

UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

IN THE MATTER OF:

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

Friday,
November 15, 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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KAYLA L. KREINHEDER, ESQ.
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ALSO PRESENT:

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

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

2 (9:03 a.m.)

3 JUDGE SOEFFING: Welcome back,
4 everyone. Dr. Elder is still on the stand. I
5 remind you, Dr. Elder, you are still under
6 oath. And Ms. Attanasio, you may conduct your
7 cross-examination.

8 MS. ATTANASIO: Thank you, Your
9 Honor.

10 CROSS-EXAMINATION

11 BY MS. ATTANASIO:

12 Q Good morning, Dr. Elder.

13 A Good morning.

14 Q Are you familiar with Dr. Alaina
15 Jaster?

16 A Yes, I am.

17 Q Have you worked together?

18 A Yes.

19 Q You've appeared on panels together?

20 A Yes, that's correct.

21 Q You've appeared on her podcast?

22 A Yes, on one of the early episodes.

23 Q Did Dr. Jaster ask you to appear at
24 this hearing?

25 A We talked together about this

1 effort, so. I wouldn't say she asked me.

2 Q You were in the courtroom during the
3 presentation of the Government's case?

4 A For some of it, yeah.

5 Q And you're aware that Dr. Alaina
6 Jaster was the first witness to appear on
7 behalf of the Government?

8 A I'm -- I'm not sure. I wasn't here
9 on the second day of the --

10 JUDGE SOEFFING: Do you mean for the
11 respondents, for Petitioners?

12 MS. ATTANASIO: Yes.

13 JUDGE SOEFFING: Okay.

14 BY MS. ATTANASIO:

15 Q Have you spoken with Dr. Jaster
16 regarding her testimony?

17 A I have not, no.

18 Q Have you spoken with anyone about
19 Dr. Jaster's testimony?

20 A No. Only to say I haven't heard it.

21 Q Have you read or watched any videos
22 about this hearing?

23 A No.

24 Q You testified that you worked in a
25 lab where the principal investigator retired

1 and terminated his DEA registration?

2 A That's right. Or transferred it,
3 the people -- I think -- I know he cancelled
4 it, and then we had to just get a new one.

5 Q Okay. Dr. Patrick Beardsley?

6 A That's correct, yes.

7 Q And Dr. Beardsley studied opioids?

8 A Dr. Beardsley had a very long
9 career, so he studied many different classes of
10 drugs, opioids were his primary focus at the
11 end there.

12 Q And he used drug discrimination
13 studies to assess abuse liability?

14 A Yes. Dr. Beardsley had done drug
15 discrimination studies among many others.

16 Q So you would agree that drug
17 discrimination studies are useful in assessing
18 abuse liability?

19 A I don't know if I would agree with
20 that. Actually, of course, they're a component
21 of abuse liability assessment, but they're not
22 the end all, be all, I guess I would say.

23 Q But still good to use?

24 A I'd say they're a piece of evidence
25 that should be taken into account, but not

1 something that's indicative -- not absolutely
2 indicative of abuse liability, just
3 similarities between drugs and their
4 interoceptive effects.

5 Q You spoke a little bit about
6 seizures of DOI and DOC, and seeing it or not
7 seeing it on the gray market?

8 A I did.

9 Q But you have no independent evidence
10 that the seizures reported to DEA of DOI were
11 not, in fact, DOI?

12 A I don't have any independent
13 evidence to suggest that what the DEA has
14 seized was not DOI.

15 Q And you have no independent evidence
16 that the seizures reported to DEA of DOC were
17 not, in fact, DOC?

18 A No. I don't have any evidence to
19 refute that.

20 Q You have no independent evidence to
21 show that the only comments about ingesting are
22 false?

23 A I also don't have any evidence that
24 they're true, so.

25 Q But no evidence that they're false

1 either?

2 A No hard evidence.

3 Q You testified yesterday that
4 comments on internet forums are unreliable?

5 A Yes, I did.

6 Q However, you've relied on those
7 kinds of reports from internet user forums in
8 your own articles?

9 A Yes. And I do believe I stated
10 yesterday that reports on internet forums can
11 be useful for background information and when
12 surveyed to provide a rationale for further
13 studies, which is how I used them, I believe.

14 Q You testified a bit yesterday about
15 clinical trials. Are you aware of any clinical
16 trials with DOI?

17 A I don't believe DOI is currently in
18 clinical trials.

19 Q DOC?

20 A Neither of the two chemicals have
21 made it to clinical trials currently.

22 Q Would scheduling DOI hurt your
23 specific research now?

24 A The research that I'm currently
25 conducting in private industry?

1 Q Yes?

2 A Materially, on a day-to-day basis,
3 probably not. In terms of background and
4 medical knowledge that we rely on for our,
5 again, rationale and designing our experiments,
6 potentially.

7 Q But you are not using DOI in your
8 research now?

9 A I am not currently. I work in
10 clinical research currently.

11 Q And you are not using DOI -- DOC,
12 excuse me, in your research now?

13 A That's correct.

14 Q You testified that an advisor, I
15 believe, again, Dr. Beardsley, retired and as a
16 result, drugs had to be returned to a reverse
17 distributor?

18 A Yes, correct.

19 Q And you acknowledged that this had
20 nothing to do with a particular scheduling
21 action, the drugs were already scheduled when
22 you obtained them?

23 A Yeah. I understand that. They were
24 of all -- many -- many different Schedules from
25 I to V.

1 Q Yesterday, you also mentioned a
2 situation where your lab was working with
3 substances that were Scheduled, and that caused
4 a disruption to research?

5 A That's correct.

6 Q Were these fentanyl-related
7 substances?

8 A In one instance they were
9 fentanyl-related substances, yes.

10 Q And the purpose of the research was
11 to aid DEA in determining the pharmacological
12 effects of these substances so DEA could
13 consider scheduling these substances?

14 A That was part of the rationale for
15 the research, correct. Another rationale was
16 to assess their respiratory depressant effects
17 and liability to produce overdose, so.

18 Q And many of these fentanyl-related
19 substances were scheduled?

20 A That's correct, they were actually
21 scheduled wholesale by a specific act, I
22 believe.

23 Q And was that a surprise to you?

24 A No. I don't -- I don't think that
25 was surprising.

1 MS. ATTANASIO: One moment, Your
2 Honor. No further questions, Your Honor.

3 JUDGE SOEFFING: Thank you. Mr.
4 Rush, would you like to conduct redirect?

5 MR. RUSH: Yes, Your Honor.

6 REDIRECT EXAMINATION

7 BY MR. RUSH:

8 Q How did you spend last night?

9 A I had to drive back to Baltimore to
10 get a different computer, drove back here, and
11 stayed at a friend's house at Arlington who's
12 unrelated to this hearing.

13 Q Regarding drug discrimination
14 studies, can you please tell us what you
15 believe to be the most accurate way of
16 determining abuse liability?

17 A Absolutely. Specifically, in
18 regards to drug discrimination studies, I
19 think, I would say that when assessing abuse
20 liability as we can see with eight factors,
21 abuse liability assessments need to be holistic
22 and not rely on a single measure.

23 So drug discrimination can tell you
24 that an animal recognizes certain interoceptive
25 effects, but internal subjective effects of a

1 drug. But that doesn't necessarily mean that
2 those effects are abuse-related, reinforcing of
3 the same exact character.

4 So I think that it can be used as a
5 component, overall component of the drug, a
6 drug's abuse potential assessment. But I think
7 it's been shown pretty clearly that various
8 drugs that are not scheduled and have no abuse
9 liability, that humans can substitute for drugs
10 of abuse.

11 MR. RUSH: Thank you, Your Honor.
12 We have no further questions.

13 JUDGE SOEFFING: Thank you, Mr.
14 Rush. Ms. Attanasio, any re-cross?

15 MS. ATTANASIO: No, Your Honor.

16 JUDGE SOEFFING: Okay. All right,
17 Dr. Elder. Thank you for your testimony. You
18 are excused. I direct you not to discuss your
19 testimony with anyone until the conclusion of
20 the hearing.

21 THE WITNESS: Thank you, Your Honor.

22 JUDGE SOEFFING: Okay. Mr. Phelps,
23 who's calling your next witness?

24 MR. PHELPS: Yes, Your Honor. It's
25 going to be Dr. Cameron calling in. If we could

1 maybe go off the record for just a minute --

2 JUDGE SOEFFING: Okay. We're off the
3 record.

4 (Whereupon, the foregoing matter
5 went off the record at 9:14 a.m. and went back
6 on the record at 9:27 a.m.)

7 JUDGE SOEFFING: We are back on the
8 record.

9 MR. PHELPS: Oh, I was just going to
10 give you a heads-up, that we actually made a
11 change, I'm going to be handling Dr. Cameron.

12 JUDGE SOEFFING: Okay. Very good.
13 So Mr. Phelps, then, you may call your next
14 witness.

15 MR. PHELPS: Thank you, Your Honor.
16 Good morning, Dr. Cameron.

17 DR. CAMERON: Good morning.

18 JUDGE SOEFFING: Okay. So Mr.
19 Phelps, you're calling Dr. Cameron?

20 MR. PHELPS: Yes. Oh, my apologies
21 --

22 JUDGE SOEFFING: No, I need to swear
23 her in?

24 MR. PHELPS: Yes. Oh, Petitioners
25 call Dr. Lindsay Cameron.

1 JUDGE SOEFFING: Okay. Good morning,
2 Dr. Cameron.

3 DR. CAMERON: Good morning.

4 JUDGE SOEFFING: Dr. Cameron, please
5 raise your right hand.
6 WHEREUPON,

7 DR. LINDSAY CAMERON
8 was called as a witness by Counsel for the
9 Petitioners, and, having been first duly sworn,
10 assumed the witness stand, was examined and
11 testified as follows:

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

15 THE WITNESS: Lindsay Cameron,
16 L-I-N-D-S-A-Y, Cameron, C-A-M-E-R-O-N.

17 JUDGE SOEFFING: Okay. And, Dr.
18 Cameron, during your testimony, you should not
19 look at any materials or documents, except
20 exhibits you are directed to look at by counsel
21 or me, do you understand?

22 THE WITNESS: Yes.

23 JUDGE SOEFFING: Okay. You can put
24 your hand down.

25 THE WITNESS: Okay.

1 JUDGE SOEFFING: Thank you. Mr.
2 Phelps, you may inquire.

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

5 DIRECT EXAMINATION

6 BY MR. PHELPS:

7 Q Good morning, Dr. Cameron. Thank
8 you for being here with us today.

9 A Thank you for having me.

10 Q Can you tell us first, you're our
11 first video witness today. Can you tell us
12 where you are calling in from?

13 A I'm in Palo Alto, California.

14 Q Okay. Thank you. So I'd like to
15 direct your attention to what has been marked
16 for exhibit purposes -- identification purposes
17 as SSDP Exhibit No. 71.

18 A Okay.

19 Q Do you have that there with you?

20 A Exhibit 71?

21 Q Yes. With your -- you may not have
22 the number on it, it's your CV.

23 A Oh, yes. I have my CV.

24 Q So, okay, so. So do you recognize
25 that document in front of you?

1 A Yes.

2 Q And can you tell us what it is?

3 A It's my CV.

4 Q Okay --

5 A So it's -- okay.

6 Q And did you prepare that document?

7 A Yes.

8 Q And is the document that you have
9 in -- is it an accurate -- the document you
10 have in front of you, is it an accurate
11 depiction of your CV as you provided it to us
12 earlier in this case?

13 A Yes.

14 MR. PHELPS: At this time, Your
15 Honor, we would move to admit what's marked for
16 exhibit purposes -- identification purposes,
17 excuse me, as Exhibit No. 71.

18 JUDGE SOEFFING: Dr. Cameron, how
19 many pages is the exhibit that you have in
20 front of you, your CV?

21 THE WITNESS: Five.

22 JUDGE SOEFFING: Okay. Government,
23 any objection?

24 MS. KREINHEDER: No, Your Honor.
25 Can you hear me?

1 JUDGE SOEFFING: Yeah. Did you get
2 that on the record, Mr. Reporter? No
3 objection --

4 COURT REPORTER: All I got was, can
5 you hear me.

6 MS. KREINHEDER: No objections, Your
7 Honor.

8 JUDGE SOEFFING: Thank you, Ms.
9 Kreinheder. Okay. Petitioner Exhibit marked
10 for identification No. 71 has been offered. In
11 the absence of objection, it is received in the
12 record as Petitioner Exhibit 71. It's in, you
13 may use it.

14 (Whereupon, the document previously
15 marked as Petitioner Exhibit No. 71 for
16 identification was received into evidence.)

17 BY MR. PHELPS:

18 Q Dr. Cameron, what degrees do you
19 hold?

20 A I hold a bachelor degree from McGill
21 University in pharmacology and therapeutics, so
22 drug design and development. I hold a Ph.D. in
23 neuroscience.

24 Q And where did -- where did you
25 pursue that undergraduate education?

1 A McGill University in Montreal.

2 Q And where did you pursue your Ph.D.?

3 A At University of California-Davis.

4 Q And what do you hold your Ph.D. in?

5 A Neuroscience.

6 Q And can you tell me a little bit

7 about your Ph.D. coursework curriculum?

8 A Sure. So I had to take everything
9 from molecular and cellular biology,
10 understanding ion channels of neurons and
11 molecular signaling pathways, up to systems
12 neuroscience, some theoretical understandings
13 of different types of frameworks, circuits in
14 the brain, up to cognitive neuroscience in
15 humans, other types of tests, those are done by
16 taking statistics and coding as well.

17 Q And in addition to your course
18 curriculum, what else did your Ph.D. program
19 consist of?

20 A I mean, other than the courses, I
21 had to do two different qualifying exams, so
22 one on general knowledge that I passed, and
23 also, one on -- that is specific to my theses,
24 which I also passed. I submitted a
25 dissertation, I defended it, yeah.

1 Q And can you talk a little bit about
2 your dissertation research?

3 A Yeah. So my undergraduate degree
4 was in drug design and development with a lot
5 of chemistry involved. For my Ph.D., I did my
6 Ph.D. in neuroscience, but I did it actually in
7 the chemistry lab.

8 So I synthesized novel compounds and
9 tested them, so I tested existing drugs and
10 synthesized novel ones. And then I would test
11 them both in vitro, in dishes of cell culture,
12 as well as in vivo in rodent models. So I'm
13 pretty well-versed in terms of drug design,
14 development, and testing.

15 JUDGE SOEFFING: Okay. Let me just
16 take a pause here and, Dr. Cameron, because
17 this is being done via VTC, it's not live here,
18 we're having a little bit of -- or the court
19 reporter's having a little bit of difficulty
20 capturing everything you're saying, I think.

21 So if you could slow down a little
22 bit and just try to enunciate your words a
23 little bit better, that way that would assist
24 in the compiling of the transcript.

25 THE WITNESS: Okay. Sounds good.

1 Do I need to speak louder at all?

2 JUDGE SOEFFING: I don't think
3 volume is -- no, volume is not a concern here,
4 thank you.

5 THE WITNESS: Okay. No problem. Do
6 you want me to reiterate what I just said?

7 JUDGE SOEFFING: No. We have
8 everything. That would just make it easier
9 going forward.

10 THE WITNESS: Okay. Great.

11 JUDGE SOEFFING: Thank you, Dr.
12 Cameron. Yes, Ms. Kreinheder?

13 MS. KREINHEDER: The Government
14 would like to point out that there is a witness
15 in the courtroom who is in violation of the
16 sequestration order.

17 JUDGE SOEFFING: Well, I guess, Mr.
18 Phelps, do you intend to recall Dr. Elder?

19 MR. PHELPS: We do not, Your Honor.
20 We would ask that he be excused as a witness in
21 this proceeding.

22 JUDGE SOEFFING: So he's been
23 excused as a witness. The Petitioners are not
24 intending to recall him, so he's welcome to
25 stay. He will not be able to be recalled, of

1 course, at this point.

2 And he's already been instructed not
3 to discuss his testimony with anybody else
4 until the conclusion of the hearing, so that
5 still applies. Thank you, Ms. Kreinheder. And
6 Mr. Phelps, you may ask your next question.

