q Top of the page is r/Psychonaut. It's  
21 a Reddit post.

22 A Let's see. Let me find it. A Reddit  
23 post, it's a picture of like a brain or  
24 something?

25 Q Yes, yes. Do you see at the bottom

1 right corner of that where it's labeled with the  
2 exhibit number?

3 A Let me see. Yes. It's written, not  
4 typed. Docket 24-24, Government Ex 10.

5 Q Thank you. And I'd like to point your  
6 attention to Page 2 of that exhibit.

7 A Mm-hmm.

8 Q And there's a comment there by a user  
9 named w00t4me.

10 A Yes.

11 Q And the comment says way more than  
12 100, referring to the use of DOI, been in events  
13 where 200 to 300 did it. What do you make of  
14 that post and its reliability in regards to proof  
15 of use?

16 MR. MANN: Objection. Outside the  
17 scope and calls for speculation. He is not an  
18 expert in the reliability of online data.

19 MR. PHELPS: He's an expert in drug  
20 use epidemiology and specifically within that  
21 expertise is the use of social media to monitor  
22 drug use. This is directly within his area of  
23 expertise. We're not going to spend much time on  
24 this, Your Honor. I just want his brief  
25 assessment.

1 JUDGE SOEFFING: Well, I think we are  
2 getting pretty far away from the prehearing  
3 statement. This was a late exhibit. It was  
4 added during the Government's case in chief. So  
5 I'm going to allow you to ask a couple questions  
6 about it. But I don't think it will be much help  
7 to the tribunal.

8 MR. PHELPS: Certainly.

9 JUDGE SOEFFING: The objection is  
10 overruled.

11 BY MR. PHELPS:

12 Q In summary, what does that post tell  
13 you about the actual use of DOI?

14 A First of all, I am an expert in the  
15 accuracy of self-report regardless of what anyone  
16 thinks.

17 MR. MANN: Objection. He's not been  
18 certified --

19 JUDGE SOEFFING: Hold on, sustained.  
20 I'm sorry, doctor, but I have to admit you as an  
21 expert for each particular thing you are going to  
22 testify about. And that was not one of the  
23 subject matter areas for this hearing.

24 So although you may be recognized as  
25 an expert in that in other forums, for purposes

1 of this hearing you're not being recognized as an  
2 expert in that. So if you could just answer the  
3 question that counsel asked you, that would help  
4 move things along. Mr. Phelps?

5 MR. PHELPS: Thank you, Your honor.

6 BY MR. PHELPS:

7 Q If you could just say what is that  
8 post and the subsequent -- or that comment and  
9 the subsequent comments under that tell you about  
10 actual use of DOI?

11 MR. MANN: Objection. Calls for  
12 speculation.

13 JUDGE SOEFFING: It is speculative.  
14 He can answer. I'll overrule the objection, but  
15 I don't know what use I can make of it.

16 THE WITNESS: As an expert and as a  
17 human, it's just I know that a lot of people  
18 write strange things on message boards. Some  
19 people exaggerate. Some people are telling the  
20 truth. I don't know the probability of this  
21 being correct.

22 But the fact that somebody says that  
23 at an event 200 to 300 people used it, something  
24 that I've learned through my studies of studies  
25 at nightclubs, which are events, which he was

1 probably talking about, is that when people are  
2 on a drug, they tend to misperceive something  
3 that, for example, just because their group of  
4 friends is on a drug, they tend to think that  
5 everybody is on the drug because they know a few  
6 people on it.

7 And I find it interesting. And that's  
8 one of the reasons I got into research because of  
9 misperceptions about drug use. Is it possible?  
10 I guess. But that's not my place.

11 And then when you receive the reply  
12 after that someone said it was a parent-teacher  
13 conference, it just shows how serious some of the  
14 posters really are.

15 So if you're asking me is it possible?  
16 It is. Is it likely? I don't think so. It's  
17 such a rare drug.

18 BY MR. PHELPS:

19 Q Thank you.

20 A And if somebody said 200 or 300 people  
21 were on Ecstasy, which is prevalent, I would  
22 still doubt it because, again, people, especially  
23 when they're on drugs, they misperceive. They're  
24 on drugs. They're on hallucinogens. They're not  
25 always the best historians also.

1           Q       Thank you. And Dr. Palamar, what if  
2 any, is your personal stake in the results of  
3 this hearing and the scheduling of DOI and DOC?

4           A       None. I mean, to be honest. I  
5 honestly don't care. I want to provide objective  
6 information because I specialize in the  
7 monitoring of drugs.

8                   To be blunt, I don't care whether or  
9 not this is made illegal or Schedule I. I have  
10 no stake in it. I care about the monitoring of  
11 drugs and that's it. I don't care either way.  
12 I'm just here to provide information.

13                   MR. PHELPS: Thank you. No further  
14 questions for this witness, Your Honor.

15                   JUDGE SOEFFING: Thank you, Mr.  
16 Phelps. Mr. Mann?

17                   MR. MANN: Yes. Thank you, Your  
18 Honor.

19                   CROSS-EXAMINATION

20                   BY MR. MANN:

21           Q       Dr. Palamar, you said you have no  
22 personal stake in the outcome of this proceeding,  
23 correct?

24           A       Correct.

25           Q       But you do have a personal stake in

1 proving that certain drug users are stigmatized.

2 Is that correct?

3 A No.

4 Q So you haven't done research to try to  
5 prove that certain drug users are stigmatized?

6 A Not to prove. I investigated it. And  
7 that was a long time ago. It's not a personal  
8 concern anymore. To be honest, I think there is  
9 too much focus on stigma lately.

10 Q You are a -- how much of the  
11 Government's case did you watch to prepare for  
12 your testimony today?

13 A None. I wasn't aware that I was able  
14 to.

15 Q Have you ever watched the Government's  
16 testimony?

17 A No.

18 Q Okay. And did you review any of the  
19 transcripts when the Government --

20 A No.

21 Q -- presented its witnesses?

22 A No.

23 Q And did you review any of the  
24 Government's exhibits?

25 A No.

1           Q       Okay. You didn't review Government  
2 Exhibits 11 through 16, correct?

3           A       No. I haven't.

4           Q       Dr. Palamar, you say you are very  
5 familiar with HIDTA, is that right?

6           A       I am more familiar than most  
7 researchers. I am not as familiar as the people  
8 at HIDTA.

9           Q       All right. So are you familiar that  
10 HIDTA is a program which allocates federal funds  
11 to local governments to fight illegal drug  
12 trafficking?

13          A       Yes.

14          Q       And would you agree with this  
15 statement that to qualify for consideration as a  
16 HIDTA, high intensity drug trafficking area, an  
17 area must meet the following criteria. The area  
18 is a significant center of illegal drug  
19 production, manufacturing, importation or  
20 distribution. Would you disagree with that?

21          A       That sounds correct.

22          Q       All right. So can you explain why  
23 anyone at HIDTA would be concerned with cracking  
24 down on non-controlled drugs?

25          A       No.

1 MR. PHELPS: Objection. Calls for  
2 speculation.

3 JUDGE SOEFFING: Overruled.

4 BY MR. MANN:

5 Q I think you just answered the  
6 question. Now, you used the term --

7 A No. I answered that --

8 JUDGE SOEFFING: Hold on.

9 THE WITNESS: -- you would know if  
10 something is seized.

11 JUDGE SOEFFERING: Hold on. Doctor,  
12 if you hadn't finished your answer, I will give  
13 you the opportunity to finish the answer. So it  
14 sounds like there was more you wanted to add to  
15 your answer?

16 THE WITNESS: Yeah.

17 JUDGE SOEFFING: Go ahead.

18 THE WITNESS: It's that they don't  
19 know whether it's illegal. A powder is seized.  
20 They don't know what is in it until it is tested.  
21 it doesn't mean they are seeking legal drugs.

22 BY MR. MANN:

23 Q That they are seeking legal drugs? Is  
24 that what your testimony is?

25 A It says it does not mean they are

1 seeking legal drugs. They are seeking probably  
2 always illegal drugs. But they don't --

3 Q All right. Thank you.

4 A -- know what it is until it is tested.

5 Q Thank you. All right. So let me ask  
6 you this. You have not reviewed any of the  
7 Micrograms, the DEA Micrograms that have been  
8 submitted as part of this case?

9 A No.

10 Q Have you read them?

11 A No.

12 Q So you cannot dispute that they relate  
13 to seizures of DOI and DOC? You have no basis to  
14 form an opinion as to whether those Micrograms  
15 are accurate --

16 A I wasn't asked to.

17 Q I'm sorry?

18 A I was asked to provide my own data on  
19 HIDTA and NFLIS.

20 Q All right. So would it surprise you  
21 that all of the DEA Micrograms that have been  
22 offered as evidence of DOI and DOC seizures, that  
23 none of them deal with any seizures in New York,  
24 where you did your principal research. Would it  
25 surprise you?

1           A       Of course not.

2           Q       That 5 out of 790 seizures in the  
3 United States relating to DOC, only five of them  
4 were in New York, the State of New York. Would  
5 that surprise you?

6           A       No.

7           Q       And would it surprise you that out of  
8 the 40 seizures of DOI -- out of the 40 seizures  
9 of DOI, zero occurred in New York State. Would  
10 that surprise you?

11          A       No, no.

12          Q       In fact, they all occurred in southern  
13 states below New York State.

14                 Now you used the term novel drugs. Is  
15 that a fair term to describe the DOx drugs?

16          A       Yes. I think novel is a better term  
17 than new because the original components go back  
18 to the 60s. So novel I think is better than new,  
19 yes.

20          Q       Okay. I want to read you something  
21 from a book entitled, Neuropathology of Drug  
22 Addictions and Substance Misuse written by Evan  
23 Herrmann and Ryan Vandrey, and I want to just ask  
24 you if you agree or disagree with these  
25 statements.

1 MR. PHELPS: Objection, Your Honor.  
2 He's referring to documents that I don't believe  
3 have been disclosed. If he's referring to direct  
4 quotes out of a book, that's something that  
5 should have been provided in their prehearing  
6 disclosures.

7 JUDGE SOEFFING: Well, this is  
8 cross-examination. Is any of this in an exhibit  
9 that is before the Court?

10 MR. MANN: No, it's not, Your Honor.  
11 I'm just asking if he agrees with these  
12 statements.

13 JUDGE SOEFFING: So I'll overrule the  
14 objection.

15 BY MR. MANN:

16 Q All right. I am quoting from Chapter  
17 88, Volume 3, of the book that I just mentioned.

18 Various DOx compounds have been  
19 available on the illicit drug market for several  
20 decades, but none sustained popularity in the  
21 20th Century. DOM was prevalent on the black  
22 market in the 1960s while recreational use of  
23 other compounds like DOC and Bromo-DragonFLY has  
24 occurred relatively recently.

25 DOx compounds have subjective effects

1 similar to those of classic hallucinogens, LSD,  
2 mescaline. And since most of these compounds are  
3 quite potent (psychoactive in doses of a few  
4 milligrams or less), DOx drugs have been  
5 misrepresented/sold as LSD.

6 And that comes from the Drug  
7 Enforcement Administration.

8 Do you have any reason to disagree  
9 with those statements?

10 A No, I don't.

11 Q All right. Now there was some  
12 discussion about data from NSDUH.

13 A NSDUH, yes.

14 Q NSDUH, is that what you call it? All  
15 right. Are you aware that there are a number of  
16 people who are not surveyed by NSDUH?

17 A Yeah. It's only between 50,000,  
18 60,000 people per year. So the vast majority of  
19 the population are not surveyed. It's supposed  
20 to be a representative sample.

21 Q I get that. But what I am asking, are  
22 you aware that there are certain classes or areas  
23 or types of people that are never surveyed at  
24 all?

25 A Absolutely.

1 Q All right. And that would include  
2 homeless people?

3 A No.

4 Q You're disagreeing with that?

5 A Absolutely, I disagree. It's homeless  
6 who don't use shelters.

7 Q Exactly. Non-sheltered homeless  
8 people.

9 A Well --

10 Q And that would include active  
11 military. They are not surveyed, are these?

12 A I agree.

13 Q And people who are incarcerated, they  
14 are not surveyed.

15 A I agree.

16 Q And people in nursing homes, mental  
17 institutions and long-term care facilities, you  
18 agree that they are not surveyed either?

19 A Yes.

20 Q And it's fair to say that when you use  
21 the term DOx you are referring to hallucinogens  
22 that begin with DO, correct?

23 A Yes.

24 Q And that would include DOI?

25 A Yes.

1 Q DOC?

2 A Mm-hmm.

3 Q And DOV?

4 A Yup, yes.

5 Q Is it also your understanding that  
6 with NSDUH, N-S-D-U-H, that the submissions made  
7 to NSDUH are purely voluntary, correct?

8 A Yes.

9 Q And that if someone claims to have  
10 taken LSD for instance, there really is no way to  
11 confirm whether that was actually LSD is there?

12 A I agree.

13 Q So it could be any variety of  
14 hallucinogen?

15 A Depending on their availability, but  
16 yes, people don't always know what they're  
17 taking.

18 Q Just one moment. Dr. Palamar, you are  
19 aware of situations in which a drug of a concern  
20 gains in popularity throughout the years,  
21 correct?

22 A I'm not sure I understand.

23 Q All right. Let me ask you. What is  
24 your belief in the abuse of MDMA?

25 A The use not the abuse.

1 Q Do you believe it's being abused?

2 A Well, abuse has a very specific  
3 definition. Use does not equal abuse. And I  
4 believe you're asking about use in an illicit  
5 manner. If you'd like me to comment on that, I  
6 can.

7 Q Well, do you believe it is being used  
8 in an illicit manner?

9 A Yes, I believe.

10 Q And are you familiar with the final  
11 order that put MDMA In Schedule I?

12 A Around 1985?

13 Q Yes.

14 A Yes.

15 Q And do you recall that at that time,  
16 the administrative law judge felt that the  
17 government had not met its burden for showing a  
18 high abuse potential for MDMA?

19 A I read about this extensively years  
20 ago. I don't recall the details. I think if I  
21 recall correctly, it was made illegal and then  
22 there was some sort of reversal, and it went back  
23 to illegal again. But I could be wrong. But I  
24 know overall it was made in Schedule I around  
25 1985 --

1 Q And --

2 A -- as a final rule.

3 Q And do you have any reason to disagree  
4 with this statement, which I'm reading from the  
5 final order, that the judge recommended that MDMA  
6 be placed in Schedule III of the CSA. He reached  
7 this conclusion after finding that MDMA has a  
8 currently accepted medical use in treatment in  
9 the United States. That MDMA does not lack  
10 acceptance of safety for use under medical  
11 submission and that it has less than a high  
12 potential for abuse.

13 MR. PHELPS: Objection, Your Honor,  
14 this is wildly beyond the scope of direct.

15 BY MR. MANN:

16 Q Do you have any reason to dispute  
17 that?

18 JUDGE SOEFFING: So hold on. I'll  
19 overrule the objection.

20 BY MR. MANN:

21 Q Do you have any reason to dispute that  
22 statement?

23 A That it should have been schedule --

24 Q Do you have any reason --

25 JUDGE SOEFFING: Hold on. Hold on.

1 Just one person at a time so we have a clear  
2 record.

3 BY MR. MANN:

4 Q I'm sorry. Let me ask the question.  
5 Do you have any reason to dispute that that is a  
6 quote from the MDMA final order?

7 A Oh, I don't dispute that it's a quote,  
8 no.

9 Q So those would be in light of the use  
10 of MDMA today, famous last words, would they not?

11 A I honestly don't know.

12 MR. MANN: That's all I have. Thank  
13 you.

14 JUDGE SOEFFING: Mr. Phelps, any  
15 redirect?

16 MR. PHELPS: Yes, just briefly, Your  
17 Honor.

18 REDIRECT EXAMINATION

19 BY MR. PHELPS:

20 Q So the Government -- Dr. Palamar, the  
21 Government asked you about what he referred to as  
22 Government's Exhibits 11 through 16, those are  
23 some Microgram Bulletins. Are you familiar with  
24 what the Microgram Bulletin is?

25 A No. What years roughly?

1           Q       So not referring to those specific  
2 ones, but in general, are you familiar with --

3           A       No.

4           Q       -- the Microgram Bulletin?

5           A       No. And I'm pretty up-to-date with  
6 most literature. That's why I asked about the  
7 years. I follow most of the current reports. It  
8 doesn't sound current to me, but I could be  
9 wrong.

10          Q       So as an expert in drug use  
11 epidemiology, the DEA's Microgram Bulletin is not  
12 a source of data or information for your studies?

13          A       Not for my studies. If they are  
14 putting out current reports, I would be  
15 interested. I do follow a lot of DEA reports. I  
16 closely follow their NFLIS reports, DEA Talks. I  
17 think it's a really cool program. I will read  
18 their annual Threat Report. I can't wait for  
19 these reports to come out. But the one you're  
20 mentioning, I honestly never heard of.

21          Q       And you stated that -- there was a  
22 question about the number of encounters of DOI in  
23 New York specifically. When we're talking about  
24 numbers in the range that you've been discussing  
25 about DOI and DOC, what does the prevalence in

1 one particular state signify, if anything?

2 A Uncommon uses within that area. And,  
3 of course, the use of drugs. I mean, the  
4 prevalence shifts from state to state. But it  
5 depends on the year. Like at NDEWS, we try and  
6 stay as current as possible. Drug trends, I  
7 mean, if we looked at a report from 10 years ago,  
8 fentanyl would probably rarely pop up. Now  
9 Fentanyl is the biggest problem. So it depends  
10 on the drug we're looking at and the area.

11 Q Why aren't mental health facilities,  
12 nursing homes or the active military included in  
13 those drug use surveys?

14 A They are considered institutionalized.  
15 So I don't know if that does not make each group  
16 specifically ineligible, but I just know that  
17 they focus on non-institutionalized individuals.  
18 It used to be just households. And as I said  
19 earlier, they expanded to that. I don't know all  
20 of their reasoning.

21 Q And why would they only survey 50,000  
22 to 60,000 people across the whole country?

23 A I've never heard only 50,000, 60,000  
24 people would get it. Research, something people  
25 don't know is how expensive it is to survey,

1 especially with a very top tier design, a survey  
2 design.

3 So, I mean, it takes a lot of  
4 planning. And you have to randomly select  
5 dwellings. And I think it's even people within  
6 dwellings, if I recall correctly. And you have  
7 to change that every year to who you are aiming  
8 for.

9 And then you have to recruit, and you  
10 need personnel, which is more and more expensive  
11 every year, paying people to go survey, to  
12 oversee the data, to oversee the study.

13 Then you pay participants. I don't  
14 recall how much participants make. It might be  
15 around \$30 or so to take the survey. But for one  
16 study here, it easily costs many, many millions  
17 of dollars for a first study like this.

18 Q And what is that number of data say  
19 relative to the entire population?

20 A We hope it's reliable. There are some  
21 ways they have tested reliabilities. For  
22 example, they would test prevalence and compare  
23 it to other national surveys.

24 So, I mean we expect different groups  
25 to be different. Like high school seniors,

1 that's the monitoring the future study. That  
2 will probably have a different prevalence than  
3 the overall population.

4 But if we see, for example, that  
5 cocaine use is going up in one survey, we expect  
6 to see it going up in the other. And 2013 should  
7 be comparable to 2014 and so on.

8 So trends typically shift in a slow  
9 manner. And that's just the way it is. So  
10 there's different ways of testing reliability.

11 MR. PHELPS: Thank you. No further  
12 questions for this witness, Your Honor.

13 JUDGE SOEFFING: Thank you, Mr.  
14 Phelps. Mr. Mann, any recross?

15 MR. MANN: Very briefly.

16 RECROSS-EXAMINATION

17 BY MR. MANN:

18 Q Dr. Palamar, you didn't do any surveys  
19 in Michigan, did you?

20 A I did not, no. I don't recall if  
21 NDEWS has. We've done it in a lot of cities.  
22 But it does not come to mind.