7 BY MR. PHELPS:

8 Q I'd like to go down to the next
9 section of your CV there, and it's listed as
10 research experience. Before we get into the
11 specifics of that, could you just talk in
12 general what has your research experience
13 consisted of as a whole? What have you
14 studied?

15 A I've done everything from like
16 chemical synthesis up to testing molecular
17 pathways and signaling pathways, both in cell
18 culture as well as in rodent models, and I've
19 done a lot of behavior.

20 So testing drugs is what I do
21 generally throughout my Ph.D., as well as a
22 primary focus of what I do now. After I
23 graduated, I joined here, which is the
24 Department of Psychiatry at Stanford
25 University, and I focus a lot on addiction work

1 here.

2 Q And so you said that you studied a
3 lot of behavior. Can you explain kind of what
4 you mean by that?

5 A Yeah. So I study animal behavior.
6 I like to say that usually, you know, for an
7 average person, you might not think mice or
8 rats are good models. But what I want to say
9 is that, so if you have a dog, and you know
10 that your dog is, you know, sad or happy, if
11 you spend enough time around rodents like I do,
12 you can very much and easily tell if they're
13 doing well or not.

14 And so we have a whole bunch of
15 different tests that we can test animals with
16 to study anti-depressant like effects, test
17 things anxiety or post-traumatic stress
18 disorder, addiction, things like rewarding
19 feelings. So these are all like very typical
20 tests that I do in lab also.

21 Q And would -- just to clarify, would
22 the way that you test or observe those
23 behaviors in the rodents in your lab, how would
24 that contrast to the way you might evaluate the
25 behaviors, like you discussed of say, a pet

1 dog?

2 JUDGE SOEFFING: So, Mr. Phelps, are
3 you going to offer her as an expert witness at
4 this point? Or are you still probing her
5 credentials?

6 MR. PHELPS: Yes -- yes, Your Honor.

7 JUDGE SOEFFING: Okay.

8 MR. PHELPS: We're going to get into
9 the research specifics, I just wanted to get
10 kind of a general overview before we went
11 through some of the specifics there.

12 JUDGE SOEFFING: Okay. All right.
13 You may proceed.

14 BY MR. PHELPS:

15 Q What's different about how you may
16 observe behaviors in rodents in your lab versus
17 behaviors in say, your pet dog at home?

18 A Well, you run very specific tests,
19 but you can test for basically like motivation
20 to get things -- motivation to escape,
21 anhedonia, you could test anxiety, you can test
22 -- and you can just -- it's very easy.

23 I mean we have ways of quantifying
24 it, but it's very obvious to see when an animal
25 is motivated to escape or get a reward or

1 something, as opposed to having given up. So
2 those are very common things to test, when
3 testing for something like depression or drug
4 seeking, addictive, drug seeking, stuff like
5 that.

6 Q And what kind of drugs did you study
7 in your Ph.D. work?

8 A I studied a lot of different drugs,
9 including synthesizing and making my own. They
10 ranged from traditional anti-depressants, ones
11 that are on the market now, like sertraline, or
12 fluoxetine, up to more what we call fast-acting
13 anti-depressants, so things like ketamine, LSD,
14 DOI, MDMA, amphetamines.

15 Yeah and now I'm allowed to study a
16 little bit more along the opioid side of
17 things, so things like -- opioids like fentanyl
18 or morphine. And then I also study cocaine and
19 methamphetamine as well, so kind of a whole --
20 a whole array of drugs I've studied.

21 Q Okay. And you said that a lot of
22 that research is focused around addiction. Can
23 you explain how that relates to the work you're
24 currently doing at, it looks to me from your
25 CV, Stanford University; is that correct?

1 A Yeah. So I'm at Stanford
2 University. I have a couple of different
3 projects going on right here. One of them is
4 understanding the neural circuits that underly
5 fentanyl seeking and fentanyl addiction. And
6 then I'm trying to find different therapeutics
7 that may be able to counteract opioid seeking.

8 Q And, Dr. Cameron, how does addiction
9 -- how does that relate to the field of
10 neuropsychiatric disorders?

11 A So addiction is a substance use
12 disorder. So you can have opioid use disorder,
13 alcohol use disorder, et cetera. And those all
14 fall under different psychiatric conditions.

15 Q And could you explain a little bit
16 what neuropsychiatric disorders as a whole are?

17 A So they're just disorders of the
18 brain, of mental health. So if there's mental
19 health dysregulation, that's a psychiatric
20 disorder, so something like depression,
21 anxiety, post-traumatic stress disorder,
22 addiction, those types of things.

23 Q And has the research described here
24 in your CV, what kind of -- how does that
25 research relate to the study of

1 neuropsychiatric disorders as a whole?

2 A So they're all animal models of
3 things like depression or anxiety, so you can
4 test those. I don't know if you're -- if you
5 want me to like name the tests that I do here
6 in the lab. So like things like the forced swim
7 test or sucrose preference are great for
8 testing the anti-depressant effects of drugs.

9 You can look at anxiolytic effects
10 using something like the open field test or the
11 elevated plus maze. We can test post-traumatic
12 stress disorder, which is usually use a
13 paradigm called fear extinction or fear
14 conditioning. And then nowadays, I focus more
15 on addiction, so I typically use studies like
16 intravenous self-administration as well as
17 conditioned-place preference.

18 Q And outside of your work
19 specifically at Stanford, what other -- where
20 else have you studied neuropsychiatric
21 disorders?

22 A I mean, I did it for my Ph.D. at the
23 University of California-Davis. And that's
24 most of what my education is in, so.

25 Q Most of your -- just to clarify,

1 most of your education has been in
2 neuropsychiatric disorders?

3 A Yeah. I kind of specialized from
4 the beginning. So I've studied
5 neuropharmacology, neuroscience, psychiatry.
6 I've kind of bounced around between all those
7 departments and fields kind of within this
8 realm.

9 Q And of the publications listed,
10 starting on Page 3 of your CV, which of those
11 are in the field of neuropsychiatric disorders?

12 A All of them.

13 Q And that's all 14?

14 A Yes.

15 Q And that's across a wide variety of
16 various neuropsychiatric disorders?

17 A Yes. But specifically those four I
18 mentioned, so anxiety, depression, PTSD, and
19 addiction.

20 Q And on -- oh, excuse me, there's a
21 15 on the Page 4. The grants that you list on
22 Page 4 of that CV, how are those related to the
23 study of neuropsychiatric disorders?

24 A I usually write grants on whatever
25 project I'm working on at certain times. So I

1 can look at like how different drugs, or I got
2 a grant for -- for example, the metabolomics.
3 So I could basically get different drugs and
4 look how that changed the metabolism of various
5 neurons, how they changed their function after
6 use.

7 They all fund basic drug discovery
8 and/or research into neuropsychiatric
9 disorders. So you can kind of look at my work
10 from two different angles.

11 One is drug design and development,
12 and the other flip side of it is developing
13 drugs, or using drugs to understand disease
14 better. So it's both kind of like an
15 understanding of the disease, but also like
16 seeing what we can do to treat that.

17 Q And of the various awards listed
18 there on Page 4, how many of those awards are
19 for your study of neuropsychiatric disorders?

20 A All of them.

21 Q And you've got several invited
22 lectures there also on Page 4. How many of
23 those are in the field -- were discussions or
24 lectures in the field of neuropsychiatric
25 disorders?

1 A All of them.

2 MR. PHELPS: Your Honor, at this
3 time we would move to have Dr. Cameron admitted
4 as an expert in the study, or excuse me, in the
5 field of neuropsychiatric disorders.

6 JUDGE SOEFFING: Okay. Government,
7 any objection?

8 MS. KREINHEDER: Can we request one
9 moment to consult, Your Honor?

10 JUDGE SOEFFING: Certainly.

11 (Pause.)

12 MR. PHELPS: Your Honor, it's only
13 the, just out of curiosity, it's only the audio
14 that's been recorded on this, right, not the
15 video?

16 JUDGE SOEFFING: That's right.

17 MR. PHELPS: I just look incredibly
18 ghostly up there in the light on that video.
19 So just checking what the record's going to
20 reflect.

21 MS. KREINHEDER: Your Honor, the
22 Government has no objection to this witness.

23 JUDGE SOEFFING: Okay. Thank you.
24 The Petitioners have offered Dr. Cameron as an
25 expert in the field of neuropsychiatric

1 disorders. In the absence of any objection by
2 the Government, the tribunal accepts the
3 witness as an expert in the field of
4 neuropsychiatric disorders.

5 BY MR. PHELPS:

6 Q Dr. Cameron --

7 MS. KREINHEDER: Objection, Your
8 Honor. The Government would like to object to
9 this witness based on the fact that we've
10 already heard two experts and one non-expert
11 testify to essentially the same issues. Her
12 pre-hearing statement has little difference
13 from the testimony we've already heard. We'd
14 like to limit the testimony to that which is
15 not unduly repetitious.

16 JUDGE SOEFFING: Okay. And so I'll
17 overrule the objection. There's no question
18 pending at this point. We have talked
19 previously about limiting repetitious
20 testimony.

21 I assume she's going to be talking
22 about things that are different and her work
23 and how the potential scheduling of these
24 substances could affect her work.

25 To the extent that she's testifying

1 as to the same matters as other witnesses, I
2 may, you know, sustain a future objection based
3 on repetition.

4 MR. PHELPS: Understood, Your Honor,
5 we agree. We do believe that Dr. Cameron is
6 going to be providing unique insight that's
7 sufficiently different from the others with,
8 point out just specifically in the pre-hearing
9 statement, the second to last paragraph on Page
10 14, that she'll be testifying about the abuse
11 potential of DOI, which is specifically listed
12 in the -- as part of the factors, so just
13 wanted to bring that up.

14 JUDGE SOEFFING: Okay. Okay, I
15 appreciate your tailoring your questions to
16 elicit new testimony.

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

19 JUDGE SOEFFING: Thank you.

20 BY MR. PHELPS:

21 Q So Dr. Cameron, could you talk a
22 little bit other labs you've collaborated with
23 to investigate psychedelic action?

24 A Yes. So I did my Ph.D. at UC-Davis,
25 in the lab of David Olson, who is kind of a

1 pioneer in terms of both novel drug design as
2 well as test -- like using drugs or chemicals
3 as tools to investigate neuropsychiatric
4 disorders.

5 I've collaborated with people like
6 Dr. John Gray, where we can look at like how
7 drugs change the excitability of cells,
8 Jennifer Whistler, Diasynou Fioravante, Anna La
9 Torre, to name a couple.

10 The lab of Jamie Peters was really
11 integral for testing the addictive properties
12 during my Ph.D. and used, well, for examining
13 the changes in cortical structure after drug
14 administration.

15 Now I'm in the lab of Dr. Rob
16 Malenka and Karl Deisseroth. So Karl
17 Deisseroth is a pioneer in the field of
18 neuroscience. And Rob Malenka is one of the
19 founders for discovering synaptic plasticity or
20 how the brain changes specifically with regards
21 to addiction. So those are kind of the labs
22 that I've worked within.

23 Q And what is -- can you talk about
24 specifically research involving the field of
25 phenethylamines in your research?

1 A Yeah. So phenethylamines are a type
2 of drug, they're a type of psychedelic, that
3 have been used. I tested them a lot, mostly
4 phenethylamines I tested in vitro a lot.

5 So you can see that they cause
6 neural growth and spine growth in cortical
7 neurons, which is suggestive of therapeutic
8 potential actually, rather than anything else.
9 And some of my lab back at UC-Davis, both with
10 me and kind of as my colleagues have looked
11 into -- almost like anti-depressant effects of
12 these compounds.

13 Q Okay. And DOI and DOC fall into
14 that class of phenethylamines?

15 A Yes. I've specifically worked with
16 DOI, I have not worked with DOC. But due to
17 its like chemical structure, I would assume it
18 has very similar effects. They're all kind of
19 in the same class.

20 Q And can you explain, well I guess,
21 can you explain how you evaluate the safety
22 profile of a drug in general, not specific to
23 these substances? But what does it mean to
24 evaluate a drug safety profile?

25 A Yeah. So you can different doses

1 and you can see at what an animal starts not
2 behaving well. Some things you can look at are
3 its locomotion ability, it's like, cardiac
4 effects. You can look at neurotoxicity. Some
5 assays you can run in lab would be like an MTT
6 Assay would be a great example.

7 I, in my Ph.D., I was specifically
8 looking about something that probably had --
9 would have heart side effects by interacting
10 with something called a hERG channel.

11 So what you can do is you can patch,
12 and you can see if that channel is affected by
13 these drugs or not. There's a whole bunch of
14 different assays you can do with that safety
15 profile.

16 Q Okay. And just to take it -- all
17 right. Just to take a step back, what exactly
18 do you mean by the safety profile of a drug?

19 A Usually like, is it -- is it safe,
20 does it cause toxicity in any way or long
21 lasting adverse effects. But also you
22 typically want something to be non-addictive or
23 non-habit forming.

24 Q Is that related to -- how does
25 evaluating a drug's safety profile relate to a

1 harm/benefit kind of analysis?

2 A Well, so you -- you want it to have
3 more benefits, so whether that be anti-
4 depressant effects, or effects for treating
5 PTSD, or effects for anti-addictive effects.
6 So you want to have your benefits outweigh your
7 costs.

8 So you want to have minimal
9 toxicity, minimal abuse or dependence
10 potential. And you want that to be, you know,
11 heavily skewed in the benefits side of things.

12 Q And we've already heard a good bit
13 of the basic chemistry of how DOI and its
14 significant selectivity to the 5-HT2A
15 receptors. So you don't need to get into that
16 specifically, but could you -- or in general
17 how it works, but could you explain
18 specifically how that significant selectivity
19 is important in understanding mental health and
20 neuropsychiatric disorders?

21 A Absolutely. So every single cell in
22 the brain has serotonin receptors. There are
23 14 different receptors, and the serotonin 2A
24 receptor is the most heavily expressed
25 receptor. So it's more common than every other

1 serotonin receptor in the brain.

2 It's heavily expressed in the
3 prefrontal cortex, which is the front part of
4 your brain that is responsible for things like
5 motivation or planning or achieving your goals.
6 You can imagine that your prefrontal cortex is
7 a part of your brain which is heavily affected
8 in neuropsychiatric disorders.

9 So things like depression, anxiety,
10 PTSD, and addiction, you actually have
11 dysfunction of the prefrontal cortex. And so
12 activating the prefrontal cortex is often seen
13 as a good way to help patients with these
14 disorders.

15 So the brain has serotonin receptors
16 everywhere and serotonin's 2A receptor is an
17 incredibly important receptor because it is so
18 heavily expressed, it's the most heavily
19 expressed. And so -- and it is a key receptor
20 in the involvement of developing anti-
21 depressant compounds.

22 Q And based on your own work using DOI
23 and your review of other literature about DOI,
24 how would you describe that specific drug's
25 safety profile?

1 A Quite safe. I have looked at it in
2 the context of neurons on dishes and looking at
3 the effects of basically treating animals and
4 then looking at their brains afterwards. And
5 what you see is it actually has beneficial
6 effects.

7 So it causes these -- growth of
8 these cortical neurons, it causes increased
9 dendritogenesis, spinogenesis, synaptogenesis,
10 as compared to other fast acting anti-
11 depressants. So they actually tend to show
12 therapeutic properties more so than anything
13 else.

14 In other literature, people have
15 shown that it seems to be quite anxiolytic, so
16 it calms animals down. And it seems to be
17 actually useful for treating addiction,
18 possibly, in that it can reverse or block a
19 preference for drug seeking of hedonic drugs,
20 like alcohol or opioids.

21 Q How does a drug's safety profile
22 relate to its abuse potential?

23 A So you want it to have low
24 dependence on what would make it safe, right.
25 So it's not a hedonic drug seeking like

1 something like fentanyl or morphine or heroin
2 or cocaine or methamphetamine.

3 So you would want to have, you know,
4 part of the safety profile would be not causing
5 this physical and/or mental dependence on these
6 drugs. And so, but that's what you would want.

7 In the case of DOI, we actually
8 worked through that, so primates who are given
9 access to DOI, do not self-administer. And
10 self-administration is probably the absolute
11 best study we could do with regards to studying
12 addiction.

13 So the fact that primates don't
14 self-administer DOI would suggest that there's
15 not really an abuse liability there.

16 JUDGE SOEFFING: Okay. Before you
17 ask your next question, Mr. Phelps, again, Dr.
18 Cameron, if you could just please slow down a
19 little bit, it would assist the court reporter
20 --

21 THE WITNESS: Yes, sorry.

22 JUDGE SOEFFING: -- and capture your
23 testimony. That's all right. Just a reminder
24 to try to speak a little more slowly. Thank
25 you. You may ask your next question, Mr.

1 Phelps.

2 THE WITNESS: Okay. Sorry. Thank
3 you.

4 MR. PHELPS: Thank you, Your Honor.

5 BY MR. PHELPS:

6 Q And based on -- based on your own
7 research using DOI and other research that
8 you've studied or are familiar with, what kind
9 of evidence have you seen for DOI's abuse
10 potential?

11 A Out of personal experience?

12 Q Well, as an expert in the field
13 who's studied, not only your own studies, but
14 other studies that you're familiar with, what
15 evidence have you seen across those for DOI's
16 abuse potential?

17 A Yes. So I have not seen basically
18 anything. I'm in a lab here that studies
19 methamphetamine, cocaine, opioids, and there's
20 not really a comparison at all. If anything,
21 DOI actually has an ability to be anti-
22 addictive, as I mentioned before. So it can
23 actually reverse drug seeking of other drugs.

24 I think that the most key evidence
25 is something that I also just -- just mentioned

1 is that animals don't seek this. They're not
2 motivated to go and seek this again, you know.
3 It's not addictive in that they return and try
4 to find more of it.

5 Q And for the -- can you sort of --
6 can you compare the abuse liability between DOI
7 and alcohol?

8 A That study, to my knowledge, has not
9 been like directly tested. There is a study
10 that said that it could probably be reduce
11 alcohol seeking.

12 MS. KREINHEDER: Objection, Your
13 Honor.

14 JUDGE SOEFFING: Yes?

15 MS. KREINHEDER: She's not answering
16 the question that was asked.

17 THE WITNESS: I don't really -
18 (Simultaneous speaking.)

19 MR. PHELPS: I can rephrase.

20 JUDGE SOEFFING: Hold on. Hold on
21 Doctor. Sustained. I will allow you to re-ask
22 your question.

23 MR. PHELPS: Thank you, Your Honor.

24 BY MR. PHELPS:

25 Q So you're familiar with the -- well,

1 let me just clarify. What's the difference
2 between abuse potential and abuse liability, if
3 there is any?

4 A I mean, abuse potential is how
5 rewarding a drug is and does it cause physical
6 and mental dependence, right. So does an
7 animal or a human go and seek it willingly?

8 And often, what we say in addiction,
9 is that it's not just a positive thing, but it
10 doesn't come to the detriment of, you know,
11 your job or your family or your income.

12 So are you willing to undergo these
13 kind of negative things because you need that
14 drug so much, right. So that's what I would
15 describe as abuse potential, is that -- that
16 seeking and that drive and that motivation to
17 get the drug.

18 Abuse liability, that sounds more
19 like a legal term to me, so I'm going to kind
20 of step back from that one. But it sounds like
21 how much could this, you know, impair. And I
22 think it's intricately tied with the abuse
23 potential.

24 So if there's low abuse potential, I
25 would guess that there's low abuse liability.

1 But liability is like a legal word, it's not a
2 scientific word, per se, so, just.

3 Q And you're familiar with the abuse
4 potential or abuse liability of other drugs
5 besides DOI?

6 A Yes.

7 Q And can you compare the abuse
8 liability of DOI to other more widely available
9 or used substances such as alcohol?

10 A I -- yeah. So there haven't been
11 animal studies that have tested this directly.
12 Because typically DOI is not considered an
13 addictive drug, so it's not even studied as
14 much in this realm. If anything, it's the
15 anti-addictive effects that are studied, not
16 the addictive effects.

17 Q Okay. So not speaking specifically
18 about direct comparison studies, but you're
19 familiar with other studies and of studies
20 specifically about the abuse potential to other
21 drugs, right?

22 A Yeah.

23 Q Okay.

24 MS. KREINHEDER: Objection, Your
25 Honor.

1 JUDGE SOEFFING: Yes?

2 MS. KREINHEDER: This question's
3 been asked and answered.

4 JUDGE SOEFFING: Well, he's asked it
5 regarding alcohol, but he seems to be
6 broadening the question to other drugs?

7 MR. PHELPS: Yeah. I think she
8 still was maybe misunderstanding the question.
9 And then I just was asking specifically --

10 JUDGE SOEFFING: I'll overrule the
11 objection. Go ahead and rephrase.

12 MR. PHELPS: Okay. Thank you.

13 BY MR. PHELPS:

14 Q Could you describe the abuse
15 potential of alcohol in --

16 A Generally?

17 Q Yes.

18 A Yeah. So animals will seek alcohol
19 if you give them access to water or alcohol.
20 They will start drinking alcohol and they will
21 drink it. They will develop a preference for
22 alcohol over water.

23 They can develop preferences for
24 even locations for where they drink alcohol,
25 they'll continue to go back to those same

1 places. This is seen in humans as well. And I
2 think you were trying to ask about other drugs
3 as well.

4 This is seen as well, so things like
5 methamphetamine or cocaine or opioids, animals
6 will self-administer these drugs. They will
7 return back to those -- those same places.
8 They quickly develop a dependence, so usually
9 it takes a little while for them to learn.

10 They're not like humans where you
11 can say here, try this drug, right. So animals
12 will have to press a lever or find a drug or
13 something and take it. And they quickly learn
14 that it makes them feel good and so they return
15 back to those same places and seek those drugs
16 again. So this is done with alcohol and other
17 addictive drugs.

18 And that's very well known, it's
19 like a hallmark of addiction research. Sorry,
20 that was really fast, I can rephrase that
21 slower if you need me to.

22 JUDGE SOEFFING: That's fine.
23 That's fine, Doctor.

24 THE WITNESS: Okay.

25 BY MR. PHELPS:

1 Q So across those, if -- and I want to
2 be clear here, right, your -- in your
3 understanding across the literature and across
4 various substances in evaluating their abuse
5 potential, if you were ranking the abuse
6 potentials of some of the drugs you described
7 from highest to lowest, where would DOI fall in
8 that ranking?

9 MS. KREINHEDER: Objection, Your
10 Honor.

11 THE WITNESS: At the bottom.

12 JUDGE SOEFFING: Yes? Hold on.

13 MS. KREINHEDER: This question asks
14 for an answer that's outside of her expertise,
15 she's not an expert in pharmacology.

16 THE WITNESS: I have a degree in
17 pharmacology.

18 JUDGE SOEFFING: Hold on -- hold on,
19 it's just the attorney's discussion for right
20 now.

21 MR. PHELPS: So similar to
22 liability, expert or expertise is a particular
23 legal term of our --

24 JUDGE SOEFFING: You're, you know,
25 you're trusting me, so, you know, I think that

1 this is getting outside of the scope of the
2 pre-hearing statement, too.

3 And she was going to testify about
4 evidence of abuse potential but now we're
5 getting into comparisons and other things which
6 seem to be -- she's not offered as a substance
7 abuse expert or anything as some of the other
8 witnesses were.

9 MR. PHELPS: And Your Honor, I would
10 say that substance abuse falls within the field
11 of neuropsychiatric disorders, that's what
12 she's testified to, that's what she's an expert
13 in. And substance abuse is certainly -- that's
14 within that field of expertise.

15 JUDGE SOEFFING: Well, I'll allow
16 her to answer this question then I think you
17 need to move on from there.

18 MR. PHELPS: Okay.

19 JUDGE SOEFFING: So I'll overrule
20 the objection, but that will end this line of
21 questioning.

22 MR. PHELPS: Okay.

23 JUDGE SOEFFING: Do you recall the
24 question, Doctor?

25 BY MR. PHELPS:

1 Q Do you need me to repeat the
2 question?

3 A Was it about the ranking?

4 Q Yes, ma'am.

5 A Yeah. So DOI would be at the
6 bottom, absolutely. Something like opioids
7 would be way at the top, with meth and probably
8 alcohol somewhere in there.

9 Q Okay. Thank you. In your
10 professional experience, how familiar are you
11 with drug discrimination studies?

12 A I am familiar with them, yes.

13 Q Okay. And in your particular
14 research, and the research that you are
15 familiar with, how is drug discrimination used
16 to study abuse potential?

17 A It's not.

18 Q Can you explain that?

19 A Yes. So drug discrimination is used
20 to compare how similar two drugs are. So for
21 example, do I need to explain how the assay
22 works, just -- just, you know, so you know?

23 Q No. We've -- I think we've had --

24 MR. PHELPS: Your Honor, just to
25 clarify, I don't want to leave anything out.

1 We've had sufficient discussion about drug
2 discrimination studies as the assays' work?

3 JUDGE SOEFFING: I think that's been
4 covered, yes.

5 MR. PHELPS: Okay.

6 THE WITNESS: Okay. Great. So the
7 idea is that an animal will press a lever if it
8 finds the test drug, for example, DOI.

9 MS. KREINHEDER: Objection, Your
10 Honor.

11 JUDGE SOEFFING: Yes, Ms.
12 Kreinheder?

13 MS. KREINHEDER: This is outside the
14 scope of the pre-hearing statement. She did
15 not discuss drug discrimination in the pre-
16 hearing statement.

17 MR. PHELPS: As an expert in this
18 field, she's certainly able to discuss the use
19 of particular tests to measure the area of her
20 expertise and what's studied there.

21 She can offer an expert opinion
22 about the use of drug discrimination studies
23 compared to other studies that she does to do
24 the research that she does.

25 JUDGE SOEFFING: Well, I think she's

1 already testified to that and she says it's not
2 used to study addiction.

3 MR. PHELPS: Yes. And I was just
4 asking her to explain why not. I think that's
5 an extremely relevant question considering the
6 seemingly entire bulk of the Government's case
7 or that the heart of the Government's case is
8 that drug discrimination studies are the,
9 quote, gold standard for measuring abuse
10 liability.

11 And she's given expert opinion in
12 direct contradiction of the Government's claim
13 so it's certainly relevant and should be
14 considered with significant weight to this
15 Court if an expert in this field is saying that
16 those studies are not used to her knowledge to
17 study this kind of thing.

18 JUDGE SOEFFING: Ms. Kreinheder?

19 MS. KREINHEDER: Your Honor. They -
20 - there was two words they could have put in to
21 the pre-hearing statement, drug discrimination.
22 And we've heard the same testimony from other
23 witnesses prior to this about what drug
24 discrimination is and why it's important or not
25 important.

1 JUDGE SOEFFING: So Mr. Phelps, I
2 will allow you to ask the question and move on.
3 But that's -- I do not think there was
4 disclosure of this in the pre-hearing
5 statement. You talked about areas to be
6 covered.

7 And this is one of the things, why
8 it's important to be specific in the pre-
9 hearing statements. I will allow you to ask
10 this question, but we have heard a lot about
11 drug discrimination, so I'd ask you to move on,
12 okay.

13 So I'll overrule the objection, but
14 we're not going to hear more going down this
15 same path.

16 BY MR. PHELPS:

17 Q Dr. Cameron, in your expertise, can
18 you explain why?

19 A Yeah. So drug discrimination
20 basically tests how similar two drugs are. And
21 that can be, you know, this -- and it's a rat,
22 so you can't ask them what they are
23 experiencing. So they can have a stomachache
24 and press the lever that gives them a
25 stomachache, it does not mean that it gives

1 them abuse potential or anything.

2 It just tests how similar the
3 experience of the drug is. And so -- and so,
4 in the case of trying to see if something is
5 addictive or not, it would make more sense to
6 compare it against something that is highly
7 addictive.

8 So if someone were to show me that
9 DOI was used in drug discrimination with
10 fentanyl and they fully substitute it, then
11 that has a huge abuse liability. Those studies
12 have not been done at all.

13 So drug discrimination is not a good
14 measure at all. In fact, it's incredibly old
15 and no one in the field of addiction uses drug
16 discrimination anymore. And in fact, NIDA,
17 which is the National Institute of Drug Abuse,
18 has said that the gold standard for studying
19 addiction is self-administration.

20 And they're -- they're basically
21 like not funding grants unless they involve
22 self-administration. Drug discrimination is --
23 is -- it just tests how similar two drugs are.
24 It says literally nothing about abuse
25 potential, there are different types of tests

1 you would want to do if you want to study abuse
2 potential.

3 Q Thank you. Just one last question
4 along this line. In your expert opinion, what
5 do you think about the statement that drug
6 discrimination studies are the gold standard
7 for studying addiction?

8 A I very much disagree with that
9 statement.

10 MS. KREINHEDER: Objection, Your
11 Honor.

12 JUDGE SOEFFING: Well --

13 THE WITNESS: It is absolutely not
14 used.

15 JUDGE SOEFFING: Overruled.

16 THE WITNESS: It's used in drug
17 discovery.

18 JUDGE SOEFFING: That's all for drug
19 discrimination.

20 MR. PHELPS: Absolutely, Your Honor.

21 BY MR. PHELPS:

22 Q Could you just describe generally
23 about what you've been finding about how DOI is
24 related to addiction?

25 A Yeah. So I mean, I'm not -- I study

1 things like fentanyl now. DOI, the studies
2 that I would want seen are self-administration,
3 which are -- which has been done in primates,
4 and animals do not self-administer, which would
5 be the key finding. It's even better than that
6 if it's done in primates. So if animals are
7 not self-administering this, that would be key.

8 Q And specifically you, I guess, let
9 me clarify that a little bit. Can you just
10 talk kind of in broad terms about what your
11 research has shown about the anti-addictive
12 properties of DOI?

13 A Yeah. So some -- there are several
14 studies that show that you can reverse the
15 rewarding effects or the rewarding memory of
16 things like alcohol or opioids.

17 My research specifically, has looked
18 on these effects on the prefrontal cortex. And
19 so it looks like you can, you know, cause parts
20 of that brain region to strengthen. And that
21 is known to override drug seeking.

22 So that's kind of the premise of a
23 lot of our studies actually, is to strengthen
24 this part of the brain which reduces drug
25 seeking. And it does do that, it increases

1 their function, it increases their growth in
2 key regions of the brain.

3 Q And in your expertise and opinion,
4 how could you see that research being applied
5 to human or clinical research?

6 A So I -- it is being applied in other
7 ways --

8 MS. KREINHEDER: Objection, Your
9 Honor.

10 THE WITNESS: To reduce alcohol --

11 JUDGE SOEFFING: Hold on a second.
12 Yes?

13 MS. KREINHEDER: This is also not
14 within her expertise, she is an expert in
15 neuropsychiatric disorders, not drug research.

16 MR. PHELPS: Can they clarify what
17 they mean, that she's not an expert in
18 research?

19 MS. KREINHEDER: She's qualified as
20 an expert in neuropsychiatric disorders
21 specifically --

22 THE WITNESS: My job title is
23 literally --

24 JUDGE SOEFFING: Hold on, Doctor.
25 This is a discussion between the attorneys,

1 sorry.

2 MS. KREINHEDER: She's giving her
3 opinion.

4 JUDGE SOEFFING: Well, she's opining
5 on where the research may lead, as I understand
6 the question, right?

7 MR. PHELPS: That's correct, Your
8 Honor.

9 JUDGE SOEFFING: I'm going to
10 overrule the objection. I will allow for her
11 to answer.

12 BY MR. PHELPS:

13 Q So in your expert opinion, where did
14 you foresee -- well, actually just to be clear,
15 your expertise in neuropsychiatric disorders,
16 is that in neuropsychiatric disorders of -- or
17 I guess -- we can skip that.

18 In your expert opinion, if this
19 research were to continue, how could you
20 potentially see it being applied in human or
21 clinical research?

22 A Yes. So the serotonin 2A receptor
23 is -- is a key receptor that will likely play a
24 role in most anti-addictive pursuits like at
25 this time. So there are clinical trials.

1 I'm not sure if there's any with DOI
2 specifically, but there's other 2A agonists
3 that are being investigated for anti-addictive
4 effects for alcohol and for opioids in multiple
5 different countries, so both the U.S. and
6 Canada, and I believe the U.K. as well.