23 Q And you didn't do any surveys in  
24 Kentucky, did you?

25 A No, I personally did not.

1           Q       And you didn't do any surveys in  
2 Florida, did you?

3           A       NDEWS has done multiple surveys there.  
4 We have a lot of Florida data. In fact Florida  
5 is probably the main state we get all sorts of  
6 data from at NDEWS.

7           Q       So on the issue of Florida, would you  
8 dispute this statement from 2008. The Palm Beach  
9 County Sheriff's Office Crime Laboratory  
10 Chemistry Section recently received two different  
11 exhibits of blotter paper, suspected LSD. The  
12 exhibits were seized in Lantana by the Lantana  
13 police.

14                   The first exhibit consisted of one  
15 quarter inch square of blotter paper, orange on  
16 one side and blank on the others. Indicated not  
17 LSD, but rather DOI. Do you have any reason to  
18 dispute that report?

19           A       No.

20           Q       And did you do any surveys in Chicago  
21 or in the State of Illinois?

22           A       Me personally, no. NDEWS, we might  
23 have.

24           Q       How about Wisconsin?

25           A       Not to my knowledge.

1           Q       Okay. So would it surprise you that  
2 there have been DOI seizures in Michigan,  
3 Kentucky, Florida and Wisconsin?

4           A       In what time frame?

5           Q       Well, would it surprise you that there  
6 were seizures at all in those states?

7           A       Ever? No.

8           MR. MANN: Okay. Thank you.

9           JUDGE SOEFFING: All right. Thank  
10 you, Doctor, for your testimony. You are  
11 excused. I direct you not to discuss your  
12 testimony with anyone until the conclusion of the  
13 hearing.

14           MR. PHELPS: Your Honor, we would ask  
15 that this witness be permanently excused.

16           JUDGE SOEFFING: Okay. No intent to  
17 recall this witness?

18           MR. PHELPS: No intent, Your Honor.

19           JUDGE SOEFFING: Mr. Mann, any intent  
20 to recall this witness?

21           MR. MANN: No, Your Honor.

22           JUDGE SOEFFING: Okay. Again, Dr.  
23 Palamar, you're excused. Please do not discuss  
24 your testimony with anyone until the conclusion  
25 of the hearing. Thank you.

1 THE WITNESS: Sure. Thank you.

2 JUDGE SOEFFING: Off the record.

3 (Whereupon, the above-entitled matter  
4 went off the record at 11:46 a.m. and resumed at  
5 11:50 a.m.)

6 JUDGE SOEFFING: All right. We will  
7 break for lunch now, and we will return at 1  
8 o'clock for the Petitioners to put on their next  
9 witness.

10 (Whereupon, the above-entitled matter  
11 went off the record at 11:50 a.m. and resumed at  
12 1:06 p.m.)

13 JUDGE SOEFFING: Okay. We are back on  
14 the record. Mr. Phelps, are you ready to call  
15 your next witness?

16 MR. PHELPS: Yes, Your Honor.  
17 Petitioners would call Dr. Mario de la Fuente  
18 Revenga.

19 JUDGE SOEFFING: Come on right up here  
20 to the witness box, Doctor. Doctor, please raise  
21 your right hand.

22 WHEREUPON,

23 MARIO DE LA FUENTE REVENGA

24 was called as a witness by Counsel for the  
25 Petitioners and, having been first duly sworn,

1 assumed the witness stand, was examined and  
2 testified as follows:

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

6 THE WITNESS: Mario de la Fuente  
7 Revenga. My first name is Mario, MARIO. My last  
8 name is de la Fuente Revenga, D-E space L-A space  
9 F-U-E-N-T-E space R-E-V-E-N-G-A.

10 JUDGE SOEFFING: Thank you. Counsel,  
11 you may inquire.

12 MR. PHELPS: Thank you.

13 VOIR DIRE EXAMINATION

14 BY MR. PHELPS:

15 Q Thank you for being here this  
16 afternoon, Dr. de la Fuente. Is that --

17 A That's --

18 Q -- okay to call you?

19 A Yes.

20 Q Thank you. Dr. de la Fuente, what  
21 degrees do you currently hold?

22 A I'm a Doctor of Pharmacy, and I'm a  
23 Doctor of Medicine in Chemistry.

24 Q And do you have any other degrees  
25 besides those two?

1           A       Those are my main degrees, medicine  
2           and chemistry with certification in pharmacology,  
3           but officially it's medicine and chemistry.

4           Q       But before you received those degrees,  
5           did you have any other schooling that you  
6           received degrees in?

7           A       Preceding those, high school and  
8           that's about it. My education -- I received my  
9           education in Spain. This is slightly different  
10          to get into pharmacy school. It is something you  
11          do right after high school. It's a longer  
12          process, but goes on as opposed to many year plus  
13          pharmacy school as it is in the U.S.

14          Q       Okay. And so how long were you in  
15          school in total, I guess, from high school to  
16          getting those two degrees?

17          A       In terms of obtaining my pharmacy  
18          degree and medicinal chemistry degree?

19          Q       Yes, sir.

20          A       That was about 10 to 11 years.

21          Q       Okay. And where did you pursue that  
22          pharmacy program?

23          A       I did University Complutense of  
24          Madrid. That's where I got my Doctor of Pharmacy  
25          diploma. And my Doctor of Medicine in Chemistry

1 is by the same institution even though the work  
2 was conducted at the Spanish National Council for  
3 Research.

4 Q Thank you. And could you talk a  
5 little bit about the coursework curriculum you  
6 did through those programs?

7 A Yeah, the Doctor of Pharmacy started  
8 from the very ground level of basic sciences that  
9 pertain to pharmaceutical sciences, chemistry,  
10 vegetable biology, plant biology, botany,  
11 pharmacology, pharmaceutical technology, public  
12 health. pharmacology obviously, organic and  
13 inorganic chemistry, pharmaceutical chemistry,  
14 just to name a few. And the medicine and  
15 chemistry program burst over pretty much the same  
16 subjects with more focus on organic synthesis  
17 and pharmacology.

18 Q Is there a difference between  
19 pharmacology and neuropharmacology?

20 A Yes. It's just a subset, if you wish,  
21 under pharmacology that pertains to the study of  
22 pharmacology within the central nervous system.

23 Q And besides your coursework for the  
24 Doctor of Pharmacy program, what else did that  
25 program consist of?

1           A       Can you repeat that again? Sorry.

2           Q       Yes. I think we'll take each of the  
3 degrees separately. So in the Doctor of Pharmacy  
4 program, what else did that program entail  
5 besides just the coursework that you described?

6           A       I took a short internship in the  
7 Department of Organic Chemistry because that was  
8 an area I was very fond of. I also went on an  
9 exchange program to the University of Uppsala  
10 where I got an undergrad thesis on biocatalysis  
11 and deep eutectic solvents. And those just to  
12 name a few in terms of things I know exactly by  
13 the book, more hands on it, more hands on.

14          Q       Is a dissertation part of that program  
15 in the Spanish system?

16          A       The undergrad thesis, yes.

17          Q       Okay. I guess we've heard a lot about  
18 the American education system. I'm just trying  
19 to make sure, or kind of make clear, you're  
20 familiar with American university dissertations  
21 that part of PhD programs?

22          A       Yes, correct.

23          Q       Okay. Was there a comparable type of  
24 work that you did in that Doctor of Pharmacy  
25 program?

1           A       I'm familiar with the dissertation at  
2       the PhD level, having worked or be acquainted  
3       with school of pharmacy functioning in this  
4       country. So I don't know exactly how that works  
5       here, but in order to obtain the Doctor of  
6       Pharmacy in Spain, you need to accumulate a  
7       certain number of credits. You need to have also  
8       an internship at a pharmacy in a hospital  
9       pharmacy and that undergraduate thesis that needs  
10      to be presented in what I would imagine is  
11      comparable to a dissertation here.

12          Q       Okay. Okay. Thank you. And in the  
13      PhD program in the medicinal chemistry, could you  
14      talk a little bit about the coursework that you  
15      did for that program?

16          A       Yes. That program was a lot more  
17      focused on drug discovery and therefore cover the  
18      subjects that go all the way from choosing what  
19      targets at the pharmacology level are worth it  
20      from a therapeutic perspective and how to design  
21      drugs to act upon them and how to use the  
22      chemistry to make them. Organic chemistry,  
23      organic synthesis, pharmacology, structural  
24      biology, analytical methods and the like.

25          Q       And then outside of the course work,

1 was there a dissertation type project that you  
2 did in that program?

3 A Yes.

4 Q Could you explain that please?

5 A Yes. The five years of my PhD  
6 program, finalized with dissertation, which I  
7 presented my work pertaining to the use of  
8 bioisosterism in the design of melatonin-like  
9 drugs with neurogenic properties and a side  
10 project that also bioisosterism related to the  
11 development of nicotinic ligands.

12 So while the program per se didn't  
13 have a specific position in neuroscience or  
14 neuropharmacology, the area of focus was heavily  
15 focused on that therapeutic area and obviously  
16 all the groundwork to get the dissertation  
17 involved a lot of neuroscience training.

18 Q Did any of your work in that program  
19 involve psychedelics?

20 A One. I discovered, and I believe this  
21 is the first time in history this was proven,  
22 that 5-methoxy-DMT is a partial agonist at the  
23 melatonin receptor, I want to say, MT1. I can't  
24 recall from memory.

25 But other than that, the modality that

1 I was working throughout my entire PhD program is  
2 akin to a triptamine. So while not exactly  
3 working on psychedelics, I was working around the  
4 exact same kind of chemistry.

5 Q So how did that work inform your  
6 understanding of the neuropharmacology of  
7 psychedelics?

8 A That was a natural transition. Some  
9 of the chemistry I was doing led me into a  
10 structure that's called beta-carbolines, which  
11 are compounds found in the Amazonian brew with  
12 psychedelic properties called ayahuasca.

13 So it was really the chemistry that  
14 led the path of my research interest to start  
15 from neuroscience and sort of final down to  
16 psychedelics where I thought there was a lot of  
17 opportunity for great science to be done.

18 Q And after you completed that program,  
19 did you conduct any post-doctoral research?

20 A Yes. As soon as I completed my PhD  
21 studies, I worked with the late Dr. Jordi Riba at  
22 the University Autonomia Barcelona although his  
23 med site was Hospital San Paolo.

24 He was at the time conducting  
25 observational studies on subjects using

1       ayahuasca, certain, ceremonies. And we were  
2       studying both through fMRI and through  
3       psychological tests looking for correlates on  
4       what the subject of experience translated into at  
5       the subjective level.

6               Q       So that would have been specifically  
7       related to the neuropharmacology of ayahuasca?

8               A       Clinical neuropsychopharmacology. But  
9       neuropharmacology is a good summary term for  
10      that.

11              Q       And did you do any other  
12      post-doctorate programs after that?

13              A       Shortly after that is when I first  
14      came to the U.S. and I joined Dr.  
15      Gonzalez-Maeso's research group. And my initial  
16      project pertained to the study of the  
17      neuropharmacology of antipsychotics.

18                    Obviously, there is a little bit of  
19      departure from the psychedelic field except that  
20      psychedelics are commonly used in this kind of  
21      research as a benchmark for the development of  
22      antipsychotics. We use certain effects with  
23      psychedelics. We block them with  
24      anti-psychotics.

25                    Over time that -- my area of interest

1 and research study shifted in balance and  
2 pertained less to antipsychotics and more and  
3 more to psychedelics.

4 And to this day, quite frankly, I  
5 joined this lab in 2015, and I still have more  
6 symbolic, than anything, appointment as an  
7 affiliate system professor at BCU, but this gives  
8 me an opportunity to continue some of the  
9 research that I initiated there.

10 Q And when did you specifically begin  
11 working with DOI?

12 A Fairly early on. I wouldn't be able  
13 to pinpoint exactly what year, but the first  
14 publication that I have where DOI is mentioned, I  
15 believe it is 2019. So it's a good estimate that  
16 one or two years prior to that would be my first  
17 hands-on experience with the drug.

18 Q And could you talk a little bit about  
19 your publication history?

20 A Yes, I have over 30 -- I think close  
21 to 35 publications. I believe about a third of  
22 those are first author publications or, you know,  
23 articles only, I believe, four to five reviews.  
24 They will be with medicinal chemistry and  
25 pharmacology. Those would be the main areas that

1 speak to my areas of expertise.

2 And I also had at the time, one patent  
3 on these medicinal chemistry efforts around the  
4 melatonin analysis, this scaffold that is similar  
5 to psychedelics.

6 Q Okay. And I got a little bit ahead of  
7 myself. You've been doing that through memory.  
8 I would like to point your direction to what's  
9 marked for identification purposes as Exhibit 82.  
10 Do you recognize that document?

11 A Yes, I do.

12 Q And are you familiar with its  
13 contents?

14 A Yes.

15 Q And could you just take a quick flip  
16 through that and confirm that it's the same  
17 document that you had provided to us?

18 A It certainly is.

19 MR. PHELPS: Your Honor, at this time,  
20 we would move to admit Exhibit 82.

21 JUDGE SOEFFING: What is this  
22 document, Doctor?

23 THE WITNESS: This is my curriculum  
24 vitae as of sometime in 2022. There has been  
25 some new responsibilities that I have had since,

1 but this is a fairly updated CV of mine.

2 JUDGE SOEFFING: Mr. Mann, are you  
3 handling this witness?

4 MR. MANN: Yes.

5 JUDGE SOEFFING: Do you have any  
6 objection to Petitioner's Exhibit 82?

7 MR. MANN: No, we don't.

8 JUDGE SOEFFING: Petitioner's Exhibit  
9 marked for identification Number 82 has been  
10 offered. In the absence of objection, it is  
11 received in the record as Petitioner's Exhibit  
12 82. It's in. You may use it.

13 (Whereupon, the above-referred to  
14 document was received into evidence as  
15 Petitioner's Exhibit No. 82.)

16 MR. PHELPS: Thank you, Your Honor.

17 BY MR. PHELPS:

18 Q So, if you could quickly just turn to  
19 Page 5, we'll turn back to the publication thing  
20 is where we left off. Could you just take a  
21 quick flip through Pages 5 to 8. And roughly how  
22 many of those papers or presentations were done  
23 on psychedelics?

24 MR. MANN: Judge, my copy is marked at  
25 the top but there are no page numbers on it.

1 JUDGE SOEFFING: There's no page  
2 numbers at the bottom?

3 MR. PHELPS: So that would have been  
4 one of the originals that were sent. We did  
5 provide updated CVs that would have had page  
6 numbers. These that are marked with exhibits  
7 should have the page numbers.

8 JUDGE SOEFFING: Is the only  
9 difference the page numbers?

10 MR. MANN: I just don't have any page  
11 numbers on this exhibit at all?

12 MR. PHELPS: I'm not sure what he has  
13 or doesn't have. It seems to be just the page  
14 numbers. I do know when we were doing discovery  
15 exchange initially, there were some that didn't  
16 have them and then there was the updated one.

17 MR. MANN: I can just use this then  
18 and refer to it.

19 JUDGE SOEFFING: Okay. So Mr. Mann is  
20 looking at a laptop that has the exhibit  
21 represented electronically.

22 BY MR. PHELPS:

23 Q So let's just start with Page 5,  
24 published original articles. How many of those  
25 articles are related to psychedelics?

1           A       So in this intermission, I was able to  
2 count them. It's a total of 11. Do you want me  
3 to tell you exactly how many and which are?

4           Q       Yes. Of the 11 on there, which are  
5 related to psychedelics?

6           A       Number 1, number 2, number 3, 5, 6, 7,  
7 8, 10 -- 10. Sorry, the numbers I listed. Ten  
8 is just like the position in there, on the page.

9           Q       Okay. Okay. And of those that you  
10 mentioned, which are specifically related to  
11 neuropharmacology in psychedelics?

12          A       I believe all of them, but let me just  
13 glance through. Yeah, all of them.

14          Q       And just to kind of back -- how does  
15 the study of medicinal chemistry relate to the  
16 field of neuropharmacology?

17          A       Well, they are very much intertwined.  
18 Medicinal chemists tend to be the laughingstock  
19 of organic chemists because they are deemed too  
20 vanilla on what they do, but medicinal chemist is  
21 doing chemistry on the basis of the biological  
22 interactions they are seeking to stimulate or  
23 block with the compounds they are making.

24                   So a medicinal chemist doesn't do  
25 chemistry unless there is target that you are

1 willing to go after. In the particular case of  
2 neuropharmacology, neuropharmacology is the  
3 ultimate frontier, if you wish, for a medicinal  
4 chemist to surpass. Do I get my compounds to be  
5 active at the neuropharmacological level? And  
6 that pretty much determines whether you are a  
7 good medicinal chemist or not.

8 Q So okay. And if you could just take  
9 kind of a quick skim through pages 6, 7 and 8.  
10 We don't have to go through every single one, but  
11 if you could just give a rough idea of how many  
12 of those publications or presentations were  
13 within the fields of neuropharmacology and  
14 psychedelics.

15 A Psychedelics, the total number is 11  
16 of publications, and neuropharmacology, in excess  
17 of 11. I would say probably all of them except  
18 for a couple of papers in biocatalysis.

19 Q And outside of your -- well, what kind  
20 of grant funding have you received for the study  
21 of neuropharmacology and psychedelics?

22 A The most recent one was a T32 research  
23 scholarship for the study of the relationship  
24 between common and rare variants and how they  
25 affect the neuropharmacology of both psychedelics

1 and antipsychotics.

2 My PhD program, I also received  
3 funding for my PhD program. I had my own  
4 scholarship. It wasn't explicitly for  
5 psychotics, but it did recognize  
6 neuropharmacology as one of the areas where my  
7 medicinal chemist efforts would be headed.

8 Q Looking now towards the bottom of page  
9 3 on your CV, could you talk a little bit about  
10 your work with the Radius Health Lab?

11 A Yes. At the beginning of 2022, I was  
12 hired by Radius Pharmaceuticals as their  
13 executive director of discovery. The goal there  
14 was to expand the neuroscience franchise.

15 Radius is a biotech company. And they  
16 have a drug for -- I'm tripping now on the  
17 indication -- endocrinology, unrelated. But the  
18 neuroscience franchise was very much focused on  
19 drugs in the sphere of cannabinoids and  
20 psychedelics and the reason that motivated my  
21 hiring or joining me on the team was based on my  
22 expertise in the field.

23 The goal of becoming part of the  
24 Radius team was to initiate a discovery effort,  
25 which would entail setting up the lab and

1 coordinating a nascent team to undertake the  
2 responsibilities.

3 Q And how does DOI relate to your work  
4 in neuropharmacology?

5 A So DOI is an excellent tool drug.  
6 Since my brave first approach to anything in the  
7 realm of narcotics and psychedelics proved to be  
8 extremely difficult for several reasons.

9 It's very stable, which is always a  
10 perk in terms of using drugs repeatedly. In a  
11 forced duration in mice, in animal models, that  
12 is crucial in my understanding because animals,  
13 small animals, small mammals, they have a high  
14 metabolic rate. What does this mean? When we  
15 give them drugs that we use in humans, they tend  
16 to be eliminated very fast.

17 So are we really getting relevant  
18 information if the mouse is exposed to five  
19 minutes of psilocin or psilocybin or any  
20 substance when the human brain is exposed to six  
21 hours of that drug? Obviously, the answer to  
22 that is no to maybe.

23 And that's the beauty of the OI. It  
24 produces a stimulation of the same receptors of  
25 that psychedelic to stimulate, but its

1 pharmacokinetics allow it to be in the mouse  
2 brain for a duration of time comparable to what a  
3 human experience would be like.

4 So that is crucial in terms of  
5 overcoming some of the limitations that we need  
6 to face when we use rodent models in the study of  
7 neuropharmacology, just to name a few.

8 DOI is also an excellent benchmark and  
9 positive control for head-twitch experiments.  
10 And this goes on because it has a privileged  
11 pharmaco dynamic profile that allows it to  
12 dissolve some of the confounders that often one  
13 can come across when you see another more common  
14 use of psychedelics.

15 Q So how familiar would you say you are  
16 in the use and study of DOI?

17 A Probably currently I would be  
18 confidently in the top three worldwide by  
19 scientific production, volume and impact factor  
20 in the use of the DOI in the research lab, not  
21 clinical.

22 MR. PHELPS: Your Honor, at this time,  
23 we would move to admit Dr. de la Fuente Revenga  
24 as an expert in the study of medicinal chemistry  
25 and the neuropharmacology of psychedelics.

1 MR. MANN: No objection.

2 JUDGE SOEFFING: Okay. Very good.

3 Dr. de la Fuente has been offered by the  
4 Petitioners as an expert in the study of  
5 medicinal chemistry and the neuropharmacology of  
6 psychedelics. In the absence of any objection by  
7 the Government, the tribunal accepts the witness  
8 as an expert in the study of medicinal chemistry  
9 and the neuropharmacology of psychedelics.

10 BY MR. PHELPS:

11 Q So, Dr. de la Fuente, could you talk  
12 a little bit about -- I'd like to point your  
13 attention to what's been marked for  
14 identification purposes as SSDP Ramos Exhibit 8.  
15 Do you recognize that document?

16 A Yes. It's an article of my  
17 authorship.

18 Q And you're familiar with its contents?

19 A Correct.

20 Q Where was this article published?

21 A In the journal called Neuroscience.

22 Q And could you just tell us what the  
23 title of this is and the general summary of the  
24 paper and maybe any conclusions that were reached  
25 in it?

1           A        Sure. The title is HDAC2-dependent  
2 Antipsychotic-like Effects of Chronic Treatment  
3 with the HDAC Inhibitor SAHA in Mice.

4                   And in more layman terms, what this  
5 article deals with, is with the fact that in view  
6 of the shortage or limited amount of tools we  
7 have to treat psychosis, we try to unveil  
8 potential routes to see what other biological  
9 paths we would come up with new possibilities in  
10 this devastating disease that is schizophrenia.  
11 And in doing so we explored not just  
12 antipsychotics, but some of the negative effects  
13 that are currently used antipsychotics have. And  
14 that's what it deals with.

15                   There are these epigenetic factors,  
16 and it is mainly regulated by a product called  
17 HDAC-2, and this seems to be responsible for some  
18 of the negative effects of the good medications  
19 that we have.

20                   So in flipping the coin, we try to  
21 explore if we could mess in a less scientific way  
22 with these protein to see if we could identify  
23 antipsychotic-like responses, which we did.

24                   In this article, I believe in Figure  
25 Number 5, we use the DOI was a model to validate

1 that. Typical antipsychotics, the ones that are  
2 most commonly used, they very characteristically  
3 inhibit some of the responses that the DOI uses.  
4 So we wanted to see if we could replicate this  
5 with a drug, that is SAHA listed in the title,  
6 that works in a completely different manner.

7 MR. PHELPS: At this time, we would  
8 move to admit what's marked as Exhibit 8.

9 JUDGE SOEFFING: Doctor, is this a  
10 complete and accurate copy of the article?

11 THE WITNESS: Let me go all the way to  
12 the bottom, but I believe it is. Yes.

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

15 MR. MANN: The only objection we would  
16 have, Your Honor, is relevance. If this is being  
17 offered to show some pharmacological effect of  
18 DOI, then I would withdraw the objection. But I  
19 don't see how this is relevant to the issue in  
20 this proceeding.

21 JUDGE SOEFFING: Okay. I'll overrule  
22 the objection. We'll find out soon enough if  
23 it's relevant. And I will act in the recommended  
24 decision accordingly on that.

25 So Petitioners' Exhibit marked for

1 identification Number 8 has been offered. Over  
2 the Government's objection, it is received into  
3 the record at Petitioners' Exhibit 8, it's in you  
4 may use it.

5 (Whereupon, the above-referred to  
6 document was received into evidence as Petitioner  
7 Exhibit No. 8.)

8 BY MR. PHELPS:

9 Q Thank you, Dr. De la Fuente Revenga.  
10 How would you say this article demonstrates --  
11 well, what's relevant about this article and what  
12 we've been talking about today? Let me just be  
13 --

14 MR. MANN: Objection. I mean,  
15 relevance is a legal term here.

16 JUDGE SOEFFING: So sustained.

17 BY MR. PHELPS:

18 Q Is there anything specific that came  
19 out of this article that's pertinent to what  
20 we're here for today?

21 A This article is the cornerstone in my  
22 career where things started to shift from an  
23 anti-psychotic focus to a more psychedelic-like  
24 orientation as it pertains to my post-doc here in  
25 the United States. So I think it speaks more to

1 my expertise. I see the article was published in  
2 2018, which means that at the very beginning of  
3 my work with DOI they know earlier than 2016. So  
4 just to put it into perspective how long I've  
5 been working with that drug.

6 Q Thank you. I'd like to turn your  
7 attention to what's been marked as SSDP/Ramos  
8 Exhibit No. 9.

9 Q Do you recognize this document?

10 A Yes, I do.

11 Q And what is it?

12 A It's an article of my authorship  
13 published in Cell Reports, the highest impact  
14 factor article published on DOI in recent times.  
15 There's been a few more in more recent years.

16 Q Can you explain what impact factor is?

17 A Impact factor is a measure that's  
18 commonly used in academia to, in a way, assess  
19 the importance of an original manuscript. The  
20 impact factor comes from the amount of times that  
21 the articles in a certain journal have been  
22 referenced and how they've been referenced, and a  
23 little bit not perfect, it's one of the metrics  
24 that academics regularly use.

25 Q And is this a fair and accurate

1 representation of the article?

2 A It is the article, including the  
3 supplementary information, so it is as complete  
4 as it gets.

5 MR. PHELPS: Your Honor, at this time,  
6 we would move to admit Exhibit 9.

7 JUDGE SOEFFING: Mr. Mann, any  
8 objection?

9 MR. MANN: Objection, relevance.

10 JUDGE SOEFFING: Okay. I'll make the  
11 same ruling. I'll give it whatever weight it  
12 deserves based on relevance. I will admit it.  
13 Petitioner's Exhibit, marked for identification,  
14 No. 9 has been offered. Over the Government's  
15 objection, it is received in the record as  
16 Petitioner's Exhibit 9. It's in. You may use  
17 it.

18 (Whereupon, the above-referred to  
19 document was received into evidence as  
20 Petitioner Exhibit No. 9.)

21 BY MR. PHELPS:

22 Q Can you just give a brief summary of  
23 what this article is about and any conclusions  
24 that maybe came from it?

25 A Yes. The purpose of the work behind

1 this article was to try to identify the  
2 responses, therapeutic responses that would  
3 emerge from stimulation of this receptor called  
4 Serotonin 2A. The choice of using DOI was paired  
5 with the use of a particular mouse model that  
6 knocks out that receptor, so we can establish  
7 very clear confusion tables, confusion matrices  
8 to the term it affects in one way or another and  
9 the term in causality.

10 Neuroscience and neuropharmacology is  
11 very heavily modeled by overinterpretation of  
12 mouse models, and that's something that I'm going  
13 to anticipate in this case. And one of the  
14 things that we wanted to include here was a very  
15 objective measure where we not only look at a  
16 behavior in the mouse that we're going to  
17 interpret within the boundaries of what we think  
18 is relevant but also molecular metrics where we  
19 look at complete assessment of the epigenome  
20 modifications that happen in the neurons that  
21 were once exposed in that mouse to the drug, DOI,  
22 and how that landscape of molecular changes  
23 evolves over time and using that framework to  
24 establish whether there's a framework, a scaffold  
25 that can support the synaptic plasticity that

1 might lie underneath some of the therapeutic  
2 effects that psychedelics seem to bear.

3 Q And what has been the impact of this  
4 article on further research?

5 A I would say pretty high. Like I said,  
6 this is the first high-impact article use in  
7 almost exclusively DOI. I believe, as of last  
8 year, we got in Nature from John Hopkins dealing  
9 with DOI's effects on the hippocampus and also  
10 trying to explain the antidepressant effects that  
11 they see in mice. And I think, as of last week,  
12 another one came out dealing with the exact  
13 population of neurons that are responsible for  
14 DOI's anxiolytic effects.

15 So this, in a way, renewed interest at  
16 the scientific level for the drug as a great tool  
17 to tease out what happens through what mechanism.

18 Q Thank you. I'd like you to now turn  
19 to what's been marked for identification purposes  
20 as SSDP/Ramos Exhibit 10.

21 Q And do you recognize that article?

22 A Yes. It's another article of my  
23 authorship.

24 Q And where was this published?

25 A This was an article published in the

1 Journal of Neuroscience Method. It's a  
2 continuation of a previous article published in  
3 Scientific Reports, but the one I have in front  
4 of me is an improvement upon a method that I  
5 developed for the full automation of head-twitch  
6 detection, a model commonly used to study  
7 pharmacological psychedelics.

8 Q And is the copy in front of you an  
9 accurate depiction of the article?

10 A Yes. It's the article in its  
11 entirety.

12 MR. PHELPS: At this time, we would  
13 move to admit what's been marked for  
14 identification purposes as SSDP/Ramos Exhibit 10.

15 JUDGE SOEFFING: Mr. Mann.

16 MR. MANN: Same objection, relevance.

17 MR. PHELPS: The relevance  
18 specifically of this one, this is a study in  
19 head-twitch response, which is specifically  
20 mentioned as something he'll be discussing in his  
21 pre-hearing statement.

22 JUDGE SOEFFING: Okay. So I'll  
23 overrule the objection. Petitioner's Exhibit,  
24 marked for identification, No. 10 has been  
25 offered. Over the Government's objection, it is

1 received into the record as Petitioner's Exhibit  
2 10. It's in. You may use it.

3 (Whereupon, the above-referred to  
4 document was received into evidence as  
5 Petitioner Exhibit No. 10.)

6 BY MR. PHELPS:

7 Q So could you tell us what this is  
8 about?

9 A The paper?

10 Q The paper, yes.

11 A Yes. The content of the paper really  
12 bears little interest because it's very technical  
13 on how one can improve the full automated  
14 detection of head-twitch. This, on its time,  
15 this was published in 2020, was, at the time, the  
16 highest throughput, least invasive methodology in  
17 a fully-automated fashion detect head-twitch.  
18 The advantage of the method that I developed is  
19 that it relies on the use of a magnetic ear tag  
20 that I placed on the mouse ears, and the mice are  
21 placed in a magnetometer, which, by virtue of  
22 electromagnetic induction, is going to measure  
23 the movement of the animal head. And then,  
24 obviously, there's an offline protocol and  
25 sequence that follows for the analysis of those

1 voltage changes to identify head-twitches over  
2 what's background noise.

3 Another point I would like to  
4 highlight is that, in my efforts to automate  
5 head-twitch, I have very little regard or  
6 consideration for any prior manuscript that uses  
7 control assessments. It's unbelievable the  
8 amount of variance that one can spot when, you  
9 know, reassessing some of the previous work that  
10 uses visual assessment of head-twitch, which I  
11 believe it's brought into this case. So any  
12 article using the semi- or fully-automated  
13 head-twitch is of much greater value to my  
14 understanding and my assessment of what a drug  
15 does than any visual, bore-me-to-death visual  
16 assessment.

17 Q And how do you in your studies use  
18 head-twitch to measure the effects of drugs?

19 A I've covered all possible angles from  
20 that vantage point. What I'm most interested in  
21 is the boundaries of what define head  
22 twitch-positive psychedelic drugs versus head  
23 twitch-negative non-psychedelic drugs. So  
24 there's these very small, nuanced feel in  
25 pharmacology if these drugs are able to share the

1 pharmacology of psychedelics, but they don't do  
2 nearly anything as much as psychedelics do. They  
3 do not produce psychedelic effect and  
4 head-twitch.

5 So I'm just in head-twitch very  
6 heavily to try to learn more on what makes these  
7 drugs different, even though they stimulate the  
8 same receptor. That's one angle.

9 I've also tried to tie the behavioral  
10 response to the underlying levels of the drug,  
11 try to make sense of how much drug is needed to  
12 get what level of response, how do things  
13 correlate, how do things happen at the same time,  
14 and also to study how these responses can be  
15 confounded or mixed up with other receptors  
16 because let's face it: psychedelics are diverse.  
17 They have different pharmacological actions. We  
18 need to tease out how each of those contribute.

19 Q So based on your studies, what does  
20 head-twitch tell you about a drug's abuse  
21 potential?

22 A Nothing.

23 Q Why is that?

24 A Head-twitch is not a model of abuse.  
25 Head-twitch is a model that has good, correlative

1 power to determine the potency of psychedelics  
2 across species more precisely, mice and human.  
3 We have plenty of drugs that induce head-twitch  
4 that are not psychedelics.

5 Q So head-twitch is not specific to  
6 psychedelics?

7 A With the appropriate constraints, you  
8 can set the boundaries to study the behavioral  
9 pharmacology of psychedelics. Head-twitch bears  
10 the power of offering a readout that is clearly  
11 dependent on the same receptor that psychedelics  
12 target, so it's more about how the data is  
13 interpreted rather than whether head-twitch is a  
14 valid model or not.

15 I would need to assess each statement  
16 one by one to tell you what my take is. If you  
17 tell me that head-twitch is a model for abuse, I  
18 can flat-out say no. If you tell me that  
19 head-twitch is a model of stimulation to a  
20 receptor, I could agree to that with caveats  
21 because it's not perfect.

22 Q So what does your interpretation of  
23 the pre-clinical data of DOI tell you about its  
24 potential therapeutic uses?

25 A It's in the eye of the beholder. I

1 make a living by advising biotechs. I'm a  
2 consultant. I advise the startups and biotechs  
3 on how to navigate the tough realm of drug  
4 discovery in neuroscience. It's probably one of  
5 the toughest in terms of getting some translation  
6 of value out of what we do in animals, cells, and  
7 whatnot. So I can tell you that most of my value  
8 comes not from advising on what models to do for  
9 what but for keeping my clients from  
10 overinterpreting the models that they are using.

11 So back to that question. In the  
12 academic world, there's a lot of literature on  
13 DOI in models of what we call mental health, and  
14 we can explore those by the titles. We don't say  
15 a mouse model of anxiety. We tend to say  
16 anxiety-like behaviors.

17 But, nonetheless, this seems to  
18 indicate there is certainly something that  
19 psychedelics do in very basic domains of behavior  
20 from which we can extract features that might  
21 bear some therapeutic potential. For instance, I  
22 can't remember the number of exhibit, Exhibit 9,  
23 I believe, the Cell Report's paper. One of the  
24 features that I identify there is that DOI  
25 accelerates fear extension. What is acceleration

1 of fear extension? Well, if you've been exposed  
2 to a negative stimuli, you will probably be  
3 fearful of that stimuli. But once that stimulus  
4 has disappeared, it's not adaptive to remain  
5 fearful. What is adaptive is to have the  
6 cognitive plasticity to realize the situation and  
7 to see how that anxiety alleviates.

8 So I wouldn't dare to say my mice have  
9 PTSD, but I can say that DOI accelerated fear  
10 extension in the absence of a negative stimuli.  
11 It improved upon an adaptive response, which it's  
12 very straightforward to extrapolate as what we  
13 could expect from a pharmacotherapy from someone  
14 that's struggling in mental health, improve upon  
15 their adaptive responses.

16 Q What are the potential problems of  
17 overinterpretation, as you described it?

18 A It depends in what realm we are. In  
19 academia, you can overinterpret as much as you  
20 want because you want the big paper and the  
21 grant. In the industry, it might be lethal.  
22 Most startups have one shot, so you better be  
23 careful how you interpret your data, how it takes  
24 you to your next step, how you leverage that data  
25 before your investors, before regulators, and so

1 on and so forth. And there's a third component,  
2 and I'm guessing that's the DEA, which has  
3 absolutely nothing at stake. So they can  
4 overinterpret as much as they want because  
5 there's nothing -- no drug is going to come back  
6 and appeal to the Supreme Court because they  
7 don't have that ability.

8 Q So what, specifically, issues do you  
9 see about overinterpretation of data regarding a  
10 drug's abuse potential?

11 A Could you repeat that question?  
12 Sorry.

13 Q Yes. Specifically, what are the  
14 issues regarding overinterpretation as it relates  
15 to the abuse potential of a drug?

16 A Yes. So the problem overinterpreting  
17 the risk for abuse comes from all the damage that  
18 is done under the argument of trying to protect  
19 the population from the data that I've been able  
20 to see is in existence. So overinterpretation --

21 MR. MANN: Your Honor, Your Honor,  
22 this is outside the scope of the statement. It's  
23 starting to sound like a political speech.

24 MR. PHELPS: And, Your Honor, this is  
25 page 33 onto page 34 of the pre-hearing

1 statement. Specifically, he will testify that  
2 DOI is a promising therapeutic using the same  
3 lens that the DEA employees in the interpretation  
4 of pre-clinical data and its projection to abuse  
5 potential.

6 JUDGE SOEFFING: I'll overrule the  
7 objection. You can finish your answer.

8 THE WITNESS: Sure. I will take on  
9 that. In my pre-hearing statement, I don't even  
10 try to apply my own subjective or personal point  
11 of view. I want to point out that phrase and how  
12 it's phrased using the same lens as the DEA does.  
13 The DEA, in the documents I have access to, makes  
14 what I would deem an overinterpretation of the  
15 pre-clinical data in its effort to establish  
16 abuse. I think it's very largely  
17 overinterpreted, but don't take my word for it.  
18 What I can do is I can adopt the same framework,  
19 the same lens, and evaluate the data on the  
20 opposite side. The data, the pre-clinical data,  
21 same models, animals, rats and mice, and look at  
22 the therapeutic benefits. We have pretty  
23 high-impact factor articles from recent times  
24 showing very, very promising therapeutic effects,  
25 and don't take my word for it. I'm just applying

1 the same criteria that they are, and probably  
2 being humble in how that therapeutic operation  
3 can apply. If they can make the statement that  
4 the data available in animals established  
5 high-abuse potential, by the same token we can  
6 conclude that they're very promising therapeutic  
7 agents.

8 BY MR. PHELPS:

9 Q Could you explain a bit about how the  
10 pharmacodynamics and pharmacokinetics of DOI may  
11 relate to its potential for abuse?

12 A Yes. DOI is very unique. Like I  
13 mentioned earlier, it gives us researchers  
14 working with small mammals the opportunity to  
15 brew mammal brain with the psychedelic for nearly  
16 as long as a human does on LSD or psilocybin and  
17 do so in a more selective way. We tease out some  
18 of the confounding factors with other  
19 interactions that LSD or psilocybin have, so  
20 that's very important as it pertains to the  
21 researchers. But that has another projection.  
22 DOI has incredibly long pharmacokinetics and  
23 pharmacodynamics. What does that mean? It takes  
24 forever to kick in, and that's something that  
25 psychonauts are not going to love, and it takes a

1 very long commitment to be high, if you wish,  
2 because it lasts for no less than 12 hours. And  
3 I think there's reports of even longer, the  
4 validity of which are questionable beyond what  
5 Alexander Shulgin reported in PiKAL.

6 So I think it all comes down to if  
7 this is a drug that has been known for decades,  
8 known for decades, available from regular  
9 chemical suppliers for decades, and it didn't  
10 quite find its niche in the community, one might  
11 wonder why is that, given that it's clearly a  
12 psychedelic, it's clearly a Serotonin 2A agonist,  
13 but there's an actual selection process. The  
14 drugs that become popular become popular because  
15 they have a distinct property around them. DOI  
16 seems to like it. I don't believe there's true  
17 use in the community of DOI, except maybe some  
18 anecdotal cases that I don't even know if I give  
19 true validity to. And I can only wonder why.

20 In my understanding, as an expert on  
21 the pharmacology and, to some extent, the PK/PD  
22 pharmacokinetics and pharmacodynamics, the drug  
23 properties in this realm, it's delayed onset of  
24 action. Those are the very deterrent for people  
25 to abuse DOI.

1 I can imagine a dealer that deals DOI  
2 under the tag of LSD. That guy is going to run  
3 out of business real fast.