7 So 2A agonists are a very hot topic
8 for trying to -- to treat these disorders. And
9 DOI is very useful because it's one of the most
10 specific 2A agonists, more so than the ones
11 that are being studied right now.

12 So it has the potential to be even
13 more epic. It needs to be studied, but that's
14 kind of where the research is heading.

15 Q And in your expert opinion, is that
16 research that you could see yourself possibly
17 potentially studying one day?

18 A Absolutely.

19 MS. KREINHEDER: Objection, Your
20 Honor. This is irrelevant testimony.

21 JUDGE SOEFFING: So we are veering a
22 little bit off course here. I see the final
23 paragraph in the pre-hearing statement is
24 talking about barriers for researchers.

25 MR. PHELPS: That was going to be

1 next --

2 JUDGE SOEFFING: Trying to relate
3 it, but okay.

4 MR. PHELPS: Yeah, that's exactly
5 where I was going, Your Honor.

6 JUDGE SOEFFING: I'll overrule the
7 objection while you move on.

8 MR. PHELPS: Thank you.

9 BY MR. PHELPS:

10 Q So, Dr. Cameron, can you explain how
11 placing DOI and DOC into Schedule I would
12 affect this potentially groundbreaking research
13 that you're finding right now?

14 A Yeah. So as I've mentioned, I
15 mentioned multiples times, I actually think it
16 has therapeutic effects, more so than any type
17 of addictive or liability effects. A lot of
18 research still needs to be done.

19 It would affect researchers like me
20 if, like it takes years to get a DEA license
21 and start up a lab. And to be able to study
22 one of these things. It would impact those --

23 MS. KREINHEDER: Objection, Your
24 Honor.

25 JUDGE SOEFFING: Hold on.

1 THE WITNESS: Okay.

2 JUDGE SOEFFING: All right. Hold on
3 a sec. What's the?

4 MS. KREINHEDER: She's speculating
5 on the future of the science.

6 JUDGE SOEFFING: Well, I'll allow
7 you to examine that on your cross. Okay.
8 Overruled. You may complete your answer.

9 THE WITNESS: Okay. It was -- it
10 would affect research groups like on an
11 individual level, but also, impair the field
12 from moving forward. There is potential to use
13 this and I just think that adding barriers
14 would -- would greatly inhibit the progress of
15 this field.

16 And then, kind of in those same
17 lines, but just to zoom out a little bit, like
18 I said, every neuron in the brain has serotonin
19 receptors.

20 The serotonin 2A receptor is the
21 most heavily expressed of it and this is one of
22 the best tools we have to just study basic
23 receptor function.

24 It is one of the most specific
25 agonists, 2A, that we have. And by blocking

1 access to it, you're -- it -- it would
2 significantly restrict any sort of progress
3 with regards to any type of serotonin research,
4 let alone just neuropsychiatric disorders.

5 BY MR. PHELPS:

6 Q And just one last question on this,
7 I think. In your expert opinion, how could the
8 impairment of this research potentially affect
9 public health?

10 A So I -- I do think that -- so one
11 thing that I think is like a huge issue right
12 now is the opioid crisis, right, fentanyl use
13 across the U.S. Something like this is -- is
14 huge and very pressing and all over the news.

15 It costs billions of dollars for
16 the -- the government, right. It -- it affects
17 millions of people across the country and other
18 countries. And something like DOI, which might
19 have the potential for -- for counteracting
20 that or giving these patients help.

21 Or even if you want to look at it
22 from financial, like reducing the amount of
23 money that the government funnels into opioid
24 abuse, this -- this has a potential.

25 And even if it's just to understand

1 the role of the serotonin to a receptor in
2 combatting opioid or addictive use. It -- it
3 would have significant effects.

4 MR. PHELPS: Thank you. If I could
5 just confer briefly? No further witness -- no
6 further questions for this witness, Your Honor.
7 Thank you.

8 JUDGE SOEFFING: Thank you, Mr.
9 Phelps. Ms. Kreinheder would you like to
10 conduct cross-examination?

11 MS. KREINHEDER: Yes. But I request
12 a moment with my colleagues?

13 JUDGE SOEFFING: Yes.

14 MS. KREINHEDER: It's getting close
15 to 10:30, should we take a break?

16 JUDGE SOEFFING: Would you like to
17 break at this point?

18 MS. KREINHEDER: Yes.

19 JUDGE SOEFFING: Okay. We'll take
20 morning break for 15 minutes.

21 MR. PHELPS: Great, so Dr. Cameron -
22 -

23 JUDGE SOEFFING: We're off the
24 record.

25 (Whereupon, the foregoing matter

1 went off the record at 10:26 a.m. and went back
2 on the record at 10:52 a.m.)

3 JUDGE SOEFFING: Okay. We are back
4 on the record. Dr. Cameron, you hear me all
5 right? Good. All right. I remind you are
6 still under oath. And Ms. Kreinheder, you may
7 conduct your cross-examination.

8 MS. KREINHEDER: Thank you.

9 CROSS-EXAMINATION

10 BY MS. KREINHEDER:

11 Q Good morning, Dr. Cameron.

12 A Good morning.

13 Q Have you conducted self-
14 administration tests using LSD?

15 A No.

16 Q Have you conducted self-
17 administration tests with psilocybin?

18 A No.

19 Q What about DOM?

20 A No.

21 Q You said that --

22 A The tests have been done before,
23 they're known in the literature. Part of the
24 reason of me not testing them, is because
25 they've been done already. So I don't -- I

1 don't know if you want me to comment on that or
2 not, but yes, I have not personally done them.

3 Q So you've read research about this
4 topic?

5 A Yes.

6 Q Did you bring any of this research
7 today?

8 A Yeah. It's like on my computer.

9 Q But you haven't presented it to the
10 Court?

11 A Do you -- is this about LSD and
12 psilocybin?

13 JUDGE SOEFFING: Just -- just answer
14 the question, Dr. Cameron, I'm sorry.

15 THE WITNESS: Sorry, I don't know
16 what you mean by bring it to the Court. I have
17 it on my laptop and I can speak about it as an
18 expert. I don't know what you mean by bring it
19 to the Court.

20 BY MS. KREINHEDER:

21 Q It is just a simple question, yes or
22 no? I'll move on. You also said that DOI and
23 DOC are similar?

24 A Yes.

25 Q Do DOM or DOB have the same or

1 similar degree of selectivity of activating the
2 same serotonin receptors?

3 A They're similar.

4 Q Did you say that DOI is being
5 investigated in the U.K. or Canada during your
6 testimony?

7 A I said that serotonin 2A drugs are
8 being investigated. I don't know about DOI
9 specifically.

10 Q Okay. Thank you. You also said
11 that DOI has a lower abuse potential than
12 alcohol; is that correct?

13 A It hasn't been tested directly, but
14 it has been tested to reduce alcohol abuse.

15 Q My question was, did you say that
16 DOI has a lower abuse potential than alcohol,
17 yes or no?

18 A It likely does, but it hasn't been
19 tested directly --

20 Q Did you also say that it has a lower
21 abuse potential than opioids?

22 A Yes. I mean again, it hasn't been
23 tested side-by-side directly, but it very
24 likely would.

25 Q In your opinion, are there any harms

1 related to DOI?

2 A Not significant, they need to be
3 investigated as development.

4 Q So you feel more comfortable giving
5 DOI to someone over a glass of wine?

6 A I'm not saying that.

7 Q Do you feel that there are any harms
8 related to psilocybin?

9 A I think there is significant fewer
10 harms of psilocybin.

11 Q Fewer harms than what?

12 A Sorry, can you repeat the question?

13 Q Do you feel that there are any harms
14 related to psilocybin?

15 A There's not many. I think that
16 they're generally quite safe as a drug.

17 Q Do you feel that there are any --

18 A If -- okay.

19 Q Go ahead.

20 JUDGE SOEFFING: You can complete
21 your answer.

22 THE WITNESS: Within an -- sorry.
23 There's not a lot of issues with psilocybin.
24 As a drug, it has a pretty good safety profile,
25 but should be administered with the right care

1 and under the right conditions.

2 BY MS. KREINHEDER:

3 Q Do you feel that there are any harms
4 related to LSD? And this is just a yes or no
5 question.

6 A It's a pretty safe drug.

7 Q You have not done any research into
8 -- I'm sorry. You have not done any surveys of
9 the entire community that researches the DOI;
10 is that correct?

11 A I don't understand the question. Do
12 you mean the entire community of humans who use
13 it, do you mean the entire scientific
14 community?

15 Q I will repeat the question. Have
16 you done a survey of the entire community that
17 researches DOI?

18 A I speak with a lot of these, and a
19 lot of them are my colleagues.

20 Q Did you say that it takes several
21 years to get a Schedule I and researcher
22 registration from the DEA?

23 A Yeah. It usually takes a very long
24 time.

25 Q Who did you speak with at the DEA

1 about this topic?

2 A I've applied for licenses under my
3 PI's here at Stanford. I've done the paperwork
4 and submitted it with them.

5 Q You applied for a DEA Schedule I
6 researcher registration?

7 A No. The professors that I work with
8 have a Schedule I license, and I worked with
9 them so that I understood the process for when
10 I do it myself. So I am aware of all the steps
11 that are taken and how long that takes.

12 Q And it's your testimony that an
13 application with the DEA would take several
14 years to be granted?

15 A Between the -- between starting it
16 at an institutional level to get a state
17 approval to getting FDA and DEA approval to
18 finally obtaining the drug can take -- I
19 haven't seen it done in less than a year, ever.

20 Q Did you work in a lab with a PI who
21 had a Schedule I researcher registration during
22 your graduate studies?

23 A Yes.

24 Q And who was that?

25 A Dr. David Olson, University of

1 California-Davis.

2 Q Just one second. Have you spoken to
3 anyone at DEA specifically about applying for a
4 DEA registration?

5 A No. It's usually done through our
6 admin.

7 MS. KREINHEDER: Okay. No further
8 questions.

9 JUDGE SOEFFING: Thank you, Ms.
10 Kreinheder. Mr. Phelps, would you like to
11 conduct redirect?

12 MR. PHELPS: Yes, Your Honor.

13 REDIRECT EXAMINATION

14 BY MR. PHELPS:

15 Q Dr. Cameron, I would just like to go
16 back over with you for a little clarification
17 about some of the things that the Government's
18 attorney was just questioning you about.

19 So while you haven't personally
20 conducted self-administration studies of LSD,
21 psilocybin, or DOM, are you aware if those
22 studies have been done?

23 A Yes. They have been done, and
24 animals do not self-administer them. They are
25 not typically -- animals do not seek them out,

1 they do not self-administer, there's no
2 motivation or any sign of hedonic drug use or
3 compulsive drug seeking. I'm not as -- full
4 disclosure, I'm not as well-versed in DOM, but
5 I can say that with certainty for LSD and
6 psilocybin.

7 Q And throughout your professional
8 experience, how thoroughly would you say you've
9 reviewed the literature regarding self-
10 administration studies of those drugs you were
11 describing?

12 A I feel like I've researched the
13 literature quite a bit. It was involved in my
14 Ph.D. dissertation, and it is pertinent to the
15 studies that I do now, which involve a lot of
16 things like self-administration assays.

17 So I've -- I've written grants on
18 it. I have bits and pieces of papers that are
19 within different papers or reviews, that I've
20 written about it as well.

21 Q And you did testify that there's
22 similarities between DOI and DOC, right?

23 A Yes. So chemically, they're very
24 similar compounds as they have a similar --
25 similar safety profile, similar receptor

1 pharmacology in terms of like which receptors
2 they target on. So generally they're --
3 they're quite similar.

4 Q And how does the pharmacology of DOI
5 and DOC compare to the pharmacology of these
6 other drugs, LSD in particular?

7 A So they all hit the serotonin 2A
8 receptor, which is again, that receptor that
9 I've been talking about that likely has very
10 high therapeutic potential. So they all kind
11 of interact with that receptor, yeah.

12 Q Okay. And in your experience
13 studying these various drugs and -- let me
14 think how I want to phrase this. How does LSD
15 interact with these brain targets, serotonin or
16 others, compared to DOI?

17 A So DOI would probably be more
18 selective and hit the serotonin 2A receptor.
19 As I've mentioned a number of times, it's one
20 of the most selective drugs that we have.

21 LSD does interact with the serotonin
22 2A receptor pretty potently, but it also hits a
23 plethora of other receptors as well. So it's
24 not as clean a drug, I would say.

25 Q Okay. And what does the

1 similarities in pharmacological profiles of
2 drugs tell you about how --

3 MR. PHELPS: I'm sorry, Your Honor,
4 I just have to say, I'm in the middle of
5 questioning and being distracted by the
6 comments coming over here from opposing
7 counsel, so I just need to collect my thoughts
8 for a moment.

9 JUDGE SOEFFING: Okay. Take your
10 time, Mr. Phelps. Ask to keep the whispering
11 to a minimum and to use note cards or
12 something, if possible, to keep the noise level
13 down.

14 MR. PHELPS: Thank you.

15 BY MR. PHELPS:

16 Q Dr. Cameron, what do similarities in
17 pharmacological profiles of drugs tell you
18 about similarities or differences of other
19 elements of those drugs?

20 MS. KREINHEDER: Objection, Your
21 Honor. This is outside the scope of my
22 cross-examination.

23 MR. PHELPS: She was specifically
24 questioning about similarities and differences
25 between these other drugs and there was -- this

1 is totally in line with her questioning.

2 JUDGE SOEFFING: Overruled.

3 BY MR. PHELPS:

4 Q Do you need me to repeat the
5 question?

6 A So can I answer it?

7 Q Oh, yes.

8 JUDGE SOEFFING: Yes, you may
9 answer.

10 THE WITNESS: So usually when you
11 have a drug with a molecular structure, if the
12 molecular structures have the same core
13 structure, they're going to have similar core
14 action.

15 So I think maybe what you're getting
16 at is the similarities between DOI and DOM
17 which is, like if we know things about DOI, a
18 lot of what we can know can be extrapolated to
19 DOM. And -- and this can be done for any type
20 of plastic drug, right. So there's like
21 classes of, for example, barbiturates, right.

22 There are different types of them
23 and they all have similar chemical structures
24 and they do similar things. The same with
25 SSRIs or whatever. So in the case of DOI, DOM,

1 DOB, DOC, whatever, they all have kind of a
2 similar core structure, which is targeting
3 serotonin 2A receptor which you've asked me
4 about before and they do similar things and
5 have similar safety profiles.

6 They do have tweaks, they aren't
7 exactly the same. But it is a class of drugs
8 that generally have a lot of similarities and
9 cross over.

10 Q So how does small differences in the
11 chemical structures of these compounds lead to
12 changes in their behavioral effects?

13 A You can modify chemical structures
14 to -- to see which modifications, which part of
15 the molecule does what. And you could do that
16 -- that's what I did for my Ph.D., is I made
17 different variations of drugs.

18 And you can test to see what drug
19 does that, and how does changing it change the
20 molecule. So you could, in theory, do the same
21 thing with DOI and the related compounds. Not
22 totally sure if that's what's the answer.

23 Q You said that there haven't been
24 side-by-side comparisons in direct testing
25 regarding abuse potential of alcohol and DOI

1 and other drugs and DOI. In your expert
2 opinion, why do you think that is?

3 A Because DOI's not typically
4 considered an addictive drug.

5 Q And --

6 A Animals don't self-administer it, so
7 we don't study it as if it were an addictive
8 drug.

9 Q And when you're going for grant
10 funding for these type of things, how do you
11 think a grant proposal of an assay directly
12 comparing alcohol and DOI would be received?

13 MS. KREINHEDER: Objection, Your
14 Honor. This is outside the scope of cross.

15 JUDGE SOEFFING: Yes, sustained.

16 BY MR. PHELPS:

17 Q Dr. Cameron, the Government asked
18 you if you had done surveys of the entire
19 community that researches DOI. How much of the
20 community that researches DOI would you say
21 you've done surveys of?

22 A I mean this is my, you know,
23 professional field. So I interact with these
24 people all the time at conferences in different
25 cities, in different countries, across a

1 variety of topics. So this is definitely the
2 community in which I operate.