4 Q Are there other drugs whose unique  
5 pharmacodynamics and pharmacokinetics may impact  
6 their level of abuse?

7 A Yes. I can think of salvia,  
8 salvinorin A. That's a drug that was somewhat  
9 hyped in the early 2000s. Most people just had a  
10 very dysphoric effect taking the drug. Luckily,  
11 it was short-lived. So imagine a drug like  
12 salvinorin A but with long extended effects.  
13 That would be completely nonsensical. It's not a  
14 drug that can be abused because, let's face it:  
15 people have better drugs to abuse, if you want to  
16 use the term.

17 So I guess that's what it comes down  
18 to, DOI, right. We're not talking about a weird  
19 drug that has very bad pharmacokinetics and,  
20 therefore, people are not really interested  
21 because it's too much. We're talking about an  
22 amazing research tool that any researcher,  
23 whether they're neuroscience or not, has access  
24 to.

25 I can give you an example. Colorectal

1 cancer has expression of Serotonin 2B receptors.  
2 That happens to be one of the receptors that DOI  
3 binds to. A colorectal cancer scientist doesn't  
4 have the time to go through the paperwork he  
5 needs to use DOI because they don't need to deal  
6 with controlled substances in their daily life.  
7 But if they want to, and, let's face it, most  
8 scientists out of small trials that are somewhat  
9 outside of the realm of what their grant is  
10 covering, to set the stage for what later becomes  
11 a finding.

12 So we're talking about an amazing  
13 research tool that I haven't seen any convincing  
14 evidence that it's abused in the community.

15 Q I'd like to now turn your attention to  
16 what's been admitted into evidence as State's  
17 Exhibit 7A.

18 JUDGE SOEFFING: So, Mr. Phelps, are  
19 you done with the prior exhibits, 8, 9, and 10,  
20 Petitioner's 8, 9, and 10?

21 MR. PHELPS: I believe so.

22 BY MR. PHELPS:

23 Q Dr. de la Fuente Revenga, is there  
24 anything else you think is relevant about any of  
25 those based on what you said?

1 MR. MANN: Objection.

2 JUDGE SOEFFING: Sustained.

3 MR. PHELPS: We'll move on.

4 JUDGE SOEFFING: So the clerk, Mr.  
5 Clerk, you may take those other three back, and  
6 then you were referring to Government's Exhibit  
7 --

8 MR. PHELPS: 7A.

9 THE WITNESS: May I say something?

10 MR. PHELPS: No.

11 JUDGE SOEFFING: Was there an answer  
12 you wanted to amend? Because there's no question  
13 pending.

14 THE WITNESS: So I believe one of the  
15 exhibits was a paper of my authorship on  
16 tolerance, and I think that's very much relevant.

17 JUDGE SOEFFING: Okay. Well, I  
18 overruled that objection, so that will be  
19 stricken. I sustained that objection, so that  
20 will be stricken. Mr. Phelps.

21 MR. PHELPS: No problem.

22 BY MR. PHELPS:

23 Q So do you have that exhibit in front  
24 of you?

25 A I do.

1           Q       Are you familiar with the Eight Factor  
2 test that the DEA uses to consider scheduling a  
3 drug?

4           A       Yes. It reminds me a whole lot of the  
5 prong analysis that I had to go through when I  
6 applied for my green card to become a permanent  
7 resident of this country, which is a process I  
8 led on my own.

9                   MR. MANN: Objection, non-responsive.

10                  JUDGE SOEFFING: Overruled.

11                  BY MR. PHELPS:

12           Q       Go ahead.

13           A       I guess what I'm trying to say is that  
14 I'm an academic researcher, so you wouldn't  
15 expect me to be too acquainted with this kind of  
16 legal framework, but I happen to be to some  
17 extent because I faced something before like  
18 this. And, yes, I had a chance to go through  
19 this factor analysis, which, like I said, it's  
20 not the first time I look at something like this.

21           Q       So I guess, to that point, in broad  
22 terms, how does this Eight Factor Analysis  
23 compare to the analysis of drugs that you do  
24 previously as an academic and now in industry?

25                   MR. MANN: Objection. This was not

1 disclosed in the pre-hearing statement.

2 MR. PHELPS: We're getting to the four  
3 prongs. That's absolutely mentioned in the  
4 pre-hearing statement, but I think it makes sense  
5 to start with what factor one is.

6 JUDGE SOEFFING: Well, why don't you  
7 tell me where you're referencing the pre-hearing  
8 statement, Mr. Phelps.

9 MR. PHELPS: Absolutely. The bottom  
10 last paragraph on the page 34. He will testify  
11 that the DEA's analysis using the CSA's  
12 four-prong analysis fails to adopt a quantitative  
13 approach and so on from there. It specifically  
14 mentions the four-prong analysis.

15 MR. MANN: This sounds like a legal  
16 conclusion that he's asking him to testify to.  
17 The four-prong analysis is in the legislative  
18 history of the CSA and has been tested in court.  
19 His opinions as to whether the four-prong  
20 analysis is adequate or not is a legal question.

21 MR. PHELPS: He's not answering  
22 whether it's adequate or not. He's speaking  
23 specifically about that approach and how it works  
24 based on his expert opinion in the field of the  
25 study of these substances.

1 MR. MANN: Your Honor, this clearly  
2 says the CSA's four-prong analysis. It does not  
3 refer to the DEA's four-prong analysis.

4 JUDGE SOEFFING: Well, we were talking  
5 about the Eight Factor Analysis originally when  
6 this started, so I'm going to sustain that  
7 objection because that is different than the --

8 MR. PHELPS: Certainly. We're not  
9 going to go through all the eight factors. I was  
10 just starting with the number one to get to the  
11 four prongs here that are mentioned. That's all  
12 we're going to be going through.

13 JUDGE SOEFFING: All right. Just to  
14 lay the basis. Otherwise, the objection is  
15 sustained.

16 MR. PHELPS: Exactly, Your Honor.  
17 Thank you.

18 BY MR. PHELPS:

19 Q So I'd like you to turn to page three  
20 of what's in front of you there, and do you see  
21 where it says factor one?

22 A Yes.

23 Q And are you familiar with the  
24 four-prong analysis used within factor one?

25 A Yes.

1           Q       And from a scientific perspective, how  
2 would you describe the -- so let's take a look at  
3 prong A there. You see where prong A is?

4           A       Yes.

5           Q       Okay. And below that, you see where  
6 there's the DEA's analysis of prong A?

7           A       Correct, yes.

8           Q       And in your scientific expertise,  
9 what's your interpretation of that analysis?

10          A       There is evidence that individuals are  
11 taking the drug or other substances in amounts  
12 sufficient to create hazard to their health or to  
13 the safety of other individuals or to their  
14 community. I don't believe there's any evidence,  
15 factual evidence, that there's anyone taking DOI.  
16 No one in an emergency room that has had a blood  
17 test that tested positive for DOI. The only  
18 credible report is probably Alexander Shulgin,  
19 and that's only one. No one would make ever  
20 decisions based on only one.

21                   I guess the main problem is with  
22 there's evidence that individuals are taking the  
23 drug or other substances and so forth. This is  
24 what I allude when I mentioned that this analysis  
25 lacks in quantitative data analysis and a true

1 assessment of the depth because we could talk  
2 about accidental intakes. For all we know, when  
3 we look at the numbers and if we were to compare  
4 the times these drugs have presented themselves  
5 before law enforcement, it's minuscule compared  
6 to any other drugs in these categories.

7 So I don't agree with the fact that,  
8 you know, there's evidence of individuals taking  
9 them. It looks like some individuals have them,  
10 but I don't believe there's any evidence that  
11 individuals are taking them. And I don't know if  
12 I can take at face value reports on Reddit or  
13 Erowid.

14 So that's as it pertains to that part,  
15 and then the other part that I have a little bit  
16 of trouble with is HHS has determined that  
17 consumption of DOI and DOC due to their  
18 hallucinogenic properties and taking them in  
19 amounts sufficient to create a hazard to their  
20 health. Again, we don't know DOI to be consumed.  
21 I believe there was, like, three reports from DOC  
22 back from more than ten years ago. And it's  
23 clearly a flawed analysis. We don't know if  
24 these people were mainly looking for desperate  
25 measures to address their mental health. It's

1 hard to prove something that doesn't exist.

2 Q If you were to bring this type of  
3 analysis into your industry position using these  
4 methods, how would that be received?

5 A I can give you an example. The FDA is  
6 very careful when it comes to the assessment of  
7 drugs, especially in the area of neuroscience. A  
8 response like this would be cake to dismiss.

9 Q I don't think we need to go through  
10 factor B. We've all stipulated that there's no  
11 diversion.

12 A I think it's very important.

13 JUDGE SOEFFING: Well, you haven't  
14 been asked about it, so we'll go on to the next  
15 question.

16 BY MR. PHELPS:

17 Q Sure. We'll go to C. Well, let's  
18 look at factor C there, individuals are taking  
19 the substance on their own initiative rather than  
20 on the basis of medical advice from a  
21 practitioner licensed by law to administer such  
22 substance.

23 Now, I want you to just take a minute  
24 to read over the analysis or conclusions provided  
25 by DEA. And based on your scientific opinion,

1       what flaws do you see with that analysis?

2               A       Yes. Give me a second.

3               MR. MANN: Your Honor, I'll just  
4       mention again that whatever flaws he wants to  
5       point out during this hearing were not disclosed  
6       in the pre-hearing statement.

7               JUDGE SOEFFING: Well, all I see here  
8       is a quantitative approach, so we're limited to  
9       quantitative approach. So if there's anything  
10      else, I'm going to find that that was not  
11      sufficiently disclosed.

12              MR. PHELPS: Certainly. And I think  
13      we can discuss the depth and contextualization of  
14      this, as well, right, based on what's in that  
15      pre-hearing statement?

16              JUDGE SOEFFING: Quantitative  
17      approach. To me, that says volume numbers,  
18      right? The volume of use. I don't see any other  
19      basis.

20              BY MR. PHELPS:

21              Q       Dr. de la Fuente, could you analyze  
22      this in the context of quantitative approach?

23              A       That was the DEA's job, not mine,  
24      because all I've had access to is that lousy  
25      table of encounters or NFLIS, I think it's

1 called, where all I see a peak of cases in which  
2 it's identified in 2009 and then a very sharp  
3 decline with a complete disappearance since. So  
4 for all we know, maybe DOI is not even out there  
5 anymore. At least if we were to interpret the  
6 data that the DEA has presented, yes, we can  
7 blame the COVID pandemic for dropping numbers in  
8 2020 and so forth, but MDMA and other drugs used  
9 in raves are very much back in business and  
10 making encounters with law enforcement.

11 So it is not my job to put the  
12 contextualization. I just singled out that they  
13 didn't do their job at doing so.

14 Q Can you explain the importance of  
15 quantitation, context, and relevance in data  
16 analysis such as this?

17 A Of course. I'm sure there's a  
18 threshold below which what we're doing here is  
19 just wasting taxpayers' money. COVID still kills  
20 people, and no one has even considered, you know,  
21 making a red alert on pandemic. COVID still  
22 kills people. And as far as I am concerned, DOI  
23 has killed no one.

24 So the measures need to be  
25 commensurate to the effort needed to buffer

1 certain risks. I think we are looking at a  
2 non-problem here, and that's why we need  
3 benchmarks, we need quantitation, and we need  
4 contextualization.

5 So I already alluded to quantitation.  
6 I think there's economic markers, there's health  
7 markers, none of which, I think, have been  
8 considered in-depth by the DEA. And in terms of  
9 contextualization, what I can say is that I don't  
10 disagree with the analogies that the DEA  
11 presented in terms of DOI having that similarity  
12 to LSD, DOI, in these animals, in these cells,  
13 and in these proteins. But the context is  
14 important because these drugs are almost all as  
15 MDMA in terms of presence in the community and,  
16 yet, people seem to love MDMA and DOI never had a  
17 chance. There's some natural selection process  
18 even when it comes to recreational use of drugs  
19 or therapeutic use, for that matter. It's a sum  
20 of factors, right? Societal, it's availability,  
21 it's distribution networks. You could even throw  
22 in, you know, mafia gangs and whatnot. But,  
23 ultimately, if there's no demand, the drugs don't  
24 get an imprint in the society, and I think that's  
25 what happened with DOI. In as much as I know

1 about this drug, I can see why the inherent  
2 properties of DOI make them an amazing research  
3 tool but not a drug that anyone would like to  
4 mess with.

5 Q Could you take a look there at prong  
6 D and just give that a quick review, and then can  
7 you put the analysis there in the context of the  
8 quantitative approach?

9 A Yes. So factor D starts saying the  
10 drug is a new drug. DOI is, by no means, a new  
11 drug. Neither is DOC. The effects on  
12 pharmacological action are similar to DOM and  
13 LSD. I think we're in full agreement there. In  
14 drug discrimination, we can comment on drug  
15 discrimination if we wish. I think it's a very  
16 imperfect study -- sorry, imperfect model to  
17 establish abuse. We can establish some  
18 similarity, but abuse is not probably something  
19 within the scope of drug discrimination.

20 And then as was stated by HHS, due to  
21 the psychological and cognitive disturbances  
22 associated with DOI and DOC, as with other  
23 Schedule I hallucinogens, it is reasonable to  
24 assume that DOI and DOC have substantial  
25 capability to be a hazard to the health of the

1 user and to the safety of the community. And,  
2 yet, the facts are that that has not happened.  
3 These are all drugs. They've been available from  
4 Sigma-Aldrich and other chemical distributors for  
5 decades, and people don't have an inclination.

6 There is the perfect channel for these  
7 drugs to be diverted by chemical suppliers that  
8 don't require a DEA license to sell them to  
9 users. And, yet, we don't seem to have any  
10 evidence of substantial use. I do see pointed  
11 out that there's three cases with DOC that made  
12 it to an emergency department, including one  
13 death. And, again, I will use the analogy of  
14 COVID. This could be very much accidental. I  
15 don't know if there's a case of pharmacology and  
16 to what extent this is something that is  
17 meaningful, as opposed to a disgraceful accident.

18 So here, rather than quantitation, I  
19 think the context is what's important. And this  
20 goes back to something that the DEA dismissed,  
21 that there's no significant diversion from  
22 legitimate channels, but I think that's the key.  
23 These drugs are available, probably more  
24 available from legitimate channels than lousy  
25 drug dealers in the street. And, yet, they

1 themselves accept that that's not a significant  
2 route of diversion. Why? There's no demand. No  
3 one prefers DOI over anything else. That's my  
4 take.

5 Q So can you explain in concise terms  
6 how placing DOI under Schedule I, in your  
7 scientific expert opinion, would do more harm  
8 than good?

9 MR. MANN: Objection, leading.

10 MR. PHELPS: He wants me to go right  
11 out of the pre-hearing statement. I do that and  
12 --

13 JUDGE SOEFFING: Overruled.

14 THE WITNESS: Apologies, but do you  
15 mind repeating, if that's okay?

16 BY MR. PHELPS:

17 Q Can you explain, based on your  
18 scientific expertise and your analysis of the  
19 evidence that's been provided by the DEA, how  
20 placing DOI under Schedule I would do more harm  
21 than good?

22 A Yes, yes. As it stands right now, DOI  
23 has harmed no one, so this effort will be very  
24 successful at protecting no one, given that DOI  
25 has had its test run out there and has yet to

1 produce any significant problems. So I don't  
2 believe this effort presents any risk. It's a  
3 non-problem. At the same time doing so, you  
4 know, if this was some random chemical that has  
5 2A activity and drug discrimination but that's  
6 about it, I wouldn't be here because I have  
7 better things to do. But DOI is an amazing tool  
8 for researchers, and researchers across any  
9 discipline for the ability of having access to  
10 one somewhat selective tool to study the effects  
11 of psychedelics in whatever system of their  
12 choosing.

13 I mentioned colorectal cancer earlier.  
14 There's an amazing study by Charles Nichols about  
15 the outstanding anti-inflammatory effects of DOI,  
16 and an oncologist doesn't have a DEA license  
17 because they don't need it.

18 So given this, as I call it, a gateway  
19 drug to do the science is the perfect entry spot  
20 for them to maybe later apply their license for  
21 LSD, psilocybin, whatever they want, but keep DOI  
22 out of the schedule since it seems to pose no  
23 problems to the community and it's incredibly  
24 helpful to the scientific community.

25 So by putting a Schedule I, you're

1 effectively suppressing a good chunk of the  
2 research that can come out of it, even research  
3 that might argue that DOI should never see the  
4 light of day ever again. We need to have that  
5 one, too. What if has, like, some crazy  
6 cardiovascular effect on a rare variant? We want  
7 to know that, and we definitely help the  
8 scientific community get there by making it  
9 available rather than putting it under Schedule  
10 I. I'm familiar with the processes to navigate  
11 the DEA licensing process and how to use  
12 substances that are under schedule in the lab.  
13 It's tedious. Any researcher working with this  
14 probably needs to be 10 to 20 percent better than  
15 their peers because a lot of time is going to be  
16 wasted on running this little math and this many  
17 milligrams go in, this many milligrams go out,  
18 oh, I have some excess that I need to put here  
19 and then initiate this process, so on and so  
20 forth.

21           It will be a botched job to get a  
22 substance like this under Schedule I. Don't take  
23 my word for it. Decades of the drug being  
24 available from chemical suppliers, not a single  
25 encounter in the emergency room.

1 MR. PHELPS: Thank you. No further  
2 questions for this witness, Your Honor.

3 JUDGE SOEFFING: Thank you, Mr.  
4 Phelps. Mr. Mann.

5 CROSS-EXAMINATION

6 BY MR. MANN:

7 Q Good afternoon, Dr. de la Fuente.

8 A Good afternoon.

9 Q Would you describe yourself as a  
10 person who likes to exaggerate?

11 A No. The opposite.

12 Q Okay. So you just said that putting  
13 this in Schedule I strips all researchers of DOI;  
14 is that correct?

15 A No. I made a clarification of  
16 multi-disciplinary approaches. I did mention an  
17 oncologist probably doesn't have a license to  
18 deal with controlled substances, he can get DOI.  
19 So, yes, this would strip it.

20 Q So you would agree --

21 A I also mentioned colorectal cancer, as  
22 well --

23 JUDGE SOEFFING: Hold on. We can't  
24 have both of you talk at the same time, so, Mr.  
25 Mann, if you'd just let him finish the answer.

1 MR. MANN: Sure. Sorry.

2 JUDGE SOEFFING: You may proceed,  
3 Doctor.

4 THE WITNESS: Yes. I don't think it's  
5 an exaggeration. Let's do a generalization.  
6 Neuroscience is just one tiny bucket of research.  
7 You're effectively stripping the entire realm of  
8 science of using this drug if you put it on the  
9 schedule because a lot of the other areas don't  
10 normally deal with DEA licenses for the use of  
11 controlled substances.

12 BY MR. MANN:

13 Q Thank you. So your testimony is that  
14 if DOI is in Schedule I, researchers will not be  
15 able to use it for any reason; is that correct?  
16 Yes or no?

17 A That is not correct.

18 Q Okay. That's just what I was trying  
19 to get to. And you have worked with people with  
20 DEA registrations, have you not?

21 A Yes.

22 Q Okay. And do you know the process for  
23 adding another drug to an existing Schedule I  
24 registration?

25 A I'm somewhat familiar. That was not

1 actually in my hands but --

2 Q And it is possible to do it?

3 A Oh, it definitely is possible.

4 Q So it doesn't strip anybody --

5 MR. PHELPS: Your Honor, if he would  
6 let the witness answer the question, please.

7 JUDGE SOEFFING: Mr. Mann, if you'd  
8 just be a little more patient with the answers.

9 MR. MANN: Okay.

10 JUDGE SOEFFING: Thank you.

11 BY MR. MANN:

12 Q So in putting DOI in Schedule I, that  
13 will not strip researchers of --

14 A Sir, you're telling me -- like it's  
15 --three months of payment. But, yes, I'm not  
16 saying that adding it is an untrivial job, but  
17 every day you work with a scheduled substance you  
18 have to go through the hassle of annotate  
19 amounts, double check, involve several people  
20 because the person that is using it might not be  
21 the person that has the license. If the person  
22 that has the license is not in the lab, then, oh,  
23 maybe I need to postpone my experiment today. It  
24 is a hassle. Have you worked with these  
25 substances?