3 Q Could you explain how the -- well,
4 let me say it this way.

5 What would you say in your expert
6 opinion, is the general scientific consensus
7 around the abuse potential of DOI?

8 A I would say the consensus is that
9 there is low abuse potential. It is a very
10 useful tool in field to study the serotonin 2A
11 receptor and could have beneficial effects.

12 Q And again, in your expert opinion,
13 what would you say is the scientific consensus
14 around the potential harms to public health of
15 scheduling DOI?

16 A I think it would impair research and
17 the progress of many molecules, not just DOI.
18 So the progress of DOI being studied might be
19 impaired. But I've kind of mentioned before
20 that it's a key tool in neuroscience studying
21 that is -- is essential for studying the role
22 of the serotonin 2A receptor specifically.

23 So if you want to study LSD or
24 psilocybin or non-hallucinogenic analogs which
25 are also being tested in clinical trials, I'm

1 sure you have all heard of the fact that these
2 drugs are being tested widely now.

3 If we want to understand how these
4 drugs work, if we want to make better versions
5 of them, safer versions of them, we need to
6 understand how they work. And they work
7 typically, it's thought, through the serotonin
8 2A receptor.

9 So it's an invaluable tool. It --
10 it could have therapeutic properties on its
11 own, but it's important for not only, you know,
12 studying DOI or studying the serotonin 2A
13 receptor, but all these other drugs and all
14 these other therapeutics that are being studied
15 now.

16 Q Okay. So thank you for that answer.
17 I want to -- if you could specifically tell me
18 what, in your expert opinion and in your
19 familiarity with the field, what would you say
20 is the scientific consensus about the potential
21 impact on public health of scheduling of DOI?

22 MS. KREINHEDER: Objection, Your
23 Honor. This is outside the scope of her
24 expertise.

25 JUDGE SOEFFING: Well, I think we've

1 heard about this as well so --

2 MR. PHELPS: The only -- no problem
3 we can move on.

4 JUDGE SOEFFING: It's been asked and
5 answer. We've covered several -- I'll sustain
6 the objection.

7 MR. PHELPS: Okay. Thank you.

8 BY MR. PHELPS:

9 Q Just a few final questions for you,
10 Dr. Cameron. There was some questioning from
11 the Government's witness about application for
12 Schedule I licenses.

13 A Uh-huh.

14 Q And you testified that you have not
15 directly applied for a Schedule I license under
16 your own name; is that accurate?

17 A Yes.

18 Q When you started at the lab you're
19 at now, just I -- I'm just trying to clarify
20 because I wasn't quite sure when you were
21 answering the other questions of. Did your PI
22 already have Schedule I licenses or did you
23 work -- or did they obtain them while you were
24 there?

25 A So they had the general license, but

1 I had to apply for a specific drug under that
2 license to do the research to do the research
3 that I wanted to do.

4 So I worked with the PI and with the
5 team in order to just add it to the license,
6 and that takes over a year. So that's -- to be
7 fair, that's not even a full license from
8 granting up.

9 Q Oh, so it was -- okay. Can you
10 explain a little bit about the general
11 licensing versus the specific licensing that
12 you mentioned?

13 A I -- I don't know a lot about it,
14 because I don't really, you know, these admin
15 things. But there's several processes,
16 including get institutional approval, getting
17 state approval, getting, I think it's FDA and
18 DEA approval and you have to get all of that
19 and then you have to obtain the drug, usually
20 through something like NIDA.

21 So that -- it's you get a license
22 and then you have to have like your safe put in
23 and there can't be any windows, and the floors
24 need to be a number of feet thick and stuff
25 like that. So that's how you get a license.

1 And then you have to like get each individual
2 drug approved or something like that, it's my
3 understanding.

4 Q Okay. So and that's your
5 understanding through going through the process
6 of getting the specific license?

7 A Yeah --

8 Q Or --

9 A So, yep. So the labs that I've
10 worked with have had these Schedule I licenses.
11 And then to add another drug is like basically
12 a year of paperwork. So getting that initial
13 license is more -- more than them. But I'm not
14 totally sure about that because I haven't done
15 that process myself. Does that make sense?

16 MR. PHELPS: Yes. Thank you. No
17 further questions for this witness, Your Honor.
18 We would ask that she be permanently excused.

19 JUDGE SOEFFING: Okay. Well, I'm
20 going to give the Government a chance to --

21 MR. PHELPS: Oh, no problem.

22 JUDGE SOEFFING: -- conduct any
23 recross first. So thank you, Mr. Phelps. Ms.
24 Kreinheder, would you like to conduct recross?

25 MS. KREINHEDER: Yes, Your Honor.

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RECROSS-EXAMINATION

BY MS. KREINHEDER:

Q Doctor, you testified -- sorry. You testified that you were familiar with the process of obtaining a Schedule I researcher registration from DEA?

A Yeah. I worked with a team to get the license to study Schedule I substances.

Q Later during your testimony, you testified that admin people handle that? Is that correct?

A You work with a team of people, including safety people, including EH&S, drug inspection people, yes. You work as a team.

Q Could you please explain what specific part of the process you are familiar with?

A So I had to write the applications with my PI, that we did together, and we submitted to various admin for approval. And sometimes there's some back and forth and some revisions, then you could submit to the next, you know, agency or whatever you need to submit to.

And we often have different admin

1 people on our team actually submit the
2 documents, give the revision questions to us,
3 we handle the revisions, and resubmit it, that
4 kind of thing.

5 Q So you filled out an application; is
6 that correct?

7 A Well, yeah, but I -- yeah. But I
8 had to like write paragraphs and letters and
9 stuff. It's not just, you know, fill in the
10 blank.

11 Q Do you know what specific
12 application you filled out in the past?

13 A I don't remember them off the top of
14 my head. This was a couple years ago now.

15 Q So your testimony that it takes
16 several years to obtain this registration is
17 founded in what, exactly?

18 A So -- so to get a Schedule I
19 license, can take a year at minimum. And that
20 is founded in the fact that my Ph.D. advisor
21 had to do this and he couldn't even start his
22 research in his laboratory until he had this
23 license.

24 And I have also had experience
25 adding drugs to an existing Schedule I license

1 and that also takes at least a year before you
2 actually are able to do experiments with it.
3 Does that?

4 Q Yes. So just so I'm clear, your PI
5 told you how long it took to get the license
6 from start to finish?

7 A Yes. Because -- yes, because I am
8 interested in doing this in the future and I am
9 going to be needing to set this up in my own
10 lab. So like my person fit very nice in being
11 open with this information and telling me what
12 the steps are that are involved.

13 MS. KREINHEDER: No further
14 questions.

15 JUDGE SOEFFING: Thank you, Ms.
16 Kreinheder. All right. Let's go off the
17 record.

18 (Whereupon, the foregoing matter
19 went off the record at 11:21 a.m. and went back
20 on the record at 11:23 a.m.)
21

22 JUDGE SOEFFING: Dr. Cameron, thank
23 you for your testimony today. You are excused.
24 I direct you not to discuss your testimony with
25 anyone until the conclusion of the hearing.

1 And Mr. Phelps, did I hear you correctly that
2 there's no intention to recall her?

3 MR. PHELPS: That is correct, Your
4 Honor. We would ask that Dr. Cameron be
5 permanently excused.

6 JUDGE SOEFFING: Okay. All right.
7 Does the Government anticipate needing to
8 recall her for any reason?

9 MS. KREINHEDER: No, Your Honor.

10 JUDGE SOEFFING: Okay. All right.
11 Dr. Cameron, you are excused. We don't expect
12 you to be recalled. But again, please do not
13 discuss your testimony with anybody until the
14 hearing is concluded. Thank you.

15 THE WITNESS: Okay. Thank you.

16 JUDGE SOEFFING: Okay. Mr. Phelps,
17 Mr. Rush, call your next witness?

18 MR. RUSH: We'd like to call Joseph
19 Hennessey.

20 JUDGE SOEFFING: Okay and is this --
21 in person. All right. Very good. Mr.
22 Hennessey. And Mr. Rush, you're conducting the
23 direct examination?

24 MR. RUSH: Yes, yes, I am.

25 JUDGE SOEFFING: All right. Mr.

1 Hennessey, please raise your right hand.

2 WHEREUPON,

3 JOSEPH HENNESSEY

4 was called as a witness by Counsel for the
5 Petitioners, and, having been first duly sworn,
6 assumed the witness stand, was examined and
7 testified as follows:

8 JUDGE SOEFFING: Please state your
9 first name, your last name, and spell them both
10 for the record?

11 THE WITNESS: Joseph Hennessey,
12 J-O-S-E-P-H H-E-N-N-E-S-S-E-Y.

13 JUDGE SOEFFING: Thank you.
14 Counsel, you may enquire.

15 MR. RUSH: Thank you, Your Honor.

16 DIRECT EXAMINATION

17 BY MR. RUSH:

18 Q Would you please refer to Exhibit
19 75?

20 A Yes.

21 Q Do you recognize this document?

22 A Yes. This is my CV.

23 Q Did you write this document?

24 A I did.

25 Q Please look at the document. And is

1 this the form that you drafted it and is it
2 accurate representation of what you wrote?

3 A Yes. This is accurate.

4 Q Would you please describe your
5 education that you have?

6 A I have a bachelor of science in
7 biomedical sciences and philosophy from
8 Marquette University. And I am currently an
9 M.D. Ph.D. student at the Medical College of
10 Wisconsin. I have finished my pre-clinical
11 years of medical school.

12 Q And are those both accredited
13 universities?

14 A Yes, it is.

15 Q During your time of study, have you
16 received any honors or awards?

17 A I have.

18 Q Could you please describe what those
19 are?

20 A Yes. These are listed on my CV.
21 These include awards for excellence in academic
22 achievement, excellence in study, and
23 excellence in research of biomedical sciences
24 and philosophy.

25 Q Have you conducted any research?

1 A I have.

2 Q Would you please describe to us what
3 that research is and what it entailed?

4 A At Marquette, I studied behaviors
5 related to drug addiction and animal models as
6 well as tracing circuitry of neuronal pathways
7 in the brain.

8 And at the Medical College of
9 Wisconsin with Dr. John McCorvy, I used
10 functional assays of receptor activation to
11 study a wide variety of aminergic G-protein
12 coupled receptors.

13 And at these GPCRs including
14 serotonin GPCRs, I personally tested hundreds
15 of psychedelics and psychedelic-related
16 compounds.

17 Q Did this involve laboratory research
18 to conduct this research?

19 A Yes, it did.

20 Q And did that research involve the
21 use of DOI?

22 A Yes, it did.

23 Q Do you have any research work that
24 you have performed that has been published?

25 A Yes, I do. Those are listed on the

1 second page of my CV and include two papers,
2 the first which is titled, "Psychedelics
3 promote neuroplasticity through the activation
4 of intracellular 5-HT2A receptors", and the
5 second is listed after that.

6 Q And were those peer-reviewed
7 articles?

8 A Yes, they were.

9 Q Utilizing your expertise and
10 knowledge, have you engaged in any sort of
11 leadership opportunities?

12 A Yes, I have while in undergrad and
13 as a medical student.

14 Q Have you participated in any
15 academic conferences?

16 A I have. They're not listed on my
17 CV, but I've attended the Society for
18 Neuroscience.

19 MR. RUSH: At this time, we'd like
20 to request that Mr. Hennessey be certified as
21 an expert in pharmacology and the therapeutic
22 effects of DOI and DOC specifically as they
23 relate to serotonin G-protein coupled
24 receptors.

25 (Crosstalk.)

1 JUDGE SOEFFING: Any objection?

2 MR. MANN: Voir dire?

3 JUDGE SOEFFING: Yes. The
4 Government may voir dire.

5 VOIR DIRE EXAMINATION

6 BY MR. MANN:

7 Q Good morning, Mr. Hennessey.

8 A Good morning.

9 Q You're still a student, aren't you?

10 A Yes.

11 Q Okay. You do not have a Ph.D.?

12 A Correct.

13 Q All right. And you're a second year
14 student; is that correct?

15 A Yeah. I'm -- I'm in my second year.
16 I finished all of pre-clinical medical school.

17 Q Okay. So I'm looking at your CV
18 here. Do you see that, Exhibit number 75?

19 A Yes, I do.

20 Q All right. It says here that your
21 expected finish date in the medical science
22 training program isn't until 2031, correct?

23 A Correct, yes. I'm --

24 Q Okay. That's all I'm asking. So
25 you're expected finish date here as a doctor of

1 medicine isn't until 2031; is that correct?

2 A Correct.

3 Q All right. And a doctor of
4 philosophy, that expected finish date isn't
5 until 2028; is that correct?

6 A That's correct.

7 Q Okay. You've won some honors and
8 awards?

9 A Correct.

10 Q The Edward Carroll Award for
11 Excellence in Academic Achievement. What did
12 that -- what was that about?

13 A That was having the highest GPA in
14 my major.

15 Q Okay. What'd it have to do with DOI
16 or DOC?

17 A That was in biomedical sciences. So
18 I took a lot of high level course work in
19 neuroscience and including topics such as
20 behavioral economics relating to addiction and
21 other neuroscientific topics.

22 Q My question was, how does that
23 relate to DOI or DOC?

24 A It does not.

25 Q This is what this hearing is about,

1 you understand. So how did that award relate
2 to DOI or DOC? Did it relate it to it at all?

3 A In that very narrow sense, it was
4 not related to DOI or DOC.

5 Q And this award from the Francis X.
6 Boden Award for Excellence in the study of
7 philosophy, did that relate to DOI or DOC?

8 A No, not in that very succinct sense.

9 Q And this award in the Biomedical
10 Science Excellence and Research award, did that
11 relate to DOI or DOC?

12 A That was related to substance use
13 but not DOI or DOC.

14 Q Okay. All right. It says here that
15 you are from June 2022 to June 2023, a research
16 technician; is that right?

17 A Correct.

18 Q All right. And you said that you
19 wrote or you've published two papers?

20 A Correct.

21 Q Did you write them?

22 A I wrote parts of them, but not the
23 entire paper.

24 Q How much of them?

25 A The sections which I did the

1 experiments for.

2 Q And what's the percentage of the
3 paper that you actually wrote, the Vargas MV
4 paper, the first one?

5 A It's hard to give an exact
6 percentage.

7 Q Okay.

8 A But it was fairly, I mean, probably
9 about 5 percent.

10 Q Okay. And what's the percentage of
11 the paper you wrote this Wallach, J paper?

12 A Also somewhat low percentage, 5 to
13 10 percent.

14 Q All right. And you understand that
15 the person who is listed first in a paper is
16 generally the one who does most of the work?

17 A I understand.

18 Q And the person who is listed last in
19 the paper is the one who did some significant
20 work, and that's the reason they're listed
21 last; is that correct?

22 A Not entirely, no.

23 Q Do you disagree with that statement?

24 A I do disagree with it.

25 Q Okay. All right. And you're not

1 listed first, nor are you listed last in any of
2 these papers; is that right?

3 A Correct.

4 Q All right. And you went to --
5 you've attended how many conferences?

6 A Conferences -- no national
7 conferences.

8 Q Have you attended any conferences
9 related to DOI or DOC?

10 A Yeah, there was work presented
11 relating to DOI at Society for Neuroscience in
12 Chicago.

13 Q How many of those conferences did
14 you attend?

15 A I've been to one.

16 Q One -- one conference. Okay.

17 MR. MANN: One moment. Well, Your
18 Honor, the Government opposes offering Mr.
19 Hennessey as an expert on the pharmacology and
20 therapeutic effects of DOI and DOC.
21 Specifically as they relate to serotonin G-
22 protein coupled receptors.

23 I do not believe that he -- first of
24 all, he does not have a degree other than a
25 bachelor's degree. He is still a student. His

1 work is still very much in progress. It
2 appears that his goals -- his educational goals
3 won't be reached until 2028 at the earliest.
4 The other two won't be reached until 2031.

5 He's listed here only as a research
6 technician. He wrote very, very low
7 percentages of these two publications. He's
8 attended only one conference involving DOC and
9 DOI. He hardly qualifies as an expert.

10 Furthermore, Exhibit 75 was never
11 offered into evidence, has never been accepted
12 into the record. So there is no CV in the
13 record here to even accompany his
14 qualification. So we would be opposed on those
15 grounds.

16 JUDGE SOEFFING: Thank you, Mr.
17 Mann. Mr. Rush, I will give you an opportunity
18 to respond.

19 MR. RUSH: Yes, Your Honor. In the
20 interest -- Yes, Your Honor. In the interests
21 of expediency, we're not going to dispute and
22 argue about whether you have to receive awards
23 specifically and not take the drug to be
24 considered an expert. We'll agree that Mr.
25 Hennessey is not an expert and we'll just like

1 him to appear as a fact witness.

2 JUDGE SOEFFING: Okay. Very well.
3 So you're withdrawing your request that he be
4 admitted as an expert in the proceeding?

5 MR. RUSH: That's correct, Your
6 Honor.

7 JUDGE SOEFFING: All right. Very
8 well. You may proceed in your questioning of
9 the witness.

10 MR. RUSH: Thank you, Your Honor.

11 DIRECT EXAMINATION (CONT'D.)

12 BY MR. RUSH:

13 Q So you had commented or -- what type
14 of research do you work on?

15 A I will begin my graduate studies in
16 January, so I'm not currently conducting
17 research. But when I was with Dr. John McCorvy
18 from 2022 to 2023, I used functional assays
19 like bioluminescence resonance energy transfer,
20 also known as BRET, to study the activation and
21 inhibition of G-protein coupled receptors by
22 drugs.

23 Q And what is a serotonin G-protein
24 coupled receptor?

25 MR. MANN: Your Honor, again, we are

1 into repeating over and over again the same
2 testimony here. To the extent that this is
3 different, I don't think it has any relevance.

4 And if it is different -- to the
5 extent that it's different I don't think it has
6 any relevance and I don't think it is
7 different. I think it's just going to be the
8 same thing over and over again.

9 JUDGE SOEFFING: Okay. So I'm going
10 to overrule the objection. We're not going to
11 spend a lot of time on this, but to kind of lay
12 the basis for the following questions, I will
13 allow some limited testimony since this
14 witness, you know, was not here for much of the
15 earlier proceedings, so overruled.

16 MR. RUSH: It's understood, Your
17 Honor. And we'll try to keep this brief and
18 move this along.

19 BY MR. RUSH:

20 Q Just briefly if you could, so we
21 just understand exactly this generally is, but
22 please keep it brief?

23 A Would you like me to respond?

24 Q Yes.

25 JUDGE SOEFFING: Yes, please answer

1 the question.

2 THE WITNESS: Oh, yes. We were
3 primarily interested in psychedelics and I was
4 involved in testing psychedelics at -- across
5 all 12 serotonin GPCRs to get a better
6 understanding of how they activate these
7 receptors and to what degree they
8 differentially activate certain receptors over
9 others.

10 BY MR. RUSH:

11 Q And you stated before you are
12 pursuing a degree, a medical degree and a Ph.D.
13 When did you say it was -- I just want to
14 refresh, when did you say the graduation date
15 was?

16 A For the Ph.D., 2028, and the M.D.,
17 2031.

18 Q All right. And the scheduling of
19 DOI, if it was added to scheduling, how would
20 that affect your current research and your
21 obtaining the degree?

22 A Yes. So I've already joined a lab
23 that has a Schedule II license from the DEA,
24 but does not have a Schedule I license. And we
25 are interested in studying psychedelics as it

1 relates to cognitive flexibility in depression,
2 like models of depression in rodents.

3 And we have already started
4 designing and conducting pilot experiments with
5 DOI in order to get this work moving. And in
6 conjunction with my Ph.D. advisor, who will be
7 John Mantsch, we are targeting a date of April
8 2nd, I believe it is, 2025, to submit an F30
9 fellowship for this work.

10 And if DOI were to be placed into
11 Schedule I, I certainly would not be able to
12 meet that fellowship deadline. And it would
13 adversely affect the timelines that I have to
14 complete my Ph.D.

15 Q Would you explain what that
16 fellowship is?

17 A Yeah. It's a fellowship for
18 M.D./Ph.D. students. It's a training grant
19 from the NIH, it's awarded through certain NIH
20 institutions like the National Institute of
21 Mental Health or NIDA, et cetera, and it's for
22 training the next generation of scientists.
23 And it's a very, very impactful award, and it
24 provides money for funding for research.

25 Q Alluding specifically to your own

1 knowledge and not applying your opinion or
2 speculation, regarding any discussions that you
3 may have had with other people or conversations
4 with other students regarding this, what has
5 responses regarding or what is your take
6 regarding their perceptions on how it would
7 affect their academic and research paths if it
8 were to be scheduled, DOI?

9 MR. MANN: Objection, Your Honor.
10 He's just asked for a whole lot of hearsay.

11 MR. RUSH: Your Honor, hearsay is
12 admissible in this Court with your discretion.
13 The rules of hearsay evidence do not strictly
14 apply here.

15 JUDGE SOEFFING: Yes. We've already
16 heard, this is also starting to get to be
17 repetitive. I mean, I'll overrule the
18 objection. But I'm not sure there's a lot of
19 weight I'm going to be giving to this
20 testimony.

21 MR. RUSH: Understood, Your Honor.

22 JUDGE SOEFFING: You may answer the
23 question.

24 THE WITNESS: Oh, yeah. In
25 speaking, in my personal experience speaking

1 with my Ph.D. mentors, the scheduling of DOI
2 would adversely affect our -- our plans for
3 future research, which includes research into
4 potential treatments for depression and
5 addiction.

6 MR. RUSH: Your Honor, we have no
7 further questions for this witness.

8 JUDGE SOEFFING: Okay. Thank you,
9 Mr. Rush. Mr. Mann, would you like to conduct
10 cross-examination?

11 MR. MANN: Thank you, Your Honor.

12 CROSS-EXAMINATION

13 BY MR. MANN:

14 Q Mr. Hennessey, you worked with John
15 McCorvy, correct?

16 A That's correct.

17 Q And John McCorvy had a Schedule I
18 DEA registration, did he not?

19 A That's correct.

20 Q Okay. Did you work with John
21 McCorvy on researching DOM?

22 A It -- it has been researched in the
23 lab. I -- I personally have not tested that
24 drug.

25 Q Was that research involving DOB?

1 A We -- we test many hundreds of
2 compounds in that lab. It's hard to know -- to
3 know specific drugs, but it has been tested in
4 the lab, not by me.

5 Q Okay. And you mentioned that you've
6 talked to a number of mentors; is that correct?

7 A Yes.

8 Q Okay. And who are they?

9 A John McCorvy and John Mantsch.

10 Q Okay. Does John Mantsch have a DEA
11 registration?

12 A He has a Schedule II license as he
13 studies cocaine and, yeah.

14 Q Okay. You're here making
15 representations about the DEA procedures and
16 how to obtain a DEA registration and how long
17 it takes. And could you please tell me who at
18 DEA did you speak with to get your information?

19 A I did not make those claims that you
20 just said. But I have not spoken to --

21 Q Oh, you have not testified about the
22 procedure for getting a DEA registration and
23 how difficult it will be?

24 A No. I have not personally testified
25 about that.

1 Q Okay. So you don't know how
2 difficult it is to get a DEA registration, do
3 you?

4 A I've spoken with people who have
5 gone through the process.

6 Q Yeah, and my question is do you know
7 how difficult it is to get a DEA registration,
8 whether it is difficult or not?

9 A Yes.

10 Q All right. And who did you speak
11 with at DEA who informed you -- who informed
12 your opinion that it is difficult to obtain a
13 DEA registration?

14 A I've spoken with John Mantsch and
15 John McCorvy, both of whom have gone through
16 the process personally.

17 Q So John McCorvy works at DEA, is
18 that your testimony? I asked you who you spoke
19 with at DEA to determine whether it is
20 difficult or not to obtain a DEA registration.
21 Who did you speak with at DEA?

22 JUDGE SOEFFING: Hold, Mr. Mann,
23 just one question at a time, let him answer.

24 THE WITNESS: I have not spoken with
25 anyone at DEA.

1 MR. MANN: Thank you.

2 JUDGE SOEFFING: All right. No
3 further questions, Mr. Mann?

4 MR. MANN: That's all, thank you.

5 JUDGE SOEFFING: Mr. Rush, anything
6 on redirect?

7 MR. RUSH: No. We have no
8 questions, Your Honor, we, I mean, release the
9 witness.

10 JUDGE SOEFFING: All right. Do you
11 expect to recall this witness?

12 MR. RUSH: No, we do not, Your
13 Honor.

14 JUDGE SOEFFING: All right. Thank
15 you for your testimony, Mr. Hennessey, you are
16 excused. I direct you not to discuss your
17 testimony with anyone until the conclusion of
18 the hearing, so can you discuss with your --
19 with your attorneys.

20 THE WITNESS: Okay. Thank you.

21 JUDGE SOEFFING: All right. Mr.
22 Phelps, Mr. Rush, do you want to call your next
23 witness?

24 MR. PHELPS: Yes, Your Honor. Our
25 next witness is going to be Dr. Pasha

1 Davoudian. He will be appearing via video. So
2 if we could have just a few minutes to make
3 those arrangements.

4 JUDGE SOEFFING: Okay. We'll go off
5 the record and I will step out while you get
6 him online.

7 MR. PHELPS: Thank you, Your Honor.

8 (Whereupon, the foregoing matter
9 went off the record at 11:47 a.m. and went back
10 on the record at 11:59 a.m.)

11 JUDGE SOEFFING: We're back on the
12 record, yes.

13 MR. PHELPS: Thank you, Your Honor.
14 Petitioners call Dr. Jason Younkin.

15 JUDGE SOEFFING: Okay, Dr. Younkin,
16 can you hear me?

17 DR. YOUNKIN: Yes, I can, sir.

18 JUDGE SOEFFING: Okay, very good.

19 Dr. Younkin, please raise your right
20 hand.

21 Whereupon,

22 DR. JASON YOUNKIN
23 a witness, was called by Counsel for the
24 Petitioners and, after having been first duly
25 sworn, assumed the witness stand and was

1 examined and testified as follows:

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

5 THE WITNESS: Jason, J-A-S-O-N,
6 Younkin, Y-O-U-N-K-I-N.

7 JUDGE SOEFFING: And Dr. Younkin,
8 during your testimony, you should not look at
9 any materials or documents except exhibits that
10 you are directed to look at by Counsel or me,
11 do you understand?

12 THE WITNESS: Yes, I do.

13 JUDGE SOEFFING: Okay, you can put
14 your hand down.

15 And Mr. Phelps, you may inquire.

16 MR. PHELPS: Thank you, Your Honor.

17 DIRECT EXAMINATION

18 BY MR. PHELPS:

19 Q Thank you for being here today, Dr.
20 Younkin. I'd like to begin by taking a look at
21 what's been marked for exhibit purposes as
22 students for -- SSDP Ramos Exhibit 83. The
23 first line on that page reads, Jason Younkin
24 Curriculum Vitae. Do you have that there?

25 A No, I assumed you were pulling that

1 up.

2 Q Oh, I apologize. Do you have access
3 to pull that up there?

4 A I actually have it open for
5 something else, and yes.

6 Q Thank you.

7 A I did have it open, but it only took
8 a second. Okay, I have it open.

9 Q And do you recognize this document,
10 Dr. Younkin?

11 A Yes, I do.

12 Q And did you write this document?

13 A Yes, I did.

14 MR. PHELPS: Your Honor, at this
15 time we would move to admit what's marked for
16 identification purposes as Exhibit 83.

17 JUDGE SOEFFING: Okay, I don't think
18 he actually said what it was.

19 MR. PHELPS: Oh, I'm sorry. Let me
20 -- let me take a step back. Yeah, a little
21 more foundation.

22 BY MR. PHELPS:

23 Q Could you tell us what that document
24 is, Dr. Younkin?

25 A It is my personal curriculum vitae,

1 or CV, same thing as a resume. Do you need
2 more details?

3 Q I think that identifies the --

4 JUDGE SOEFFING: Let me just ask,
5 Dr. Younkin, how many pages is it?

6 THE WITNESS: Seven.

7 JUDGE SOEFFING: Okay, thank you.

8 MR. PHELPS: Thank you, Your Honor.

9 At this time, Petitioners would move to admit
10 what's marked for identification purposes as
11 SSDP Ramos, Exhibit 83.

12 JUDGE SOEFFING: Okay. Government,
13 who's handling this witness? Ms. Attanasio,
14 any objection to this?

15 MS. ATTANASIO: No objection, Your
16 Honor.

17 JUDGE SOEFFING: Okay. Petitioner's
18 Exhibit marked for identification number 83 has
19 been offered. In the absence of objection, it
20 is received in the record as Petitioner's
21 Exhibit 83.

22 (Whereupon, the document marked as
23 Petitioner Exhibit No. 83 for identification
24 was received into evidence.)

25 JUDGE SOEFFING: It's in. You may

1 use it.

2 MR. PHELPS: Thank you, Your Honor.

3 BY MR. PHELPS:

4 Q Dr. Younkin, what degrees do you
5 hold?

6 A A PhD in neuroscience from Virginia
7 Commonwealth University, bachelor's degree in
8 neuroscience from College of William & Mary,
9 associate's in science from Thomas Nelson
10 Community College. That is it.

11 Q And where was that that you pursued
12 your undergraduate education?

13 A The College of William & Mary.

14 Q And what specifically did you study
15 there?

16 A Neuroscience.

17 Q And where did you pursue your PhD
18 program?

19 A Virginia Commonwealth University.

20 Q And what do you hold your PhD in?

21 A Neuroscience.

22 Q Can you talk just a little bit about
23 the PhD coursework curriculum you completed to
24 obtain that degree?

25 A Started with a five credit course in

1 biochemistry, a first half and a second half.
2 Five credits each. There were two neuroscience
3 classes. I don't remember the exact titles of
4 those classes, but they reached three credits.

5 One was basically the anatomy, the
6 other was basically the function. And then
7 after that, there was a 600 level course in
8 pharmacology. There was a 500 level course in
9 biostatistics. There were multiple 600 level
10 courses in physiology and biophysics. That was
11 the actual department that I was in. The
12 neuroscience degree is a program, not a
13 department.

14 There were numerous different
15 seminar versions along the way. Also present
16 classes that basically were presentations.
17 Either presenting my work in progress to a
18 different group or presenting a journal article
19 called Journal Club.

20 Q And in addition to that coursework
21 curriculum, what else did your PhD program
22 consist of?

23 A Much time spent in the actual
24 dissertation lab of my dissertation advisor.
25 That was also considered a course. Whatever

1 credits we had up to that point, we would add
2 on however much to make 15 credits.

3 So, at the beginning, it was like
4 two or three credits, but once those courses
5 were done, it was more like 15 credits. So
6 full-time research in my dissertation lab.

7 Q And can you talk a little bit about
8 your dissertation research?

9 A It was about anti-psychotic drugs
10 and their effects on three different receptors,
11 their GPCRs. The main one was the serotonin 2A
12 receptor. It forms a heteromer with the
13 metabotropic glutamate receptor 2.

14 It also forms a separate heteromer
15 with the dopamine 2 receptor. So previous work
16 had been done on the mGlu2/2AR version. I did
17 some work that brought it into mammalian cells.

18 And then the brunt of the rest was
19 with a fairly newly discovered heteromer
20 between the D2R and the serotonin 2AR. And
21 about two-thirds of my dissertation was looking
22 at the functional changes when they formed a
23 heteromer together.

24 Q And is there any particular
25 scientific terminology used to describe this

1 interplay of dopamine and serotonin receptors?

2 A The receptors themselves, they can
3 either bind as a heteromer, but also the
4 functional crosstalk between the two.

5 Q Can you please define for us what
6 crosstalk is?

7 A In this case we were looking at
8 actual physical contact that would change the
9 crosstalk. And the crosstalk means if one
10 receptor is functioning the way it functions,
11 it can affect the function of the other
12 receptor.

13 So basically the signaling
14 downstream gets changed depending on the
15 binding of the two receptors together and what
16 drugs are added on one side affecting the
17 function of the other side.

18 In this case, at that time, mostly
19 anti-psychotics, but also what we were calling
20 pro-psychotics, which are essentially
21 psychedelics.