1           Q       Sir, sir, I'm the one I'm asking the  
2 questions. If your attorney wants to ask you  
3 other questions, that's fine, but you don't ask  
4 me any questions, okay? And my questions are yes  
5 or no questions.

6           JUDGE SOEFFING: So hold on a second.  
7 So, Doctor, if you could just do the best you can  
8 to answer the questions that are asked. And, Mr.  
9 Mann, if you could just do the best you could to  
10 wait for the response to be completed, and I  
11 think that will make it easier to follow both the  
12 question and the answer.

13           BY MR. MANN:

14           Q       Doctor, let me ask you my next  
15 question. Did you listen to the Government's  
16 case?

17           A       Listen?

18           Q       Yes. Did you listen to the testimony  
19 the Government presented in this proceeding? Yes  
20 or no.

21           A       I came here today at 1:30.

22           Q       The Government has presented two  
23 witnesses --

24           JUDGE SOEFFING: Hold on, Mr. Mann.  
25 Mr. Phelps, I can't hear you --

1 MR. PHELPS: I was just going to  
2 instruct him. I don't know if a little  
3 clarification maybe on exactly what he's --

4 JUDGE SOEFFING: If you want to make  
5 an objection, make an objection, but I can't have  
6 you making motions while the witness is  
7 testifying like that.

8 MR. PHELPS: Certainly, Your Honor.

9 JUDGE SOEFFING: Okay. That's all.

10 MR. PHELPS: We just object to the  
11 form of the question.

12 JUDGE SOEFFING: Overruled. Mr. Mann.

13 BY MR. MANN:

14 Q The Government put two witnesses on as  
15 part of its case in chief. Doctor, did you  
16 listen to those witnesses testify?

17 A No.

18 Q Did you read any transcripts of their  
19 testimony?

20 A If it's not here, no.

21 Q Okay. Now, I believe you testified  
22 that DOI is not used because it has a very  
23 delayed reaction; is that correct?

24 A No.

25 Q Did you say that DOI is not used

1 because it lasts a long time?

2 A That's most likely, yes.

3 Q Okay. So you're aware that heroin  
4 doesn't kill as many people as fentanyl, correct?

5 A Yes.

6 Q All right. And that fact doesn't  
7 deter people from using fentanyl apparently, does  
8 it?

9 A Yes. People --

10 MR. PHELPS: I would object. This is  
11 beyond the scope of direct.

12 MR. MANN: He answered the question.

13 JUDGE SOEFFING: Overruled. He was  
14 drawing a comparison, the witness was drawing a  
15 comparison to COVID and the number of people that  
16 was killing to the harm of DOI. I think Mr. Mann  
17 is further exploring ratios of harm, so I'll  
18 overrule the objection, and he may answer this  
19 line of questioning.

20 BY MR. MANN:

21 Q I believe your testimony was that  
22 you've used psychedelics to mimic psychosis,  
23 correct?

24 A No.

25 Q You did not? What did you use the

1 antipsychotics to do in your experiments --

2 A You want me to answer?

3 Q Yes.

4 A All right. So psychedelics -- I don't  
5 think the question makes sense because you first  
6 asked about psychedelics and antipsychotics. Can  
7 you clarify?

8 Q Well, my question was have you used  
9 psychedelics to mimic psychosis?

10 A No.

11 Q I thought that's what you testified  
12 to. So you didn't use the antipsychotics to  
13 block the effects of the psychosis?

14 A Yes. Okay. Now, we talk. So that's  
15 a very important nuance because head-twitch can  
16 be used as a model to identify antipsychotics,  
17 but flipping that statement to say that DOI  
18 produces psychosis is ridiculous. Head-twitch --

19 Q So how did you produce psychosis,  
20 Doctor?

21 MR. PHELPS: Your Honor, he's trying  
22 to answer the question.

23 JUDGE SOEFFING: I think he was  
24 beginning another sentence, Mr. Mann. So you can  
25 finish that sentence, Doctor.

1 THE WITNESS: One needs to be very  
2 careful in the interpretation of mice models. A  
3 mouse model can very well serve for identifying  
4 antipsychotics, but that does not mean that the  
5 model, per se, models psychosis. So it's a  
6 nuance that's important, and, if I were to engage  
7 in the elected conversation on models of  
8 psychosis, head-twitch has been used as a model  
9 for psychosis. But let's bear in mind  
10 head-twitch is about as special as yawning in  
11 human. It's a very clear drug-induced response  
12 by psychedelics and other serotonergic drugs.

13 So I think the nuance is important.  
14 And let's face it: science moves forward. So  
15 things that maybe five years ago were more, you  
16 know, consistently used as solid evidence of --  
17 not solid evidence but more comfortably used as  
18 this is a model of, there's been an NIH framework  
19 that researched the main criteria that's by  
20 researchers and being very careful. This is a  
21 more recent development, so, obviously, the  
22 language has changed over time.

23 BY MR. MANN:

24 Q All right. I'd like you to take a  
25 look at what's been marked as Petitioner's

1 Exhibit 9, please. Okay. And direct your  
2 attention to page two.

3 A Yes.

4 Q You wrote this article, did you not?

5 A I did.

6 Q Did you write this article?

7 A Yes, alongside my co-authors.

8 Q And I'd like you to look at page two,  
9 the second column at the bottom, the last  
10 paragraph. I'm going to read. Psychedelics,  
11 which can be classified into two main groups,  
12 phenethylamines, such as mescaline and the  
13 substituted amphetamine, DOI and tryptamines,  
14 such as psilocybin and lysergic acid diethylamide  
15 (LSD), are psychoactive compounds that profoundly  
16 affect various mental domains, particularly  
17 sensory perception and thought processes.

18 Do you still concur with that  
19 statement?

20 A Yes.

21 Q Okay. And further on down, about  
22 two-thirds of the way down on the second column,  
23 despite these striking effects, their acute  
24 psychotic symptoms and drug abuse potential  
25 preclude the routine use of psilocybin and other

1        psychedelics in daily clinical practice. Do you  
2        still concur with that statement?

3            A        Can I clarify?

4            Q        I'm just asking you, yes or no, do you  
5        concur with --

6            A        No.

7            Q        -- that statement?

8            A        No.

9            Q        So you don't concur with the statement  
10       that is placed in an article that you wrote?

11          A        That's correct.

12          Q        Okay. Thank you. All right. I'd  
13       like you to look at page four. Let's move on to  
14       Exhibit 19, if you could take a look at that.  
15       And I'd like to direct your attention to page two  
16       of Exhibit 19 at the top of the page. Classical  
17       psychedelics such as LSD, psilocybin, mescaline,  
18       and DOI have been recognized for their capacity  
19       to profoundly disregulate various mental domains,  
20       particularly sensory perception and thought  
21       processes.

22                    You wrote this article, did you not?

23          A        I participated in the article. You  
24       can see that I'm the fourth author in the list,  
25       so my involvement is a little bit more --

1           Q       And do you disagree with that  
2 statement?

3           MR. PHELPS: Your Honor, I don't  
4 believe this article has been introduced into  
5 evidence.

6           JUDGE SOEFFING: It's not in evidence.  
7 Mr. Mann, did you want to move this into  
8 evidence?

9           MR. MANN: Well, okay.

10          BY MR. MANN:

11          Q       Is this an article that you wrote?

12          A       Partially.

13          Q       All right. And could you take a look  
14 at the exhibit and tell me if it's a true and  
15 accurate copy of the entire article?

16          A       I believe so.

17          MR. MANN: Your Honor, we would move  
18 Exhibit 19 into the record.

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

21          MR. PHELPS: No objection, Your Honor.

22          JUDGE SOEFFING: Okay.

23          MR. MANN: Should this be marked as a  
24 Government exhibit?

25          JUDGE SOEFFING: I think we'll just

1 keep it as Petitioner's Exhibit just for clarity  
2 in the record. We'll note that the Government  
3 moved it in. So Petitioner's Exhibit, marked for  
4 identification, No. 19 has been offered by the  
5 Government. In the absence of objection, it is  
6 received in the record as Petitioner Exhibit 19.  
7 It's in, and you may use it.

8 (Whereupon, the above-referred to  
9 document was received into evidence as Petitioner  
10 Exhibit No. 19.)

11 MR. PHELPS: Just one quick point of  
12 clarification. I just wanted to double check the  
13 exact exhibit number of the previous article that  
14 had been discussed before we go too much further.

15 MR. MANN: 9.

16 MR. PHELPS: 9. Thank you, sir.  
17 We're good, Your Honor.

18 BY MR. MANN:

19 Q Okay. So let's go back to my original  
20 question. Do you agree with this statement,  
21 quote: Classical psychedelics such as LSD,  
22 psilocybin, mescaline, and DOI have been  
23 recognized for their capacity to profoundly  
24 disregulate various mental domains, particularly  
25 sensory perception and thought process.

1 Do you disagree with that statement?

2 A I don't.

3 Q Okay. Thank you. Doctor, where are  
4 your studies on the abuse liability of DOI?

5 A Excuse me?

6 Q Where are your studies on the abuse  
7 liability of DOI?

8 A As in what publications or what lab or  
9 --

10 Q Do you have any studies on the abuse  
11 liability of DOI?

12 A Yes.

13 Q And are they in any of these exhibits  
14 here?

15 A No, I don't believe so.

16 Q Okay. So you didn't bring them. All  
17 right. I'd like to ask you -- just one moment.  
18 Doctor, you would agree that, in general, people  
19 abuse drugs, in part, because they enjoy the  
20 effects of the drugs; is that correct?

21 A I don't know if I identify  
22 recreational use as abuse. So semantics matter.

23 Q Well, do people use drugs, in part,  
24 for recreational purposes because they enjoy the  
25 effects of the drug?

1           A       I could agree to that, yes.

2           Q       And, for instance, euphoria is an  
3 effect of a drug; is that correct?

4           A       Yes.

5           Q       All right. Hallucinations are an  
6 effect of a certain drug; is that correct?

7           A       Yes.

8           Q       Okay. In assessing the effects of a  
9 drug, you will acknowledge that drug  
10 discrimination studies are a useful tool in  
11 determining comparable effects of certain drugs,  
12 correct?

13          A       No.

14          Q       You would not?

15          A       No.

16          Q       All right. One moment. Doctor, do  
17 you recall writing an article for the Psychedelic  
18 Science Review called Quipazine: A Long-Standing  
19 Enigma in Psychedelic Research?

20          A       Yes.

21          Q       September 8th, 2020.

22          A       Yes.

23          Q       Okay. And I'm going to read from this  
24 article, quote: The best-known psychedelics can  
25 be grouped into two major families based on their

1 core chemical structures: tryptamines which  
2 include psilocybin and LSD, and phenethylamines,  
3 mescaline. Although quipazine does not belong in  
4 either lineage, it engages the serotonin  
5 receptors relevant to the effect of classic  
6 psychedelics. It also produces comparable  
7 effects in animal models, such as drug  
8 discrimination and the rodent head-twitch  
9 response. Did you write that?

10 A Yes.

11 Q Okay. Thank you. Doctor, I believe  
12 you made a comment that no drug is going to come  
13 to the Supreme Court.

14 A Yes.

15 Q What does that mean?

16 A So what I was trying to allude there  
17 is that when the FDA makes a call into whether it  
18 lets a drug pass onto the next stage in  
19 development, they have something at stake. There  
20 is accountability. They're going to be held  
21 responsible for the decisions they make in  
22 approving a drug for a certain use or not.

23 I don't think that's the same case for  
24 the DEA that can send drugs into oblivion for  
25 them to remain there so, meaning as it is

1 currently set up, the framework, it's very easily  
2 liable for false positives, if you wish, in terms  
3 of drugs that might have a utility down the road  
4 but that utility gets curved by the intense  
5 effort into --

6 JUDGE SOEFFING: Hold on one second,  
7 Doctor. So we have somebody who popped up on the  
8 VTC who needs to be taken off the VTC.

9 MR. PHELPS: May I address the --

10 JUDGE SOEFFING: Off the record.

11 (Whereupon, the above-entitled matter  
12 went off the record at 2:42 p.m. and then went  
13 back on the record at 2:43 p.m.)

14 JUDGE SOEFFING: Back on the record.

15 THE WITNESS: Yes. So that was a  
16 silly analogy to make the case that the same  
17 degree of actionability to repair a wrong that  
18 doesn't exist in the case of DEA in scheduling  
19 drugs that have absolutely no reward potential.

20 BY MR. MANN:

21 Q Doctor, are you saying that the  
22 proponents of DOI and DOC have no legal remedies  
23 beyond this hearing?

24 MR. PHELPS: Objection, Your Honor.  
25 He's asking for legal analysis.

1 JUDGE SOEFFING: Sustained.

2 BY MR. MANN:

3 Q I guess I don't really understand what  
4 you mean by a drug cannot go to the Supreme  
5 Court, but I'll withdraw the question.

6 Doctor, are you aware of any  
7 pharmacokinetics -- is that a proper term -- a  
8 pharmacokinetic study in humans involving DOI or  
9 DOC?

10 A No.

11 Q Are you aware of any pharmacodynamic  
12 studies in humans involving DOC or DOI?

13 A To the extent that one wants to  
14 consider Alexander Shulgin's self-testing, that's  
15 a yes. But in general, no.

16 Q Have you reviewed, are you aware of  
17 what DEA Micrograms are?

18 A Some bulleting of sorts.

19 Q And did you review those before your  
20 testimony today?

21 A I did not.

22 Q And would it surprise you that DEA  
23 Micrograms contained reports of seizures with  
24 DOI?

25 A I wouldn't say surprise --

1 MR. PHELPS: Objection. Discussion of  
2 the Micrograms is beyond the scope of direct.

3 MR. MANN: I think he testified over  
4 and over again there's no evidence of this being  
5 abused or used or seized.

6 MR. PHELPS: And that's an incorrect  
7 characterization. First of all, seizures relate  
8 to illegal drugs, so every reference that the  
9 Government is making to seizures of DOI is  
10 incorrect on its face. He did not say that.

11 JUDGE SOEFFING: I'll overrule the  
12 objection. You may answer.

13 THE WITNESS: Seizure is one thing.  
14 Someone in the emergency room with bloodwork that  
15 proves positive for DOI is a different thing.

16 BY MR. MANN:

17 Q I get that you're trying to answer  
18 another question, but my question is does it  
19 surprise you that there were seizures of DOI in  
20 the United States?

21 A It's not for me to have an element of  
22 surprise. Whatever happens, happens. I look at  
23 the numbers of the NFLIS, and the numbers seem  
24 really clearly low.

25 Q And that's not going to change any of

1 your opinions?

2 A No.

3 Q Okay. And would it surprise you to  
4 know that DOI, in some cases, was found on  
5 blotter paper? Are you familiar with that term?

6 A I am familiar with that term.

7 Q Okay. So you have used DOI in your  
8 experiments, correct?

9 A Correct.

10 Q And have you used it in the form of  
11 blotter paper?

12 A No, but that doesn't change anything.

13 Q Blotter paper doesn't make any  
14 difference to you?

15 A The route of administration being  
16 sublingual, that can be replicated through other  
17 means, not necessarily just blotter paper.

18 Q Is blotter paper used in sublingual  
19 studies?

20 A No. Blotter paper leads to a --

21 Q Thank you. That's all I have.

22 A -- a sublingual route.

23 JUDGE SOEFFING: Thank you, Mr. Mann.  
24 Mr. Phelps, you may conduct redirect.

25 MR. PHELPS: Yes, Your Honor. Thank

1       you.

2                       REDIRECT EXAMINATION

3                       BY MR. PHELPS:

4               Q       Doctor, are you aware of any  
5 non-psychoactive substances that can cause  
6 head-twitch?

7               A       Yes, 5-hydroxytryptophan. You can buy  
8 it --

9                       MR. MANN: Objection, Your Honor. I  
10 don't think I ever mentioned head-twitch once.

11               MR. PHELPS: That was exactly where he  
12 started his --

13                       JUDGE SOEFFING: Overruled.

14                       BY MR. PHELPS:

15               Q       Please, tell us about the drug you  
16 just described.

17               A       I wouldn't even call it a drug. It's  
18 a supplement. It produces very reliable heavy  
19 head-twitch. I recently published a pre-print  
20 showing so, but I'm not the only one. It's not  
21 psychoactive. Well, let's leave psychoactivity  
22 aside. It's not psychedelic by any stretch of  
23 the imagination. It produces a head-twitch, as I  
24 mentioned. There's a certain degree of  
25 substitution. I think animals treated with

1 5-hydroxytryptophan can generalize for LSD, and,  
2 yes, it's what we would call a false positive.

3 Q And where is that substance available?

4 A Any pharmacy, CVS, Walgreens, you name  
5 it.

6 Q And what do you mean when you say that  
7 it can substitute for LSD?

8 A In drug discrimination studies, I  
9 believe it's animal treated with  
10 5-hydroxytryptophan, to distinguish  
11 5-hydroxytryptophan stimulus can exhibit full  
12 substitution for LSD. I don't have the paper  
13 before me, but I would be happy to look into the  
14 reference if that's a possibility.

15 Q I'd like to point your attention to  
16 Exhibit No. 9, the Cell Reports paper.

17 JUDGE SOEFFING: Is this Petitioner's  
18 9?

19 MR. PHELPS: Yes, Your Honor.

20 BY MR. PHELPS:

21 Q There was a sentence in there that the  
22 Government mentioned that you said you didn't  
23 agree with even though it's in your paper. Can  
24 you explain why you don't agree?

25 A Yes. Any paper of this nature is

1 collaborative. If you look at the list of  
2 authors, there's well over ten of them. And  
3 writing the paper is, in and of itself, an  
4 exercise of diplomacy, as well, because you might  
5 not have the same ideas in some aspects as, for  
6 instance, your mentor or collaborators or the  
7 like.

8 So I would like to point out to  
9 sentence -- so in the second column --

10 Q Which page?

11 A Sorry. In page number two, second  
12 column, fourth line, here's where the sentence  
13 starts: With the aim of elucidating the molecular  
14 and neuro circuit mechanisms responsible for  
15 their psychotic-like states, and it follows with  
16 two references: Hanks and Gonzalez-Maeso and  
17 Nichols 2016.

18 So the name might sound familiar,  
19 Gonzalez-Maeso. This is the last author in this  
20 paper, the corresponding author, and the person  
21 who has the last word in some of the content. So  
22 I wouldn't call this a disagreement between my  
23 mentor at the time and myself, but he definitely  
24 had more different outlook into how he  
25 traditionally approached psychedelics.

1           May I remind this Court that I  
2       initiated my career looking at anti-psychotics in  
3       order to make a case before any regulatory  
4       agency. You sometimes need to overstretch the  
5       interpretation of some of the things you do.

6           So Gonzalez-Maeso was using quite  
7       consistently these models, in his own wording  
8       considering them models of psychosis. This is a  
9       paper published in 2019. References go back to  
10      2013 and 2016. If you look at his most recent  
11      research output, you could clearly see that  
12      there's absolutely no claims of psychotic-like  
13      depiction of psychedelics in his most recent  
14      work.

15           So science evolves. Science is  
16      plastic, and so are the concepts.

17           Q       So how is it possible that co-authors  
18      of a paper could disagree on something like that?

19           A       This goes back to what I put in my  
20      pre-hearing statement on using the same lens to  
21      look at data. So that's enough that we can turn  
22      up or down. If I want to get someone hyped, I  
23      would definitely overinterpret a model. If I  
24      want to draw a clear path to move forward, I  
25      would be a lot more humble in the interpretation

1 so as to not go places that I cannot come back  
2 from.

3 So it's not so much a disagreement but  
4 the nuance. Dr. Gonzalez-Maeso's trajectory has  
5 been more of a molecular neuropharmacologist,  
6 where, at the time, I was more invested in the  
7 behavioral neuropharmacology.

8 So, obviously, the area of focus might  
9 have an impact in how certain things are recorded  
10 and not necessarily on the basis of disagreement  
11 but more in the nuance of how things are  
12 interpreted.

13 Q And so are there certain elements of  
14 an article or publication that are more strongly  
15 indicative of the first author's position  
16 throughout a paper?

17 A That's a complicated question. It  
18 depends. So this article I wrote myself,  
19 obviously, back and forth with the corresponding  
20 author and, lastly, with inputs from our  
21 collaborators. I can say that's the norm. It's  
22 common practice to do things like that. Some  
23 people go as first author, even though they  
24 haven't even wrote the paper. Some people even  
25 use science writers. I don't have a clear

1 answer, but articles of my authorship where I'm  
2 first author are on my own writing.

3 Q Would you say that the final  
4 conclusions of a paper, based in your experience  
5 authoring and publishing, are reflective of the  
6 first author?

7 A To a large extent. And I think that's  
8 also sometimes impacted by the state someone is  
9 in at their career. Earlier on, you probably  
10 have more influence from your mentors and  
11 advisors. Later on, probably, you have more  
12 leeway and a greater independence in terms of  
13 making a case of your own.

14 Q Okay. I'd like to turn your attention  
15 to what's been marked as SSDP/Ramos Exhibit 11.

16 Q Do you have that in front of you?

17 A Yes.

18 MR. MANN: Excuse me. Was this an  
19 exhibit?

20 JUDGE SOEFFING: 11. It's not in  
21 evidence yet. It hasn't been addressed yet.

22 MR. MANN: All right. Well, that's  
23 certainly not in the scope of --

24 MR. PHELPS: Well, it is a paper,  
25 actually, on the abuse liability of DOI as

1 mentioned in the Government's cross-examination.  
2 He asked where that paper was and if it was in  
3 evidence, and here it is.

4 JUDGE SOEFFING: You may proceed.

5 BY MR. PHELPS:

6 Q Do you recognize this article?

7 A I do.

8 Q What is it?

9 A It's an article of my authorship from  
10 probably the last period in Dr. Gonzalez-Maeso's  
11 lab before I move on to Radius, and it looks at  
12 tolerance and cross-tolerance between  
13 psychedelics and non-psychedelic 2A agonists, and  
14 it's basically an attempt to, you know, use to  
15 the fullest extent the head-twitch to see to what  
16 extent we can recapitulate some of the human  
17 nuance or what is actually modeled by  
18 psychedelics in mice.

19 Q Is this an accurate copy of the  
20 article as you know it?

21 A It is.

22 MR. PHELPS: Your Honor, we would move  
23 to admit SSDP/Ramos Exhibit 11.

24 JUDGE SOEFFING: Mr. Mann, any  
25 objection?

1 MR. MANN: Only to the extent that it  
2 wasn't covered in cross, and I don't know if it's  
3 relevant. I don't think it's relevant.

4 JUDGE SOEFFING: I'll overrule the  
5 objection, and this exhibit, Petitioner's  
6 Exhibit, marked for identification, No. 11 has  
7 been offered and, over the Government's  
8 objection, is received in the record as  
9 Petitioner's Exhibit 11. It's in, and you may  
10 use it.

11 (Whereupon, the above-referred to  
12 document was received into evidence as Petitioner  
13 Exhibit No. 11.)

14 BY MR. PHELPS:

15 Q Dr. de la Fuente, what does this paper  
16 tell us about the abuse liability of DOI?

17 A So something that is actually quite  
18 well known is that psychedelics produce this very  
19 fast, the right term is tachyphylaxis, most  
20 commonly and somewhat erroneously known as  
21 tolerance. Tolerance is the result of repeated  
22 exposure to the same drug resulting in a reduced  
23 effect, and it's literal definition is needing  
24 higher dose to obtain the same level of  
25 responsiveness.

1                   So we know in humans that repeated  
2 exposure with certain psychedelics, like LSD,  
3 leads to basically no effect, at least not the  
4 effects that are more distinctive, elicited by  
5 the substances. So what I am to do with this  
6 paper is to explore to what extent can  
7 head-twitch replicate or recapitulate that aspect  
8 of psychedelics pharmacology, and it seems to do  
9 so, and it seems to do so alongside a very clear  
10 molecular determinant is the fact that there is  
11 less of that receptor after the first exposure.  
12 So imagine turning on all the lights in a room,  
13 and the next day you have half the switches.  
14 You're not going to be able to get the same  
15 response. That's what happened on day two.

16               Q       And how does that translate to abuse  
17 liability as it relates to DOI?

18               A       It couples very well with another  
19 fact. Even if psychedelics had a very high  
20 effect on reward, the subject will get nothing  
21 out of doing more. The subject will basically  
22 have the same flat response, no matter how high  
23 the craving is. But if we couple with the  
24 tolerance with the fact that there's no reward  
25 effect, the take of most people is, well, I need

1 to take a break before I do this again in the  
2 sense that there is no necessarily a consequence,  
3 be it withdrawal or negative effect, with the use  
4 of psychedelics. But as it pertains to the  
5 paper, we just go on to show that this is  
6 something that we can model in mice and get a bit  
7 creative to learn more about how that happens.

8 MR. PHELPS: Thank you. No further  
9 questions for this witness, Your Honor.

10 JUDGE SOEFFING: Mr. Mann, any  
11 recross?

12 MR. MANN: Yes, Your Honor.

13 RECROSS-EXAMINATION

14 BY MR. MANN:

15 Q So, Doctor, let me get this straight.  
16 Head-twitch response is insufficient to determine  
17 abuse liability, correct?

18 A Yes.

19 Q And Petitioner's Exhibit 11 is an  
20 article about using head-twitch response to  
21 assess abuse liability; is that correct?

22 A Can you repeat the question?

23 Q And Exhibit 11 offered by the  
24 Petitioners is used to assess -- is it an article  
25 about assessing abuse liability using head-twitch

1 response?

2 A Not directly, but it has ramifications  
3 into abuse.

4 Q All right. So you understand that  
5 those two statements seem to contradict. If you  
6 said that head-twitch response is insufficient to  
7 assess abuse liability and now you're citing an  
8 article in which you discussed head-twitch  
9 response to assess abuse liability, how do you  
10 put those two statements together?

11 A Because the clarification here is that  
12 head-twitch can give you insights into how  
13 psychedelics don't produce abuse liability, which  
14 is a completely different angle and direction.

15 Q All right. So in Exhibit 11, I  
16 believe it's Exhibit 11, you tested LSD, DOB?

17 A I don't believe I tested DOB.

18 Q Well, DOB is definitely discussed in  
19 your article, is it not?

20 A It could be, yes, some reference to  
21 historical literature.

22 Q One moment. If you look at Exhibit  
23 11, Page 9, I believe. And the first full  
24 paragraph on the left-hand side, I believe LSD  
25 and DOB are both mentioned, are they not?

1           A       Yes. I believe this is part of the  
2 discussion. Let me just look at that real quick.  
3 Yes. That constitutes part of the body of the  
4 discussion. It's not work that is done in this  
5 paper. It just references some other findings.

6           Q       And there was discussion on redirect  
7 about -- well, first of all, you reviewed  
8 Government Exhibit 7A; is that correct?

9           A       Could you refresh my memory on what  
10 that contains?

11                   MR. MANN: Could the witness please be  
12 shown 7A?

13                   THE WITNESS: Yes, yes.

14                   BY MR. MANN:

15           Q       So you're very critical of using  
16 head-twitch response; is that correct?

17           A       I'm critical of overinterpreting it.

18           Q       Where in that exhibit do you see the  
19 word, or the term head-twitch response?

20           A       Page number six, overt behavioral  
21 responses. According to HHS 2020, overt  
22 behavioral effects have been published for DOI  
23 but not for DOC. DOI administration induces an  
24 increasing wet dog shakes and back muscle  
25 contraction. These behaviors are attributed to

1 2A's activation since pretreatment with MDL. A  
2 serotonin 2A antagonist reduces behavioral  
3 effects of DOI.

4 Q All right. My question was where do  
5 you see in that article the term head-twitch  
6 response?

7 A Head-twitch response in mice and wet  
8 dog shakes in drugs are the same thing, sir.

9 Q I'm sorry.

10 A Head-twitch response in mice and wet  
11 dog shakes are equivalent on a pharmacological  
12 level.

13 Q So you're saying they're the same  
14 thing?

15 A They're pretty much the same thing  
16 when it comes to what is trying to be said here,  
17 but this is a clear exercise of cherry-picking  
18 because there's very ample evidence --

19 Q I'm sorry. Pretty much the same or  
20 the same?

21 MR. PHELPS: Objection, Your Honor.  
22 He's interrupting him from answering the question  
23 again.

24 JUDGE SOEFFING: Overruled.

25 BY MR. MANN:

1 Q Pretty much the same or the same?

2 A Look, wet dog shakes happen to a much  
3 lesser magnitude than head-twitches, so this is  
4 not a clear distinction into them being  
5 different. You can look through the literature.  
6 Some people have called head-twitches wet dog  
7 shakes for years. Only more recently the term  
8 head-twitch has been more commonly the leading  
9 one.

10 So we can go into the semantics all  
11 you want, but this is the true answer.

12 Q Okay. So this report was written in  
13 2023. Head-twitch response, that term didn't  
14 exist in 2023?

15 A Yes --

16 Q Okay. Thank you.

17 A -- by 2023, it was the leading term,  
18 yes.

19 Q Now I want to ask you about the paper  
20 that we pointed out where you disagreed with a  
21 statement in the paper. That would be  
22 Petitioner's Exhibit 9. And you're the lead  
23 author on that paper, correct?

24 A I'm the first author, yes.

25 Q All right. So why did you allow this

1 paper to be published if you disagreed with what  
2 was in it?

3 A That's not accurate.

4 Q I'm not making a statement. You  
5 allowed this article to be printed, correct, and  
6 published?

7 A Yes, yes.

8 Q All right. Even though you disagreed  
9 with the statement in the paper; is that correct?

10 A No. If you heard what I mentioned  
11 earlier, I elaborated into how sometimes there's,  
12 like, divergences into how the researchers  
13 interpret or overinterpret or agree or disagree  
14 on some nuances, but that doesn't decrease my  
15 enthusiasm, it didn't decrease my enthusiasm for  
16 seeing this paper published. If I review this  
17 paper, this is from 2021. I'm sure if I review  
18 it with what we know now about DOI from other  
19 more recent papers, I'm sure there's some things  
20 that might have been disproved, might have been  
21 disproved, and some others that have been  
22 validated by others.

23 So just, you know, I think I clarified  
24 very clearly on that nuance. There's -- I don't  
25 know how many words. Three-thousand words?

1 Three hundred statements? Just the fact that I  
2 didn't agree in full with my senior advisor on  
3 that particular aspect doesn't decrease any of  
4 the content.

5 Bear in mind, that was a discussion in  
6 the introduction. An introduction is just a  
7 piece that oftentimes goes in just to set the  
8 stage for what's going to be discussed, so it's  
9 definitely not the main reason to be proud. No  
10 one is proud of a paper because of what's said in  
11 the introduction.

12 Q So even if there's something  
13 inaccurate, something you disagree with in the  
14 paper, the ends justify the means, correct?

15 A No. That's ridiculous. This is two  
16 scientists that are writing a paper jointly,  
17 having a more nuanced approach into how they view  
18 something versus not. The truth of the matter is  
19 that the two references that Dr. Gonzalez-Maeso  
20 include there are peer-reviewed articles.  
21 Therefore, he's within his right to make that  
22 reference if so he wishes. And I have absolutely  
23 no hesitation in tolerating that going in a paper  
24 of my authorship because the focus of the paper  
25 is not those two lines of the introduction. The

1 focus on the paper is, like, the three or four  
2 figures that I ensue. So I think it's very, you  
3 know, very weird that we're focusing on such  
4 minutia when we actually have a paper with  
5 relevance that goes well beyond that.

6 Q So your testimony is that the  
7 statement that has psycho -- what is it? Let me  
8 go back. The statement that, despite the  
9 striking effects, the acute psychotic symptoms  
10 and drug abuse potential preclude the routine use  
11 of psilocybin and other psychedelics in daily  
12 clinical practice. Was that the statement you  
13 disagreed with?

14 A Yes. And I even handed you another  
15 one --

16 Q It was a yes-or-no question. That's  
17 a statement you disagree with, correct?

18 A I only disagree with the psychotic  
19 symptoms. It's been apparent on this testimony.  
20 I'm very careful with the anthropomorphization of  
21 mice, which obviously is something that can slip  
22 when one works with --

23 Q My questions are yes-or-no questions.  
24 Is that the statement you disagree with?

25 A And I'm a scientist, and I need to

1 clarify because the nuance is important.

2 JUDGE SOEFFING: Okay. I think that  
3 was a yes.

4 BY MR. MANN:

5 Q Okay. I'm going to take that as a  
6 yes. And that, in your opinion, is just minutia,  
7 correct?

8 A Yes.

9 Q Okay. Thank you.

10 JUDGE SOEFFING: All right. Thank you  
11 for your testimony, Doctor. You are excused. I  
12 direct you not to discuss your testimony with  
13 anyone until the conclusion of the hearing.

14 MR. PHELPS: We would ask this witness  
15 be permanently excused, Your Honor. No intend to  
16 recall.

17 JUDGE SOEFFING: Okay. Mr. Mann, any  
18 intent to recall this witness?

19 MR. MANN: No, Your Honor.

20 JUDGE SOEFFING: Okay. Again, thank  
21 you, Doctor. You are excused.

22 (Witness excused.)

23 JUDGE SOEFFING: Let's go off the  
24 record.

25 (Whereupon, the above-entitled matter

1       went off the record at 3:11 p.m. and then went  
2       back on the record at 3:29 p.m.)

3               JUDGE SOEFFING: All right. We are  
4       back on the record, and, Mr. Phelps, you may call  
5       your next witness.

6               MR. PHELPS: Your Honor, we've decided  
7       we're not going to be calling Dr. Davoudian.  
8       Petitioners would rest their case in chief.

9               JUDGE SOEFFING: Okay. Very good.  
10       Mr. Mann, would you like to put on a rebuttal  
11       case?

12              MR. MANN: Judge, we would like to put  
13       on a rebuttal case and, with the Court's  
14       permission, we'd like to start tomorrow morning  
15       if it's possible, but we can begin now.

16              JUDGE SOEFFING: Well, Mr. Phelps, do  
17       you have an opinion?

18              MR. PHELPS: I think we would like to  
19       just keep this moving along and get started with  
20       the rebuttal.

21              JUDGE SOEFFING: Okay. Mr. Mann,  
22       let's go ahead and proceed.

23              MR. MANN: Okay. We'll call Dr.  
24       Carbonaro again.

25              JUDGE SOEFFING: Doctor, I remind you

1       you're still under oath. Mr. Mann, you may  
2       inquire.

3       WHEREUPON,

4               THERESA CARBONARO  
5       was called as a witness by the Government and,  
6       having first been duly sworn, assumed the witness  
7       stand, was examined and testified as follows:

8                       DIRECT EXAMINATION

9               BY MR. MANN:

10              Q       Dr. Carbonaro, if the witness could  
11       please see what has been marked for  
12       identification as Government Exhibit 18.

13                       (Whereupon, the above-referred to  
14       document was marked as Government Exhibit No. 18  
15       for identification.)

16              BY MR. MANN:

17              Q       Do you have that in front of you?

18              A       Yes.

19              Q       Do you recognize this?

20              A       Yes.

21              Q       And what is this?

22              A       It is HHS's Evaluation or Assessment  
23       of Abuse Potential of Drugs, the guidance for  
24       industry.

25              Q       And is this a document that you used

1 in your work?

2 A Yes.

3 Q Okay. And did you use it in  
4 preparation of your report in this particular  
5 matter?

6 A Yes.

7 MR. MANN: Okay. The Government would  
8 move Exhibit 18 into the record, please.

9 JUDGE SOEFFING: Mr. Phelps, any  
10 objection?

11 MR. PHELPS: It's only to the extent  
12 that she did not disclose in any prior testimony  
13 that this was a document she had used in the  
14 preparation of her reports when asked.

15 JUDGE SOEFFING: I'll overrule the  
16 objection. I'll allow this to come in on  
17 rebuttal. The Government Exhibit, marked for  
18 identification, No. 18 has been offered. Over  
19 the Petitioners objection, it is received in the  
20 record as Government Exhibit 18. It's in, and  
21 you may use it.

22 (Whereupon, the above-referred to  
23 document was received into evidence as Government  
24 Exhibit No. 18.)

25 BY MR. MANN:

1           Q       Dr. Carbonaro, during the presentation  
2 of the Petitioners case, there was discussion  
3 about something called ICSS, intracranial  
4 self-stimulation. Do I have that correct?

5           A       Yes.

6           Q       And what is that?

7           A       To my understanding, it's similar to  
8 self-administration where a rodent is doing an  
9 activity to receive the drug. I'm not as  
10 familiar with the specifics of how it's done, but  
11 it's another test to assess if a drug is  
12 rewarding or reinforcing.

13          Q       And does the Food and Drug  
14 Administration take any position with respect to  
15 ICSS to assess the abuse liability of a  
16 particular substance?

17          A       It's not in this guidance document.  
18 To my knowledge, with personal communications  
19 with our counterparts at FDA, I'm not aware of  
20 them.

21          Q       And there was a lot of discussion and  
22 testimony about self-administration with respect  
23 to assessing abuse liability.

24          A       Yes.

25          Q       Can you explain, is

1 self-administration a reliable indicator of abuse  
2 liability with respect to hallucinogens?

3 A Not with respect to hallucinogens. As  
4 FDA points out and has been discussed throughout  
5 the hearing is that this is not a behavior that's  
6 often shown with hallucinogens, specifically that  
7 go through the Serotonin 2A receptor, and I  
8 believe in this document it says that a company  
9 could say that it's not actually applicable and  
10 not conduct that study.

11 Q When determining abuse liability, do  
12 all hallucinogens act the same?

13 A Not necessarily.

14 Q All right. I want to ask you about  
15 the experience that DEA has had with intracranial  
16 self-stimulation. Has DEA ever considered using  
17 that to assess hallucinogens?

18 A We had a principal investigator come.  
19 I think it was a virtual presentation  
20 specifically about ICSS. He talked about the  
21 data that they had collected for a number of  
22 substances, including hallucinogens. It was  
23 discussed about, like, if it would be something  
24 that DEA would consider doing a contract to get  
25 such data in the future. And, in that time, DEA

1 decided that it was not the route we were going  
2 to take.

3 Q Now, there was some discussion during  
4 the Petitioners' case regarding conditioned place  
5 preference.

6 A Yes.

7 Q Okay. And that is another type of  
8 experiment or test that can be conducted on  
9 laboratory animals?

10 A Yes.

11 Q And can you explain for the Court what  
12 is conditioned place preference?

13 A I believe it was already described to  
14 some degree already, but, essentially, animals  
15 pair the effects of drugs with one side of a  
16 chamber or one, like, condition, if you will, and  
17 then are given a test drug to see if it produces  
18 effects that might be considered, like,  
19 reinforcing. Again, it's not a rewarding assay,  
20 it's more reinforcing; but it is useful to some  
21 degree in assessing abuse liability. But, again,  
22 I believe, even in this document, HHS notes that  
23 it is -- let me find the words -- it's not  
24 considered to be sensitive or reliable as  
25 self-administration. There are a lot of external

1 factors that play into conditioned place  
2 preference that make it well known to be less  
3 reliable to assess drug abuse liability.

4 Q Okay. Let's go over this document,  
5 Government Exhibit, I believe it's 18. If you  
6 can turn to Page 22 on the document.

7 A Okay.

8 Q And do you see the section that  
9 references conditioned place preference?

10 A Yes.

11 Q What is your assessment of this  
12 paragraph? What is being said here?

13 A It just gives a summary of what  
14 conditioned place preference is. This is the  
15 statement that I just read, that it's not  
16 sensitive or reliable as self-administration, and  
17 that those should be done in a concentration  
18 that's known to have some effect, basically.