22 Q So you use psychedelics as part of
23 your study of crosstalk in dopamine and
24 serotonin receptors?

25 A Yes, specifically DOI.

1 Q I'd like to -- well besides your
2 academic education that you -- that you
3 discussed, do you have any other -- have you
4 completed any other education programs?

5 A Yes, along the way on the CV that I
6 assume you're all looking at, I listed it as
7 professional military. Here, the strategic
8 education part was an online learning to be
9 able to teach online.

10 But then also in the military I went
11 through Naval Nuclear Electronics Technician
12 Schools, the A-School, the Power School, and
13 Prototype. That was in the United States Navy
14 in Orlando, Florida and Ballston Spa, New York.

15 Q Could you talk a little bit about
16 that Navy or Naval Nuclear Electronics
17 Technician A-School?

18 A The A-School was the beginning of
19 the two-year program. It was seven weeks and
20 it was intensive learning of electronic systems
21 and electrical circuitry. Do you want me to
22 segue into Power School and Prototype?

23 Q Oh yes, please, if those are -- yes.
24 The Power School then was the nuclear -- at the
25 beginning of the nuclear side of that. Now

1 that we had a trade essentially, then we went
2 through six months of Power School and it is
3 considered the top school in the world for
4 anything involving nuclear power ahead of MIT,
5 Duke, places like that.

6 And finally the Prototype was the
7 final six months where we actually operated and
8 maintained a nuclear reactor before we
9 graduated all that and went to the fleet.

10 Q And -- in that -- in that Navy
11 nuclear program, did you -- well, I guess how
12 did it -- how did your -- how did your --
13 you're moving through those Navy -- Naval
14 nuclear programs. Well, let me clarify. Is
15 there any relationship between what you learned
16 in that Navy nuclear program to your other
17 academic education?

18 A I would say that it was mostly a
19 completely different topic, but it was -- being
20 nuclear, was obviously heavily physics, which
21 led to the biophysics department that I was in
22 for the PhD at VCU.

23 And that led to a knowledge of
24 electrophysiology, which was a heavy part of
25 that dissertation work that I did. And then

1 later on as a postdoc at -- sorry, VCU, it also
2 led to a good knowledge of the physics behind
3 certain photonics methods involving
4 fluorescence, luminescence, things like that.

5 Q Okay.

6 A And all of those I'm describing were
7 used to test psychedelics, or potential
8 psychedelics.

9 Q And Dr. Younkin, have you published
10 -- have you published research regarding your
11 crosstalk study?

12 A Yes.

13 Q And looking at pages four and five
14 of that CV, could you give -- could you just
15 give us the number of those publications that
16 were specifically related to the crosstalk
17 study?

18 A So out of the eight publications,
19 six of them are related to the crosstalk.

20 Q And out of the -- the presentations
21 that are listed on pages six and seven, how
22 many of those presentations that you gave were
23 dealing with your crosstalk studies?

24 A So I'm counting right now. All but
25 the -- all but the top three. So 1, 2, 3, 4,

1 5, 6, 7, 8, 9, 10. The top three were later on
2 as a postdoc, specifically for psychedelics.

3 Q And Dr. Younkin, what's your current
4 title or position?

5 A Assistant Professor, Biology
6 Department at VSU.

7 MR. PHELPS: Your Honor, at this
8 time we would move to admit Dr. Younkin as an
9 expert in the study of crosstalk between
10 dopamine and serotonin receptors.

11 JUDGE SOEFFING: Ms. Attanasio, any
12 objection?

13 MS. ATTANASIO: Yes, Your Honor. We
14 object to him being qualified as an expert in
15 crosstalk between dopamine and serotonin
16 because there was nothing in the pre-hearing
17 statement that really discloses or relates to
18 the expertise noticed to it. It appears that
19 he's really, in the pre-hearing statement, that
20 he is really just talking about research harm.

21 There's no facts about DOI and DOC.
22 He says he may use DOI in one of his studies.
23 He calls himself a junior investigator, so --
24 and he does not talk about anything relating to
25 the eight-factor test.

1 JUDGE SOEFFING: Okay. Did you want
2 to conduct any voir dire or just make the
3 objection?

4 MS. ATTANASIO: Just make the
5 objection.

6 MR. PHELPS: And if I could respond
7 to that, Your Honor, we're specifically -- if
8 we look at -- first of all, in regards to
9 notice, there was notice in the supplemental
10 pre-hearing statement that this is what he was
11 an expert on. And looking at the
12 original pre-hearing statement, the second
13 sentence specifically mentions his study of
14 crosstalk between dopamine and serotonin
15 receptors. The motion was specifically related
16 to that expert designation.

17 Anything else that she was talking
18 about is not relevant to the court's
19 determination of his expertise. And there's
20 been no voir dire or questioning of his
21 qualifications in the very specific limited
22 topic that he's listed in as an expert.

23 MS. ATTANASIO: There -- excuse me,
24 Your Honor, if I may. There is no need to voir
25 dire him as an expert in this, because there's

1 no facts in the pre-hearing statement that
2 talks about it.

3 All it says is that he studied the
4 crosstalk between dopamine and serotonin
5 receptors. Nowhere in the pre-hearing
6 statement does it talk about what this even
7 means, what's it about, et cetera.

8 JUDGE SOEFFING: Okay. So what I'm
9 going to do is -- all right. The Petitioners
10 have offered Dr. Younkin as an expert in the
11 study of crosstalk between dopamine and
12 serotonin receptors. The Government has
13 objected to the qualification of Dr. Younkin as
14 an expert in that field.

15 However, based on the witness's
16 knowledge, skill, experience, training, and
17 education, I will overrule the objection. The
18 Tribunal will accept the witness as an expert
19 in the study of crosstalk between dopamine and
20 serotonin receptors.

21 I do think the Petitioners have
22 shown that he is qualified to be an expert in
23 that area. Whether, and to what extent, it
24 relates to the additional testimony he may
25 provide, we will see on that.

1 It may not have any bearing on the
2 facts that he testifies to, but I will
3 recognize him as an expert based on his
4 credentials and his knowledge, skill,
5 experience, education, so.

6 MR. PHELPS: Thank you, Your Honor.

7 JUDGE SOEFFING: So to be clear, the
8 witness is being accepted as an expert in the
9 study of crosstalk between dopamine and
10 serotonin receptors.

11 MR. PHELPS: Thank you.

12 BY MR. PHELPS:

13 Q Dr. Younkin, can you explain what
14 DOI has to do with your expertise in the
15 crosstalk between dopamine and serotonin
16 receptors?

17 MS. ATTANASIO: Objection, Your
18 Honor, outside the scope of the pre-hearing
19 statement.

20 MR. PHELPS: Your Honor, this is
21 exactly what they were asking us to show, so.

22 JUDGE SOEFFING: Well, let's see
23 where it is.

24 MR. PHELPS: Well, it mentions DOI
25 there at the bottom of the first paragraph.

1 And again, I mean, this is -- I think what the
2 Government seems to be asking for is they
3 wanted written word-for-word testimony to know
4 word-for-word what they want to say. If that
5 was --

6 JUDGE SOEFFING: No, that's not the
7 standard. And certainly that's not the
8 standard I've been holding anybody to. There's
9 been a lot of leeway given by the Tribunal for
10 people to talk about things that were maybe not
11 specifically identified here. I do appreciate
12 the efforts that both sides have made to try to
13 limit to be the most relevant to what I've
14 allowed.

15 MR. PHELPS: Just a single question,
16 Your Honor, and that's -- we don't even have to
17 go into details or follow-up. I just would
18 like him to be able to answer that one question
19 of how DOI relates to his expertise in that
20 field.

21 JUDGE SOEFFING: I'll allow it.
22 Overruled.

23 THE WITNESS: Can you repeat the
24 question?

25 BY MR. PHELPS:

1 Q Yes, sir. Can you explain the
2 significance of DOI in your study of crosstalk
3 between dopamine and serotonin receptors?

4 A So I had mentioned placing drugs
5 into the system. They're going to bind to one
6 receptor or the other. The only known and used
7 agonist for the serotonin 2A receptor, an
8 agonist means it activates it.

9 MS. ATTANASIO: Objection, Your
10 Honor. He's becoming cumulative now.

11 JUDGE SOEFFING: Overruled. I'll
12 let him finish his answer to this question.

13 MR. PHELPS: Thank you, Your Honor.

14 BY MR. PHELPS:

15 Q Please continue, Dr. Younkin.

16 A So to study the effect of an agonist
17 on that side of a heteromer, of the heteromer
18 between the two receptors, DOI is basically the
19 only one we can use because it is a pro-
20 psychotic, which is what we were calling it at
21 the time. Now we call it psychedelic. That's
22 why DOI is integral to that study.

23 Q So, Dr. Younkin -- you say, I guess
24 I'm -- maybe I can seek a little clarification
25 from your Court -- from the Court, Your Honor,

1 based on the Government's repeated objections.

2 At the bottom of the first paragraph
3 of the joint pre-hearing statement, there is a
4 -- this is where he mentioned specifically the
5 use of DOI. I just want to seek the Court's
6 permission to just let him explain that one
7 sentence and then we'll move on from the
8 specifics of his research.

9 JUDGE SOEFFING: Go ahead.

10 MR. PHELPS: Thank you, Your Honor.

11 BY MR. PHELPS:

12 Q Dr. Younkin, can you talk a little
13 bit about your future plans to use DOI in
14 studies with zebrafish?

15 A So as the only unscheduled
16 psychedelic, and the strongest one in many
17 different assays, it becomes the only real
18 comparison. So when I -- when I am established
19 and have my zebrafish rig set up, there are
20 several ways to study the zebrafish and I admit
21 that I cannot speak on that right now. I just
22 know they exist.

23 Once that's set up, I need DOI to be
24 able to compare any of the new potential
25 therapeutic psychedelic drugs to the DOI and

1 its effects. And there are other agonists of
2 the serotonin 2a. However, DOI is the only
3 psychedelic one that is not scheduled, or
4 hallucinogenic one, I should say.

5 Q Thank you. And we've heard a lot of
6 testimony so far about experiments or assays
7 using rodents and cells. What is it about
8 zebrafish specifically that's -- why zebrafish?

9 A So, much cheaper to begin with. A
10 practical reason is I have that rig already
11 here at BSU waiting for me to use. And with
12 several different ways to do it, it becomes an
13 excellent complement to other studies would be
14 things you just mentioned that I'm sure have
15 been already mentioned many times, the head
16 twitch in mice and various other assays.

17 So with the zebrafish, cheap, quick,
18 and the availability of DOI makes, makes it not
19 only easy to compare to DOI, but like I said,
20 DOI is the comparison for a psychedelic that
21 affects the serotonin 2a.

22 Q Thank you. So, how would -- how
23 would DOI being placed in Schedule I impact
24 your research with the zebrafish?

25 A So to do the research here with the

1 zebrafish at BSU, I would not have a comparison
2 and it will take -- I estimate at least a year
3 to get a DEA license to be able to have DOI
4 again, plus all the other various psychedelics
5 that are scheduled currently. So it would be a
6 minimum of a year delay to just get started.

7 The term junior PI was brought up.
8 Junior PI really just means new PI. To
9 establish myself as a PI and get funding, I'm
10 going to need to be able to run this zebrafish
11 assay and have something to compare it to. So
12 any delay, a year or more, is going to cost me
13 time to become a PI. And we haven't even
14 said what PI is, principal investigator, and
15 the ability -- and the ability to get funding.
16 If I can expound, I mean, the whole point of me
17 joining this was to give a real-life version of
18 what happens if this goes on a schedule.

19 It will delay me and anybody else
20 who wants to do new research involving
21 psychedelics, because they will have to get --
22 they'll either have to join a lab that has a
23 DEA license or get their own DEA license.

24 Q Thank you. How did you -- how did
25 you come to your estimate that it would take

1 you a year? Actually, let me be more specific
2 on that. Who did -- who did you specifically
3 talk to or consult with to make that
4 determination?

5 A At one point, while I was a postdoc
6 in the Javier Gonzalez-Maeso Lab, I asked him -
7 - I asked him how long it took him to get his
8 DEA license. He estimated about six months.

9 MS. ATTANASIO: Objection, Your
10 Honor, hearsay.

11 JUDGE SOEFFING: Okay, it is
12 hearsay. We have allowed other testimony on
13 this based on the experiences of the
14 researchers and their various labs, so I'll
15 overrule the objection.

16 MR. PHELPS: Please continue.

17 JUDGE SOEFFING: You can continue
18 your answer.

19 THE WITNESS: Yeah, so having talked
20 to him and getting an idea of how long it took
21 him, I applied that to BSU where none of this
22 has been done. I think a year is actually a
23 lowball estimate, in all honesty. I think
24 it'll probably take upwards of two years, but I
25 wanted to be fair and say two, and say the one

1 year.

2 Nothing like this has been done
3 here. There is no DEA license on this campus.
4 It's a whole new thing that I have to figure
5 out.

6 BY MR. PHELPS:

7 Q Have you consulted with anyone
8 employed through the DEA -- employed through
9 the DEA directly, and you're learning about
10 this process?

11 A Not yet, no.

12 Q Thank you. No further questions for
13 this witness, Your Honor.

14 JUDGE SOEFFING: Okay, thank you,
15 Mr. Phelps.

16 Ms. Attanasio, would you like to
17 conduct a cross-examination?

18 MS. ATTANASIO: Yes, Your Honor, one
19 moment.

20 No further questions, Your Honor,
21 actually.

22 JUDGE SOEFFING: Okay, very good.

23 Dr. Younkin, thank you for your
24 testimony. You are excused. I direct you not
25 to discuss your testimony with anyone until the

1 conclusion of the hearing. Thank you.

2 THE WITNESS: Thank you.

3 MR. PHELPS: We would ask that Dr.
4 Younkin be permanently excused as well.

5 JUDGE SOEFFING: Okay, no intention
6 to recall him?

7 MR. PHELPS: No, Your Honor.

8 JUDGE SOEFFING: Government, no
9 intention to recall?

10 MS. ATTANASIO: No, Your Honor.

11 JUDGE SOEFFING: We don't expect you
12 to be recalled, Mr. Younkin, or Dr. Younkin.
13 Thank you.

14 All right, let's go off the record.

15 (Whereupon, the above-entitled matter went
16 off the record at 12:26 p.m. and resumed at
17 12:27 p.m.)

18 JUDGE SOEFFING: Back on the record.
19 We will adjourn for one hour for lunch.

20 (Whereupon, the above-entitled matter went
21 off the record at 12:27 p.m. and resumed at
22 1:38 p.m.)

23 JUDGE SOEFFING: We're back on the
24 record. Welcome back, everybody.

25 Mr. Phelps, are you ready to call

1 your next witness?

2 MR. PHELPS: We are, Your Honor.

3 Petitioners would call Dr. Mario de la Fuente
4 Revenga.

5 JUDGE SOEFFING: All right. Shall I
6 refer to you as -- what's the best way to refer
7 to you, Doctor? First of all, can you hear me?

8 DR. DE LA FUENTE: Dr. de la Fuente
9 would be appropriate.

10 JUDGE SOEFFING: Dr. de la Fuente?

11 JUDGE SOEFFING: Okay. Very good.
12 Welcome. Doctor, please raise your right hand.
13 Okay. Let's go off the record.

14 (Whereupon, the above-entitled matter went
15 off the record at 1:38 p.m. and resumed at 2:01
16 p.m.)

17 JUDGE SOEFFING: All right. Back on
18 the record. Okay. So we were not able to
19 establish a good connection with Dr. de la
20 Fuente so he will be subject to being called
21 later in the case.

22 Mr. Phelps, you may call your next
23 witness.

24 MR. PHELPS: Thank you, Your Honor.
25 Petitioners call Dr. David Earl Nichols.

1 JUDGE SOEFFING: All right. Dr.
2 Nichols, please raise your right hand.
3 Whereupon,

4 DAVID NICHOLS
5 a witness, was called by Counsel for the
6 Petitioners and, after having been first duly
7 sworn, assumed the witness stand and was
8 examined and testified as follows:

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

12 THE WITNESS: My name is David Earle
13 Nichols. Did you ask me to spell it?

14 JUDGE SOEFFING: Yes, please.

15 THE WITNESS: D-A-V-I-D N-I-C-H-O-
16 L-S.

17 JUDGE SOEFFING: Thank you. Dr.
18 Nichols, during your testimony, you should not
19 look at any materials or documents except
20 exhibits you are directed to look at by Counsel
21 or me. Do you understand?