19 Q Now, in your testimony, and it was  
20 disputed, that drug discrimination studies can be  
21 used to assess abuse liability, correct?

22 A Yes.

23 Q All right. And what does this  
24 document say about the use of drug discrimination  
25 studies?

1           A       It's on the same page. It talks about  
2 a test drug produces interoceptive cues, or  
3 subjective effects also coined by others. But,  
4 essentially, it's whatever bodily sensations that  
5 an animal has known to be paired with a known  
6 drug of abuse, a test drug could be assessed to  
7 see if it has similar effects compared to a known  
8 drug of abuse and some degree if it substitutes  
9 based on some parameter, generally over 80  
10 percent responding on the drug-paired lever, that  
11 it may have abuse potential.

12           Q       The sentence at the end of the second  
13 to the last paragraph, if the test drug produces  
14 full or partial generalization to the training  
15 drug, a known drug of abuse, it may have abuse  
16 potential. What does that mean?

17           A       So when animals are trained to press  
18 a lever for their known drug of abuse, and we  
19 have to compare it to, like, a drug that's in a  
20 similar class. When given a new drug and given a  
21 different dose, if they press the lever that's  
22 paired with the known drug over 80 percent of the  
23 time, then that's coined full substitution.

24                   Partial substitution is generally over  
25 40 percent lever responding of the drug-paired

1 lever versus the saline-paired lever or  
2 vehicle-paired level.

3 Q And in this particular matter, what  
4 other known drugs were being used in drug  
5 discrimination studies?

6 A I believe for both drugs, it was LSD,  
7 DOM, and DOB, I believe, for both drugs.

8 Q And did it produce full substitution?

9 A In those three, yes.

10 Q And the last paragraph, drug  
11 discrimination is dependent on mechanism of  
12 action, so only those test drugs that have  
13 pharmacological activity similar to that of the  
14 training drug will likely produce a significant  
15 degree of generalization of the training drug.  
16 Can you explain what that means?

17 A Yes. So like the exhibit that was  
18 presented by Dr. Lance McMahon, drug  
19 discrimination is sensitive to the mechanism of  
20 action. So for this assay to work, we have to  
21 have a training drug that has that same mechanism  
22 of action to see if that drug will have an effect  
23 similar to that. So for this, it has to be  
24 something that goes through the Serotonin 2A  
25 receptor. And if the new drug has an effect

1 through the Serotonin 2A receptor, then it should  
2 substitute.

3 Q I think you said it was presented by  
4 a Lanus McMahon?

5 A Oh, Lance McMahon. The author of the  
6 paper was Dr. Lance McMahon.

7 Q Oh, okay.

8 A It was his commentary piece.

9 Q Not one of the witnesses.

10 A It was discussed. I don't remember at  
11 what point.

12 Q All right. Now, you heard the  
13 testimony of Dr. Jaster.

14 A Yes.

15 Q And she presented a one-page with a  
16 number or graphs on it. Are you able to  
17 interpret that in any possible way?

18 A Not without understanding what drug  
19 was administered, when it was administered, how  
20 it was administered, if there were other drugs  
21 also administered. You saw the table with DOI  
22 with oxycodone. Were there other studies with  
23 psilocybin or LSD and to compare that back to it?  
24 It's hard to know just based on, like, the graphs  
25 and no other context.

1           Q       Can you describe what is the  
2 relationship between mechanism of action and  
3 abuse liability?

4           A       So for us to assess a drug in the  
5 Eight Factor Analysis, we have to compare it to a  
6 drug with a similar mechanism of action and known  
7 effects. And so for us to assess abuse  
8 liability, it really is dependent on a drug that  
9 has a similar mechanism of action, which is why  
10 we use drug discrimination.

11          Q       I'd like to direct your attention to  
12 page nine of Exhibit 18.

13          A       Okay.

14          Q       There was a lot of discussion about  
15 self-administration. Is that an adequate test to  
16 determine the abuse liability of a drug?

17          A       I believe in, like -- are you talking  
18 about question two?

19          Q       Yes.

20          A       So I believe that they say, for new  
21 drugs that are determined to have CNS, which is  
22 central nervous system, activity, that the next  
23 step would be to conduct abuse-related studies,  
24 animal behavioral studies, such as drug  
25 discrimination and self-administration.

1           Q       And what do you know about using  
2 self-administration studies to determine the  
3 abuse liability of hallucinogenics or  
4 hallucinogens?

5           A       Specific for Serotonin 2A receptor  
6 agonist, it's not a behavioral profile that's  
7 generally shown.

8           Q       So would self-administration studies  
9 offer anything?

10          A       Not generally speaking, no, for this  
11 class of substances. It would for other  
12 substances, but not for Serotonin 2A  
13 receptor-mediated hallucinogens.

14          Q       And further down on that page, the  
15 second bullet point, generalization similar  
16 effects to a known drug of abuse in animal drug  
17 discrimination studies. What does that mean?

18          A       That before a drug that's going  
19 through clinical trials, before they take it into  
20 humans, they have to show whether or not it has  
21 these similar effects to a known drug of abuse in  
22 animal drug discrimination studies.

23          Q       I'd like to direct your attention to  
24 page seven of Exhibit 18.

25          A       Okay.

1           Q       And these are basic definitions. Can  
2 you describe for us what is abuse potential?  
3 What does it refer to?

4           A       My definition or the definition that  
5 is provided in this document?

6           Q       Do you concur with this definition?

7           A       Yes. It's the likelihood that abuse  
8 will occur with a particular drug product or  
9 substance with CNS activity. Yes, I would agree  
10 with that.

11          Q       Okay. Now, we've heard a lot of  
12 discussion about drug discrimination and also  
13 this organization NIDA, correct?

14          A       Yes.

15          Q       Do you know what NIDA's position is on  
16 using drug discrimination to assess abuse  
17 liability?

18          A       Yes. They've had a longstanding  
19 contract in place that's sole function is to  
20 assess -- well, not its whole function, but one  
21 of the primary things is to assess drug  
22 discrimination. I believe it's been a contract  
23 that they've had at least since the early '00s,  
24 so I think, like, going on 25, maybe 30 years.  
25 And their primary focus is to use it to assess

1 drug discrimination for various drug classes.

2 Q Okay. Could I direct your attention  
3 back to Page 23? There was discussion about  
4 psychic dependence versus physiological  
5 dependence. What is the difference there?

6 A Physiological dependence usually is  
7 essentially, like, the body has adapted, so it  
8 needs the drug, whereas my understanding of  
9 psychic dependence is, like, using the drug in a  
10 way that, like, harms are known but still willing  
11 to use it.

12 Q And what is the relevance of  
13 determining whether there's psychic dependence  
14 with respect to the Eight Factor Analysis?

15 A So I believe that factor in particular  
16 is really most relevant for drugs that fall into  
17 Schedules II through V to assess where they go  
18 within the schedules, but I believe in the 1970  
19 bill it doesn't make a note of needing dependence  
20 liability for a drug to be placed in Schedule I.  
21 I think really it's the marker to assess  
22 Schedules II through V.

23 Q And did you determine that there could  
24 be psychic dependence with respect to DOI and  
25 DOC?

1           A       I concurred with FDA or HHS's  
2       evaluation that there could be.

3           Q       All right. And you said that in the  
4       bill, the 1970 bill, it does not require  
5       dependence liability?

6           A       I don't believe that it does.

7           Q       Now, what does that mean when you say  
8       that?

9                   MR. PHELPS: Your Honor, she's  
10       testifying to matters of law and how they relate  
11       to the statute.

12                  JUDGE SOEFFING: Mr. Mann.

13                  MR. MANN: Well, I'm asking her what  
14       her definition of dependence liability means or  
15       is.

16                  JUDGE SOEFFING: Overruled. You may  
17       answer.

18                  THE WITNESS: Can you re-read the  
19       question? I'm sorry.

20                  BY MR. MANN:

21           Q       What is dependence liability?

22           A       Essentially, I think it's the  
23       predictive measure if a drug could produce  
24       dependence, whether it be physiological or  
25       psychological, depending on how it's used.

1           Q       Now, I remember when Dr. Cameron  
2 testified that Dr. Cameron seemed to, and I don't  
3 want to mischaracterize this, but used alcohol as  
4 an example of abuse liability, correct?

5           A       I believe so.

6           Q       Is it fair to compare DOI and DOC to  
7 alcohol when assessing abuse liability?

8           A       Not when we do the Eight Factor  
9 Analysis. We have to use a drug in a similar  
10 class.

11          Q       And is alcohol in the class of DOI or  
12 DOC?

13          A       Alcohol is not under the CSA.

14          Q       When going through the Eight Factor  
15 test, is there any number of users that we have  
16 to prove to satisfy the Eight Factor test?

17                 MR. PHELPS: Again, Your Honor, this  
18 is calling for a legal conclusion.

19                 JUDGE SOEFFING: Overruled. We've  
20 talked about volume evidence, so overruled.

21                 THE WITNESS: I'm not aware of a  
22 specific criteria.

23                 BY MR. MANN:

24          Q       Is there any number of adverse events,  
25 such as emergency room visit?

1           A       I'm not aware of any specific.

2           Q       Is there any given number of deaths  
3 that have to occur first?

4           A       Death is not a specific factor in the  
5 Eight Factor test. It's a component of harm, but  
6 we don't need death, specifically.

7           Q       And for assessing the safety and  
8 efficacy of a drug, did you hear any evidence  
9 during the Petitioner's case regarding any  
10 adequate safety studies?

11          A       I believe Dr. Cameron made some note  
12 of neurons on dishes, but did not present any  
13 data related to the safety of the drug. But  
14 again, I really need clinical evidence to assess  
15 safety. It's in totality, so I don't believe any  
16 clinical evidence has been shown.

17          Q       And when you say clinical evidence,  
18 what do you mean?

19          A       Clinical trials, generally speaking.

20          Q       So, in terms of the efficacy of DOI or  
21 DOC, have any clinical trials been performed?

22          A       Not that I'm aware of.

23          Q       At least one, or several of the  
24 witnesses, talked about the aggravation of having  
25 to get what they called IACUC approval. What is

1 IACUC approval?

2 A It's the Institutional Approval of  
3 Care and Use Committee.

4 Q All right. To the best of your  
5 knowledge, do researchers get IACUC approval  
6 before using DOI or DOC in their research?

7 A In animal studies that have vertebrae.  
8 So, there are some point worms and zebrafish that  
9 would not meet the USDA definition of what would  
10 need IACUC approval. But in those studies,  
11 before a drug is administered to an animal, a  
12 study must be approved first.

13 Q And they would have to get that  
14 whether the drug was controlled or not, correct?

15 A Yes.

16 Q Okay. So, in your -- based on your  
17 knowledge of the Drug Enforcement Administration,  
18 which employs you, if a drug is added to Schedule  
19 I, would that researcher then have to go back and  
20 get this IACUC approval again?

21 A They should already have it.

22 Q Your knowledge of -- when issuing  
23 Schedule I researcher registrations, what is your  
24 knowledge of the history of -- has that increased  
25 or decreased in the last ten or fifteen years?

1 A The number of researcher?

2 Q Yes.

3 A I believe it has increased.

4 Q Do you know by how much?

5 A I think when I started really noticing  
6 it was like in the 600s or so and has gone up. I  
7 think now it's like a little -- I think the last  
8 number I saw was like in the 820s or so.

9 Q Now, there was discussion during the  
10 Petitioner's case of 2C substances. Correct?

11 A Yes.

12 Q And what is your knowledge about the  
13 state of 2C substances? Are they controlled, or  
14 not controlled?

15 A They have a similar mechanization  
16 where they're, again, similar to these  
17 substances.

18 In 2012, there was a congressional act  
19 known as SDAPA, the Synthetic Drug Abuse  
20 Prevention Act of 2012, and that controlled 26  
21 substances. Of those, nine of them were 2C  
22 substances.

23 Not all 2C substances are controlled,  
24 but there are at least nine controlled.

25 Q And the nine controlled, are they

1 similar to DOI and DOC?

2 A They're very similar in structure and  
3 activity.

4 Q All right. And forgive me if I've  
5 asked you this already. We discussed -- did NIDA  
6 take a position with the HHS recommendation that  
7 DOC and DOI should be scheduled?

8 A Yes. During HHS's evaluation, there  
9 is an MOU, or an MOA, in place where FDA is the  
10 primary drafter. And they get concurrence from  
11 NIDA before they send us their scientific and  
12 medical evaluation and recommendation.

13 Q All right. I want to ask you about  
14 this term -- more a slang term -- that was used  
15 by, I know at least Dr. Ramos, talking about  
16 piggybacking. In other words, being able to work  
17 with another researcher in order to use their DEA  
18 registration. Are you familiar with that  
19 testimony?

20 A Yes.

21 Q All right. In your experiences, is  
22 that possible? Can that be done?

23 A I would say for students and  
24 post-docs, that's, like, mostly how it is done.  
25 Usually, we -- schedule and research

1 registrations are given to -- principal  
2 investigators are receiving the funds. And then  
3 there are some pieces where investigators work  
4 with other investigators that are not students,  
5 they're just another principal investigator, but  
6 they will work with another scheduling  
7 registrant.

8 Q Now, you've heard from Dr. Nichols.

9 A Yes.

10 Q You remember that testimony? And Dr.  
11 Nichols seemed to indicate that his son tried to  
12 obtain a DEA Schedule 1 registration. You  
13 remember that?

14 A Yes.

15 Q And that it took more than a year?

16 A I believe so.

17 Q Have you had a chance to look into the  
18 records to see how long it took his son to obtain  
19 a DEA registration?

20 A I'm not sure if that falls under  
21 privacy of the scheduling researcher program, but  
22 it was less than a year. I don't want to get  
23 specifics about somebody's registration.

24 Q Do you know how many months it was?

25 A It was less than a year.

1 MR. PHELPS: Objection, Your Honor.  
2 She is referring to documents that haven't been  
3 provided or disclosed. If she's going to be  
4 discussing specifics of an application, we have a  
5 right to review those and see the veracity.

6 JUDGE SOEFFING: Well, I'll allow you  
7 to cross-examine on it. She's testifying on,  
8 based on her memory of what she's looked up in  
9 the government's records. So, I'll allow you to  
10 cross-examine on it, but overruled.

11 THE WITNESS: I believe it was less  
12 than a year. But for privacy reasons, I don't  
13 want to speak on anyone's registration.

14 MR. MANN: I'd like to direct your --  
15 just one moment, Your Honor. That's all I have.  
16 Thank you.

17 JUDGE SOEFFING: Thank you, Mr. Mann.  
18 Mr. Phelps, would you like to cross-examine?

19 MR. PHELPS: Yes, Your Honor. If I  
20 could have just a moment to confer with counsel.

21 CROSS-EXAMINATION

22 BY MR. PHELPS:

23 Q Afternoon, Doctor.

24 A Good afternoon.

25 Q I'd like to talk a little bit about

1 some of the study methods that you were  
2 discussing in your rebuttal testimony.

3 Could you explain how ICSS, the  
4 intracranial studies, work?

5 A I think when I did my testimony, I'm  
6 not as familiar with, like, the basics of how the  
7 study works.

8 Q Not even the basics?

9 A I mean, when he gave us the  
10 presentation, we went through the details. I  
11 know it has to do with rewarding facts, but I  
12 don't -- other than that, no.

13 Q And you've never done an ICSS study  
14 yourself?

15 A I have not.

16 Q And other than that single  
17 presentation that you received that you  
18 mentioned, have you done any other further study  
19 on the topic?

20 A I have gone to conferences where I've  
21 seen ICSS data presented, but not specific to  
22 hallucinogens.

23 Q So, it would be fair to say then that  
24 you don't have an accurate enough understanding  
25 of how those studies work to provide your own

1 --perform your own independent analysis of how  
2 their reliability may compare to something like  
3 self-administration?

4 A I did it one time and I have not  
5 reevaluated that. I know for specific  
6 hallucinogens, they produce a different  
7 behavioral profile. And within that behavioral  
8 profile they're very similar.

9 They have, like -- I don't remember  
10 the key terms, but it's a different effect than  
11 most other drugs. So, it's not really effective  
12 for this class of drugs.

13 Q And can you describe how condition  
14 place preference works?

15 A Again, it's more based on its  
16 reinforcing effects on the drug, where an animal  
17 is administered a drug. They learn to pair the  
18 effects of the drug with a certain, like,  
19 condition, whether that be different, like --  
20 usually, there's two chambers, one with a  
21 different -- like, holes on the floor, grids on  
22 the floor, different textures on the walls, and  
23 then that's different in the other chamber.

24 And then they learn to, when given a  
25 drug, they pair those effects with whatever

1 stimulus they have geared to.

2 It can be done in different ways. And  
3 then when a novel drug is given, they put them in  
4 the center, and then they can choose which  
5 paradigm they like, even when they're used to  
6 drug they know, or the other drug, is my  
7 understanding.

8 Q And can you explain why that type of  
9 test, in particular, is considered less reliable  
10 than self-administration, based on the way that  
11 test works?

12 A Yes. So, there are a number of  
13 external factors that have been tested in  
14 different studies, to see if that could change  
15 the preference of a drug. And there is evidence  
16 that that does happen. That was something that  
17 my lab was doing when I was a grad student. And  
18 I'm not sure if that's published, but they were  
19 changing room conditions, and that would change  
20 behavior profiles of known drug-abuse potential.  
21 So, it can alter the effects, just that are not  
22 dependent to the drug.

23 Q Okay. Are you aware of any  
24 non-psychoactive substances that could  
25 discriminate for psychoactive substances in a

1 drug discrimination study?

2 A I believe there are some cases of  
3 that, yes.

4 Q So, based on the analysis that you've  
5 applied to DOI and relying almost entirely on the  
6 discrimination studies, would you say then that  
7 -- well, let me rephrase that.

8 Your essential claim is that DOI is a  
9 drug of abuse because it discriminates with other  
10 similar drugs of abuse. Correct?

11 A That is a large portion of my Eight  
12 Factor Analysis, yes.

13 Q Okay. So, by that logic, would you  
14 say that a non-psychoactive substance that  
15 discriminates with a psychoactive or controlled  
16 substance should be placed in the same schedule?

17 A I believe there's enough drug  
18 discrimination evidence. It's not just one  
19 study. Many labs have done it and there's been  
20 the cross-substitution as well. So, it makes me  
21 believe that this is not in a false-positive or  
22 false-negative.

23 Q Okay. But I'm specifically saying if,  
24 as you said, the major portion, the bulk of your  
25 reason for why this drug is considered -- should

1 be scheduled, is because it discriminates for  
2 schedule drugs.

3 So does that same logic apply, using  
4 that same logic, you should then have to schedule  
5 even non-psychoactive substances, if they  
6 discriminate for a controlled substance.

7 A No.

8 Q What's the difference?

9 A Well, so we know the activity based on  
10 this. So, that is a serotonin 2A receptor  
11 agonist, similar to these drugs in the drug  
12 discrimination paradigm.

13 I believe every paper that we reviewed  
14 calls this a psychedelic or a psychoactive 2A  
15 receptor agonist.

16 I think there is common knowledge that  
17 these drugs are psychedelics or hallucinogens,  
18 based on the evidence that is out there. And  
19 there are drug seizures for both DOI and DOC.

20 So, it's not just drug discrimination.  
21 But there is other data that also show that it  
22 has activity.

23 Q So, your testimony from Dr. de la  
24 Fuente about a drug called 5-HTP, are you  
25 familiar with that substance?

1           A       I believe it's a precursor to  
2 serotonin, I believe. Yes.

3           Q       So, it operates on those same  
4 receptors.

5           A       It can, yes.

6           Q       Okay. And it substitutes in drug  
7 discrimination, for other controlled substances  
8 that act on the same receptors.

9           A       I don't recall seeing that data so I  
10 can't speak on it.

11          Q       Okay. Well, if that were in fact the  
12 case, wouldn't the logic then follow that DEA  
13 should schedule 5-HTP?

14          A       No.

15          Q       I'd like to move on to  
16 self-administration studies.

17          A       Okay.

18          Q       So, for all other classes of drugs,  
19 self-administration studies are considered strong  
20 support for abuse liability, right?

21          A       It shows that they have rewarding  
22 affects and reinforcement properties, yes.

23          Q       So, it does show abuse liability, in  
24 your terms.

25          A       Yes.

1           Q       Okay. And it's well-known that in  
2 animal studies, rats don't self-administer  
3 psychedelics. Correct?

4           A       Correct.

5           Q       So, your testimony was that that  
6 doesn't show anything. I think, was that  
7 self-administration studies with psychedelics  
8 don't show that. But doesn't it in fact show?

9           A       No, because it's known that they don't  
10 have that same profile. And we know that people  
11 use psychedelics in a different way than other  
12 drugs.

13                   But just because it doesn't work in  
14 this model, doesn't mean that they don't have  
15 abuse potential.

16           Q       Why is that not proof that they don't  
17 have abuse potential, if they don't  
18 self-administer?

19           A       So, again, we have to compare back to  
20 profiles of the drugs of the same class. So, in  
21 this case, we would compare it to DOM, LSD, other  
22 serotonin 2A receptor agonist.

23                   And we can't really compare it to a  
24 cannabinoid, a stimulant, another depressant.  
25 Where the behavior, like, every drug has -- like,

1 the profiles change by drug class. And  
2 routinely, self-administration could pick up that  
3 behavior.

4 But it is well-known and  
5 well-discussed that that's just not something  
6 that happens with psychedelics through the 2A  
7 receptor.

8 Q And it's your position that the fact  
9 that it doesn't self-administer in those studies,  
10 shows nothing about potential for abuse?

11 A We, again, know that people use these  
12 substances. So, they have known abuse potential,  
13 known harms.

14 And so, based on the knowledge that  
15 they don't produce it, doesn't mean that they're  
16 not abusable substances.

17 Q But wouldn't that be an indication of  
18 abuse, or lack thereof?

19 A For most drug classes, yes. But  
20 because this is, like, well-established that this  
21 is not a behavior that is done, then, like, it's  
22 not a marker for the serotonin 2A receptor  
23 agonist.

24 Q I'd like to talk a little bit about  
25 psychic and physiological dependence.

1                   And is there any evidence showing  
2 physiological dependence in DOI?

3           A       It's generally not shown for most  
4 classic hallucinogens that work through the 2A  
5 receptor.

6           Q       So, no.

7           A       Not to my knowledge, no. I'm not sure  
8 it's been tested.

9           Q       Do you know why it hasn't been tested?

10          A       My understanding is it's not normal  
11 for this class of substances. Normally, physical  
12 dependence relies on a dopamine effect. And  
13 these drugs are going through a different pathway  
14 in the brain.

15          Q       And then psychic dependence, that's  
16 something that's demonstrated through  
17 self-administration studies, right?

18          A       It could be, but not necessarily.

19          Q       So, what evidence is there of the  
20 psychic dependence of DOI?

21          A       I believe for this one I relied on  
22 HHS's evaluation, which said that the known  
23 effects were similar to DOM and LSD, and people  
24 use those substances in intensity behavioral  
25 profiles, or the pharmacological profiles were

1 similar, that they believed that the effects met  
2 the definition of psychic dependence.

3 So, willingness to take it knowing  
4 that that there are harms, is similar to DOM and  
5 DOB, specifically, is what I believe is in that  
6 factor.

7 Q So, it's your position that there's a  
8 willingness to take DOI in the general public?

9 A Yes.

10 Q And what evidence have you seen to  
11 show this willingness?

12 A I mean, we have seen law enforcement  
13 seizures of DOI. So, it seems that people are  
14 willing to take it.

15 We have seen with DOC there's even  
16 more of them. But also, this factor is not,  
17 like, a strong contributor in the Eight Factor  
18 Analysis for putting something into Schedule I.  
19 It's for Schedules II through V, predominantly.

20 Q And can you remind us exactly what  
21 independent evaluation you did for your Eight  
22 Factor Analysis?

23 A I reviewed what information was given  
24 to me at that time.

25 Q You didn't conduct any experiments

1       yourself?

2               A       With DOI, specifically? I mean, I did  
3       some research with DOI when I was a graduate  
4       student.

5               Q       As part of your Eight Factor Analysis.

6               A       I did not do any experiments with DOI.

7               Q       And so, did your analysis consist of  
8       anything more than reading the HHS report and  
9       signing off on it?

10              A       No, I read it, I reviewed it, but I  
11       largely concurred with it, and then added more  
12       law enforcement. Or at least updated the law  
13       enforcement encounter data that we had submitted  
14       to them.

15              Q       That was the NFLIS data?

16              A       Yes.

17              Q       So, based on the criteria for placing  
18       a drug in Schedule I, the three criteria of the  
19       high potential for abuse in the known recognized  
20       medical value, would you agree that alcohol meets  
21       those same criteria?

22              A       That's regulated under a whole  
23       different --

24              Q       That wasn't my question. I'm not  
25       asking about how it's regulated. I'm asking, as

1 a substance, does it meet those criteria?

2 A Yes.

3 MR. MANN: Objection, relevance.

4 MR. PHELPS: He was asking her about  
5 alcohol --

6 JUDGE SOEFFING: Overruled. She  
7 answered it.

8 BY MR. PHELPS:

9 Q So, based on the scientific criteria,  
10 alcohol would qualify as what would be considered  
11 a Schedule 1 substance?

12 A I'm not aware of a medical use for  
13 alcohol.

14 Q So, it's strictly a policy decision  
15 for why it's treated differently?

16 A That's outside my scope. Yes, I  
17 guess.

18 Q Well, your scope is science. And it's  
19 not based in science, right?

20 A I believe for that, it has its own  
21 regulatory framework. So, yes, I guess.

22 Q Now, on your rebuttal testimony, you  
23 were asked about if there was any certain number  
24 of encounters required to schedule a substance,  
25 right?

1           A       Yes.

2           Q       And just to be clear, you would agree  
3 that the term, seizure, in fact, doesn't apply to  
4 DOI or DOC at all at this point. Correct?

5           A       Sure, yes, I think so.

6           Q       Okay. Just want to make that clear,  
7 because we've heard a lot of talk about seizures  
8 of DOI. But they're in fact encounters, correct?

9           A       Correct.

10          Q       Okay. And there's no number of  
11 encounters that are required as some kind of  
12 threshold amount for scheduling?

13          A       Not that I'm aware of.

14          Q       So, there's no bottom level of what's  
15 required?

16          A       To place something in Schedule 1?

17          Q       Yes.

18          A       I believe there have been some with as  
19 little as one, to be placed in Schedule I. I  
20 think for SDAPA, some of those 2C-I substances  
21 have never been used in the United States, even  
22 after controlling.

23          Q       And you mentioned that there's  
24 currently no clinical trials that have been  
25 conducted with DOI, right?

1           A       Not to my knowledge.

2           Q       As a scientist, do you think that  
3       clinical trials using DOI could help our  
4       understanding of the drug?

5           A       Yes.

6           Q       And its potential therapeutic uses?

7           A       I think we're pretty far away from  
8       having potential therapeutic uses of DOI. But  
9       yes, if the data got that far, yes.

10          Q       And would you acknowledge that placing  
11       DOI in Schedule I would impact the ability of  
12       researchers to eventually get to those clinical  
13       trials?

14          A       I mean, there might be some impact,  
15       but I don't think it would be a significant  
16       impact.

17          Q       So, it's your position that all of the  
18       testimony we heard about how research would be  
19       impacted is not significant?

20          A       No, the research is significant. But  
21       my understanding from the testimony here, is that  
22       all of them worked in a Schedule I Researcher  
23       lab, or they had -- other than Dr. Ramos, who  
24       does not but has some in his building -- but  
25       those data have not been published.

1                   The other data that have been  
2 published seemed to be in labs that have Schedule  
3 I Researcher registrations.

4           Q       But you would agree that many of the  
5 researchers working on DOI do not have Schedule 1  
6 licenses. Correct?

7           A       I don't think I agree with many of  
8 them. I think most of them have a Schedule I  
9 Researcher registration, based on reviewing  
10 papers.

11          Q       Have you ever applied for a DEA  
12 license?

13          A       I have not.

14          Q       Have you ever been involved in the  
15 application of a DEA license?

16          A       I've been involved in adding protocols  
17 to a Schedule I Researcher registration.

18          Q       There was some discussion about Dr.  
19 Nichols' testimony in his son Chuck's attempts to  
20 get a DEA license. Do you recall that?

21          A       Yes.

22          Q       And you said, following that  
23 testimony, you went and reviewed his DEA file for  
24 that license?

25          A       Yes.

1           Q       And you said based on what you had  
2       seen, that that was about four months?

3           A       I did not give an amount of time. I  
4       said it was less than one year.

5           Q       You don't remember saying it was four  
6       months?

7           A       I did not say four months.

8           Q       Okay. But whether it was four months  
9       or something else, what is the start date that  
10      you're using to base that on?

11          A       When it was applied to DEA. When the  
12      registration application was submitted to DEA.

13          Q       So, it was four months from the time  
14      you received the application, until the license  
15      was granted.

16                 MR. MANN: Objection. She said she  
17      did not say four months.

18                 JUDGE SOEFFING: Sustained.

19                 BY MR. PHELPS:

20          Q       The timeline, whatever it was, was  
21      from when you received the application to when it  
22      was granted. Correct?

23          A       Yes.

24          Q       So, that would not include any of the  
25      time that went into the preparation for applying

1 for that license?

2 A Correct.

3 Q And based on having gone through  
4 somewhat of that process yourself, you would  
5 agree that there is a substantial amount of  
6 preparation that goes into submitting one of  
7 those applications. Correct?

8 A Yes, but most of it would be needed  
9 for general research anyway.

10 Q The preparation for applying for a DEA  
11 license would be needed for other research?

12 A Well, generally, I mean, I think  
13 others have talked about the protocol and things  
14 like that, but a protocol would have to be in  
15 place to do any kind of bona fide research.

16 Obviously, a safe would be different.  
17 So, getting a safe or working with a registrant  
18 that has a safe, would be different. But most of  
19 the procedures to getting a DEA registration  
20 would follow in line with doing bona fide  
21 research.

22 Q But you would agree that the timeline  
23 that you've been referring to throughout these  
24 proceedings, is not actually the entire timeline  
25 that somebody puts into completing one of these

1 applications, wouldn't you?

2 A Yes. I only know the part that DEA is  
3 involved in.

4 Q Okay. And based on your judge of the  
5 credibility of the witnesses you heard before  
6 them, would you say it's accurate that almost to  
7 a T, every single one of those witnesses said it  
8 took them a year?

9 A I mean, if it's from beginning a study  
10 up and going up to the DEA registration, I think  
11 that those numbers vary, depending on the type of  
12 study that it is. If it's a cell study or an  
13 animal study. If you need IACUC approval or not.  
14 I think that it can vary pretty drastically.

15 Whether you need a DEA registration  
16 could take a year, even with a drug that's not  
17 controlled, to get it through that same process.

18 Q Do you recall in your original  
19 testimony, that you said the average time to get  
20 a license is three months?

21 A Yes. About three months.

22 Q Based on what you heard from the  
23 evidence presented in this case, would you still  
24 say that's an accurate representation of the  
25 total time it takes to get a DEA license?

1           A       Again, I'm only opining on the part  
2       that DEA receives.

3           Q       So, you would agree then that your  
4       testimony has not provided a full picture of what  
5       it actually takes to get a DEA license?

6           A       Only the part that DEA receives. So,  
7       yes.

8           Q       Okay. Is your definition of addiction  
9       different for alcohol than psychedelics?

10          A       I don't think that I've used the word  
11       addiction to describe either one of them. I  
12       think the abuse profile is different.

13          Q       You would agree there's certainly been  
14       testimony throughout these hearings about  
15       addiction?

16          A       Yes.

17          Q       And how do you define addiction?

18          A       Usually, it's the presence of  
19       dependence, tolerance, and withdrawal.

20          Q       Do any of those factors apply to  
21       psychedelics?

22          A       Well, there is the notion of  
23       tolerance, as we've seen with the head twitch  
24       assay. But again, I don't need to show -- like,  
25       one of the components of the Eight Factor is not

1 addiction, specifically. It is a harm component,  
2 but a drug must not cause addiction for it to be  
3 controlled in any of the five schedules.

4 Q But you wouldn't disagree that the  
5 concept of addiction is relevant to these entire  
6 proceedings?

7 A I'm not sure it's as applicable for  
8 this drug class, as it is for other drug classes.

9 Q And do you recall hearing testimony  
10 that DOI may actually reduce alcohol addiction?

11 A I believe those that was another  
12 condition-placed preference study. And I'm not  
13 sure if I reviewed that paper for this report.  
14 But there are many questions about how DOI is  
15 used in some of these pre-clinical models, and  
16 whether that was self-administration or  
17 condition-placed preference.

18 Normally, for clinical trials it's a  
19 moderate high dose of a drug, and then it's a  
20 long-term effect of having an anti-addictive, if  
21 you will, or a less use of a drug long-term.  
22 It's not while the effects of the drug are in the  
23 body. It's afterwards.

24 And many of those studies, I don't  
25 know for the alcohol-specific one, are tested

1 with the drug onboard and looking at either lever  
2 responses, or preferenced in, like, CPP.

3 Q So, there was testimony provided about  
4 research potentially showing DOI reducing alcohol  
5 addiction, wasn't there?

6 A I believe so.

7 Q And are you aware of any other studies  
8 or testimony provided about DOI having  
9 anti-addictive properties to other drugs?

10 A I believe there was that graph that  
11 was presented by Dr. Jaster, with, I believe  
12 again, CPP and oxycodone preference. But again,  
13 without the context of that data, I can't really  
14 interpret it to understand what those data mean.

15 Q Would you say that it would be, in the  
16 broader context, would you say that it would be  
17 important to continue studying DOI and its  
18 potential anti-addictive properties?

19 A I think all research is good. So,  
20 yes.

21 Q Dr. Carbonaro, what's your Reddit  
22 handle?

23 A I don't know it.

24 MR. MANN: Objection.

25 JUDGE SOEFFING: What's the basis?

1 MR. PHELPS: I can explain the  
2 relevance, Your Honor.

3 MR. MANN: A question such as this is  
4 offered only to harass or embarrass the witness,  
5 and it has no relevance and was not covered on  
6 cross.

7 JUDGE SOEFFING: Mr. Phelps?

8 MR. PHELPS: I can -- it was asked on  
9 cross initially. And the relevance --

10 MR. MANN: I'm sorry. It wasn't  
11 handled on directive rebuttal.

12 MR. PHELPS: The relevance to this,  
13 Your Honor, is that they're relying on these  
14 Reddit posts as evidence of use.

15 And they testified that there's no  
16 information that -- they have no idea who's  
17 behind these posts. And so, my question is, if  
18 the Government is posing these as true and saying  
19 there's no way to know who they are, how are we  
20 supposed to know that it's not Government  
21 employees that are going and making these Reddit  
22 posts to bolster their case. And I think that  
23 bears directly on the relevance when she said  
24 that she's a ten-year user of the site.

25 JUDGE SOEFFING: I'm going to sustain

1 the objection. I don't think it was covered on  
2 direct, and for several other reasons as well.  
3 So, I sustain the objection.

4 MR. PHELPS: Certainly, we just make  
5 a formal objection to that ruling for the record.  
6 With that, no further questions.

7 JUDGE SOEFFING: Thank you, Mr.  
8 Phelps. Mr. Mann, any redirect?

9 MR. MANN: Briefly.

10 REDIRECT EXAMINATION

11 BY MR. MANN:

12 Q Dr. Carbonaro, there's now a dispute  
13 about the meaning of the term seizure. We can  
14 agree that during this hearing, the term seizure  
15 was used to describe instances where DOI was  
16 found by law enforcement. Correct?

17 A I believe so.

18 Q And that if someone were to seize what  
19 they thought was an illicit drug, such as LSD,  
20 and it later turned out to be DOI, that that  
21 would be a seizure.

22 A I believe so.

23 Q Does DOI have any currently accepted  
24 medical use?

25 A Not that I'm aware of.

1           Q       Does DOC have any currently accepted  
2 medical use?

3           A       Not that I'm aware of.

4           Q       There's been discussion about the  
5 impacts that scheduling would have. You watched  
6 the entire testimony of these proceedings,  
7 correct?

8           A       Yes.

9           Q       Did you hear a single person say that  
10 this would cause them to end their research?

11          A       No.

12          Q       And you recall that Dr. Ramos was  
13 specifically asked would he end his research,  
14 even though he didn't have a DEA registration.  
15 And his answer was, no. Correct?

16          A       Yes.

17          Q       Thank you.

18                   JUDGE SOEFFING: Mr. Phelps, any  
19 re-cross?

20                   MR. PHELPS: Just very briefly, Your  
21 Honor.

22                   RE CROSS EXAMINATION

23                   BY MR. PHELPS:

24           Q       Would you say that getting a better  
25 understanding of the potential therapeutic uses

1 of DOI, or potential therapeutic drugs that could  
2 be developed through its research, would be a  
3 benefit to public health?

4 A Yes.

5 MR. MANN: Objection.

6 MR. PHELPS: No further questions.

7 JUDGE SOEFFING: Overruled. All  
8 right, thank you again for your testimony,  
9 Doctor. You are excused. I direct you not to  
10 discuss your testimony with anyone other than  
11 Government counsel until the conclusion of the  
12 hearing.

13 Mr. Mann, do you have any other  
14 rebuttal witnesses?

15 MR. MANN: That's all, Your Honor.  
16 Thank you.

17 JUDGE SOEFFING: Mr. Phelps, would  
18 you like to put on a surrebuttal case?

19 MR. PHELPS: No, Your Honor. No more  
20 witnesses for Petitioners.

21 JUDGE SOEFFING: Very well. Then,  
22 we'll move to closing arguments. The parties may  
23 make closing statements and file post-hearing  
24 briefs. They can do both, or one, or neither.  
25 But you have the option now for closing

1 statement, Mr. Mann, if you'd like to make one.

2 MR. MANN: May I confer?

3 (Pause.)

4 MR. MANN: Mr. Phelps has said that he  
5 feels that there will not be sufficient time to  
6 do it before five o'clock.

7 I feel like if we're going to do  
8 closing arguments, we should do it tomorrow  
9 morning.

10 JUDGE SOEFFING: Okay. So, both  
11 parties wish to make closing statements for the  
12 record? Is that --

13 MR. MANN: Yes.

14 JUDGE SOEFFING: -- what I'm getting  
15 here? Okay.

16 MR. PHELPS: And just to be clear,  
17 that wouldn't preclude the post-hearing brief,  
18 correct?

19 JUDGE SOEFFING: That's correct.

20 MR. PHELPS: Okay. And just one other  
21 question on that. Will the briefs be prior to  
22 receiving the final transcripts? Or what is the  
23 --

24 JUDGE SOEFFING: No. You'll get the  
25 transcripts and have an opportunity to file

1 exceptions to the transcripts. And then I'll  
2 receive post-hearing briefs. And I'll give dates  
3 for all that after the case concludes tomorrow.

4 MR. PHELPS: Okay, great. That's what  
5 I thought. I just wanted to double-check. So,  
6 we're good to come back tomorrow and do closings,  
7 and call it a hearing.

8 JUDGE SOEFFING: Okay, very good. In  
9 that case, I'll look forward to hearing the  
10 closing statements of the parties tomorrow  
11 morning at nine o'clock.

12 We are concluded for today and are off  
13 the record. Thank you.

14 (Whereupon, the above-entitled matter  
15 went off the record at 4:40 p.m.)  
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| A                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                  |                                                                                                                                                                                                                     |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
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| <b>ability</b> 1160:7 1179:9<br>1253:11                                                                                                                                                                                                                                                                                                                                                                                                   | <b>abuse-related</b> 1228:23                                                                                                                                                     | <b>actual</b> 1063:9 1065:14<br>1068:25 1070:19<br>1105:13 1106:10<br>1163:13                                                                                                                                       |
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Before: US Drug Enforcement Administration

Date: 11-18-24

Place: Arlington, Virginia

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