22 THE WITNESS: Yes.

23 JUDGE SOEFFING: Okay.

24 Counsel, you may inquire.

25 MR. PHELPS: Thank you, your honor.

1 DIRECT EXAMINATION

2 BY MR. PHELPS:

3 Q Good afternoon, Dr. Nichols. Thank
4 you for being here on short notice. I'd like
5 to direct your attention to what's been marked
6 for identification purposes as Exhibit No. 79.
7 It has the title Curriculum Vitae across the
8 top.

9 A Okay. Do you want me to bring it up
10 to my computer here?

11 Q Yes, sir, please.

12 A Just give me a second. Okay.

13 Q Do you recognize this document, sir?

14 A Just a minute. My computer started
15 going faster when I did this. Just a second.
16 Can you ask your question again? Maybe I could
17 --.

18 Q Yes. Do you recognize that
19 document?

20 A Yes. It's my curriculum vitae.

21 Q And did you -- are you familiar with
22 the contents of that document?

23 A In essence, yes.

24 Q Did you create that document?

25 A Yes.

1 MR. PHELPS: Your Honor, Petitioners
2 would move to admit what's marked for exhibit
3 purposes -- identification purposes as Exhibit
4 No. 79 into the record.

5 JUDGE SOEFFING: Mr. Mann, any
6 objection?

7 MR. MANN: Only to the extent that
8 the document hasn't really been described, its
9 number of pages and what it contains.

10 JUDGE SOEFFING: Okay.

11 MR. PHELPS: Certainly, we can lay a
12 little more foundation.

13 BY MR. PHELPS:

14 Q The document that you're -- that
15 you're looking at, how many pages is that, Dr.
16 Nichols?

17 A Let me scan to the back really
18 quickly. It totals 57 pages.

19 Q Thank you. And I don't want you to
20 go through the entire 57 pages, I don't think,
21 but as you're scrolling back up, could you make
22 note if you recognize the contents within those
23 57 pages?

24 A Well, yes, I wrote the CV, so yes.

25 Q Okay.

1 MR. PHELPS: Your Honor, at this
2 time, Petitioners would move to admit what's
3 marked for identification purposes as Exhibit
4 Number 79.

5 MR. MANN: No objection.

6 JUDGE SOEFFING: All right.
7 Petitioner's exhibit marked for identification
8 number 79 has been offered. In the absence of
9 objection, it is received in the record as
10 Petitioner's Exhibit 79.

11 (Whereupon, the document marked as
12 Petitioner Exhibit No. 79 for identification
13 was received into evidence.)

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

16 MR. PHELPS: Thank you, Your Honor.

17 BY MR. PHELPS:

18 Q Dr. Nichols, what degrees do you
19 hold?

20 A My first degree is a Bachelor of
21 Science degree in chemistry, and I have a PhD
22 in medicinal chemistry.

23 Q And where did you pursue your
24 undergraduate education?

25 A My undergraduate degree in chemistry

1 was from the University of Cincinnati. I
2 completed that in 1969.

3 Q And what did you study as an
4 undergrad?

5 A Basically, I was a chemistry major
6 with a minor in biological sciences, so all the
7 standard chemistry tests and basic biology,
8 biochemistry, and then, of course, the usual
9 history and English and literature courses,
10 things like that.

11 Q And where did you pursue your PhD?

12 A I was in the College of Pharmacy at
13 the University of Iowa in the Department of
14 Division of Medicinal Chemistry.

15 Q And what do you hold your PhD in?

16 A It's in medicinal chemistry, which
17 is the subject that sort of describes the
18 relationship between chemical structures and
19 their biological activities.

20 Q Can you talk a little bit about your
21 PhD coursework curriculum?

22 A So in medicinal chemistry, it's
23 somewhat interdisciplinary. We took all the
24 same courses that a chemistry major would take.
25 Analytical chemistry, organic chemistry,

1 advanced organic chemistry, mechanistic
2 chemistry.

3 And in addition, those are the major
4 courses. And then we also took minor courses
5 in things like biochemistry, pharmacology, to
6 round things out. And then specialized courses
7 we took in actually medicinal chemistry and
8 drug design, interpreting dose response curves
9 and that sort of thing.

10 Q And in addition to that curriculum
11 you just described, what else did your PhD
12 program consist of?

13 A Well, we had laboratory research
14 where we actually made specific molecules to be
15 tested. I also worked closely with the
16 pharmacology department, which was in the next
17 building over in the College of Medicine. Many
18 of the compounds that I made as a graduate
19 student were tested in the pharmacology
20 department.

21 And then subsequently, after I got
22 my PhD in January of 1973, I then spent time as
23 a postdoctoral fellow in pharmacology, learning
24 more about how biological assays were run, how
25 to interpret biological data, that sort of

1 thing.

2 Q And what was the topic of your
3 dissertation research?

4 A I was studying what were called
5 psychotomimetics, which also could have been
6 called hallucinogens, and more popularly were
7 called psychedelics. So my PhD work was on the
8 synthesis of novel molecules that fit into that
9 category of psychedelics, basically.

10 Q Can you explain what you mean about
11 the synthesis of those chemicals?

12 A So, we would actually envision the
13 structure of an organic molecule, and then
14 think about ways to make it and actually do the
15 laboratory work to put the reagents together.

16 Usually those were multiple-step
17 syntheses, and you couldn't just put two things
18 together and get a molecule. You would have a
19 sequence of steps you would have to carry out
20 to get to the final molecule.

21 Most of the molecules that I did
22 were related, in terms of their chemical
23 structure, to the molecule mescaline, which is
24 a naturally occurring compound from the peyote
25 cactus.

1 Q Was DOI involved at all in your
2 dissertation research?

3 A Actually, while I was a graduate
4 student, I received a patent for the synthesis
5 of those types of molecules related to people.

6 MR. MANN: Your Honor --

7 JUDGE SOEFFING: Hold on.

8 MR. MANN: -- specific questions be
9 asked and answered, and we don't go on to a
10 narrative about something else.

11 JUDGE SOEFFING: I think we can give
12 some free reign in exploring his background so
13 overruled.

14 MR. PHELPS: I just want to note, we
15 will be keeping this tailored, too, as we've
16 been doing.

17 BY MR. PHELPS:

18 Q Please continue, Dr. Nichols.

19 A Actually, I developed the synthesis
20 for making the optical isomers of DOI, and that
21 was the patent that I received while I was a
22 graduate student.

23 Q So we've heard a lot of chemistry
24 talk in the last few days, but I haven't heard
25 specifically about the isomers. Could you just

1 explain the basic chemistry behind that?

2 A Basically, all living organisms are
3 made of amino acids. They're comprised of
4 proteins, which are made of amino acids. All
5 amino acids are of only one type.

6 If you think about your left hand
7 and your right hand, they're mirror images. So
8 if you hold your right hand in front of a
9 mirror, the image in the mirror is actually of
10 your left hand. Many organic molecules have
11 such optical isomers or mirror images.

12 They're called, sometimes,
13 enantiomers or optical isomers. Hallucinogenic
14 amphetamines like DOI have both a right and
15 left-handed mirror image. They're called
16 enantiomers or optical isomers. I developed a
17 method for making the optical isomers of
18 substituted hallucinogenic molecules, including
19 DOI.

20 Q Is there a difference in how
21 different isomers of the same chemical
22 function?

23 A Yes, because the body is made of
24 amino acids of only one type. They're called
25 L-amino acids. Amino acids also have these

1 optical isomers.

2 In nature, the ones that comprise
3 our bodies are made only of the L-amino acids.
4 The receptors that drugs bind to are made of
5 these proteins and amino acids that are only of
6 one type of what's called chirality, left-
7 handed or right-handed.

8 If you have a drug where you have
9 two possible mirror images, like DOI, they
10 interact differently with the receptors because
11 the receptors are only one kind of amino acid.

12 For example, DOI, the most potent
13 isomer of DOI, is designated as R, and it
14 rotates plane polarized light to the left.
15 It's a levorotatory. That's the more potent of
16 the isomers of DOI.

17 Q Approximately how many peer-reviewed
18 articles have you published on your research?

19 A I think it's around 300. I mean, I
20 can check my CV, but somewhere around, let's
21 see. I guess I could scroll down here pretty
22 quickly.

23 Actually, peer-reviewed
24 publications, as of today, I have 293. Then I
25 have a number of book chapters and monographs

1 that were written. They're not peer-reviewed,
2 but also they're scientific publications. About
3 300 are peer-reviewed.

4 Q Thank you. Of those 300 -- so peer-
5 reviewed articles and the other publications
6 you described, how many of those would you say
7 deal with the structure activity relationships
8 of psychedelic agents?

9 A More than half. I had three
10 research grants that were supported by the
11 government. One had to do with psychedelics or
12 hallucinogens, and that ran for 28 years, I
13 think.

14 Then I had one to study drugs that
15 could potentially be used in treating
16 Parkinson's disease or schizophrenia. There
17 was a fewer of those.

18 Then I had a third grant that I
19 worked on for 12 years that was to study drugs
20 related to MDMA or ecstasy.

21 Q Where have you published that
22 research?

23 A Mostly in scientific journals. Many
24 of mine were in the Journal of Medicinal
25 Chemistry, which is the main publication of the

1 American Chemical Society. But I also had a
2 joint appointment and was a pharmacology
3 professor at Purdue as well. Many of my
4 publications were also published in
5 pharmacology journals.

6 Q And in addition to your PhD program
7 that you described, do you have any other
8 educational experience that's relevant to the
9 study of the structure activity relationships
10 of psychedelic agents?

11 A Well I did a postdoctoral fellowship
12 in pharmacology. I did behavioral
13 pharmacology. And when I was at Purdue, I
14 actually was given a joint appointment as a
15 professor of pharmacology.

16 I also taught pharmacology. I also was an
17 adjunct professor in the Indiana University
18 School of Medicine. I taught portions of
19 courses in pharmacology to the medical
20 students. So I jointly taught in
21 chemistry, medicinal chemistry, and
22 pharmacology. And that really facilitated my
23 research in psychedelics because most medicinal
24 chemists are principally chemists. They send
25 their compounds to someone else for testing,

1 but I could do the testing in-house.

2 So I taught -- I had graduate
3 students that were trained both in chemistry
4 and also in pharmacology. It was kind of a
5 mixture of doing two different things.

6 Q And could you just explain
7 specifically what is the study of the structure
8 activity relationships of psychedelic agents?
9 What does structure activity relationships
10 mean?

11 A So every organic molecule has a
12 specific structure. We have mixtures of carbon
13 atoms and aromatic rings and so forth. And
14 they interact in the body with various types of
15 enzymes or receptors.

16 So in the absence of a photograph of
17 what that receptor actually looks like, what
18 you do is make a series of chemical molecules,
19 and then you put them into that biological
20 system to see what is their relative activity.

21 Do they activate that receptor, or
22 do they inhibit that receptor, or do they
23 activate some enzyme, et cetera. And so the
24 degree to which a molecule will activate a
25 receptor or an enzyme is related to its

1 chemical structure.

2 So if you modify a molecule, it will
3 change its activity. So by making a series of
4 molecules, a series of structurally related
5 molecules, and then looking at how they
6 interact with that biological target, which
7 ones are more potent, which ones are less
8 potent, you can actually infer something about
9 what the shape of that receptor is.

10 We were trying to understand what
11 the receptor was that these hallucinogens or
12 psychedelics are bound to. We didn't have a
13 picture of it, so we made a series of
14 molecules, and then we would test them in these
15 biological systems to see which were more
16 potent than others.

17 And that would lead us to inferences
18 about what that receptor looked like, sort of
19 the mirror image, if you will, of the molecule.

20 Q And is the study of structure
21 activity relationships limited to only
22 psychedelic agents?

23 A All drugs that are out there, every
24 drug that's been made, every pharmaceutical
25 company, all medicinal chemists basically focus

1 on that. What is it about the molecule itself
2 that gives it the particular properties it has
3 in activating a receptor, or turning on an
4 enzyme, or turning off an enzyme?

5 This is basically the way that drugs
6 are developed, by understanding when you modify
7 one molecule and it changes its biological
8 activity, and does that give you a new drug, or
9 does it give you a new direction? Or you can
10 do a series of modifications and find something
11 that's the most active.

12 Q And could you please describe any
13 experience you may have testifying as an expert
14 witness in other proceedings?

15 A I've testified in a couple of
16 criminal cases. I don't usually do that. And
17 then I was qualified as an expert, and I
18 testified as an expert in a number of cases
19 where pharmaceutical companies had a patent,
20 and some other company was trying to invalidate
21 their patent.

22 And I testified as an expert with
23 respect to the chemistry and pharmacology of
24 those drugs and whether it was a legitimate
25 discovery or not. So I've been in a number of

1 courtroom situations, maybe 10 or 12 over the
2 years.

3 DR. PHELPS: Your Honor, at this
4 time we would move to have Dr. Nichols admitted
5 as an expert in the study of the structure-
6 activity relationships of psychedelic agents.

7 JUDGE SOEFFING: Mr. Mann?

8 MR. MANN: Judge, we have no
9 objection to him being admitted as an expert.
10 We can move on to the subject matter disclosed
11 in the pre-hearing statement.

12 JUDGE SOEFFING: Okay. The
13 Petitioners have offered Dr. Nichols as an
14 expert in the study of the structure-activity
15 relationships of psychedelic agents.

16 In the absence of any objection by
17 the Government, the tribunal accepts the
18 witness as an expert in the study of the
19 structure-activity relationships of psychedelic
20 agents.

21 MR. PHELPS: Thank you, Your Honor.

22 BY MR. PHELPS:

23 Q Dr. Nichols, could you tell us when
24 you first started working with psychedelic
25 agents?

1 A That was actually the subject of my
2 graduate work, which I began in 1969.

3 Q And when you were doing that
4 research, did your lab have a DEA Schedule I
5 license?

6 A Yes, I did. I had a Schedule I
7 license that included 15 specific compounds.

8 Q And was -- maybe I got confused
9 there. Was that during your grad school that
10 you were talking about that you had one?

11 A No. The Controlled Substances Act
12 was not passed until 1970, and I started in
13 1969.

14 And I don't know what the licensing
15 requirements were when it first started, but
16 the laboratory where I was working, Dr. Charles
17 Barfknecht did not have a Schedule I license.
18 So we made a lot of compounds, which ultimately
19 became controlled substance, but at the time we
20 made them in 1969, 1970, and so forth, they
21 weren't actually controlled substances. Later
22 on, they were included in the Schedule I
23 category, but not when I was a graduate
24 student.

25 Q Were there significant differences

1 in how you studied those chemicals prior to the
2 passage of the Controlled Substances Act?

3 A When I was a graduate student and a
4 post-doctorate fellow, the compounds that I
5 worked with, by and large, were not included as
6 controlled substances in the DEA registration.
7 It was after I got to Purdue and wanted to
8 continue this work in my own laboratory that I
9 had to get a Schedule I license and started
10 putting the compounds in that license that I
11 was working with.

12 Q How did that change the practices in
13 your lab?

14 A Well, when I was a graduate student
15 and even a post-doc, we basically just kept
16 them -- we just kept the substances in bottles
17 that were in drawers. We didn't really have to
18 worry about diversion, which is what the DEA
19 was really focused on.

20 When I got to Purdue, to get my
21 Schedule I license, I had to have a safe. I
22 actually have a locked file cabinet. It had to
23 be in a specific area with a locked entry door
24 and restricted access. And then, I had to keep
25 an inventory of all the controlled substance.

1 We had to have an inventory book of how much we
2 had and how much was taken out at various times
3 by specific individuals who were authorized to
4 work with those. So we had -- the record-
5 keeping was more onerous then.

6 Q What other kinds of -- well, let me
7 take a step back. Other than your own personal
8 research into the structure activity
9 relationships of psychedelic agents, did you
10 stay up to date with other researchers
11 conducting similar work?

12 A Oh, yes. I, basically, to be a
13 researcher in the field, you pretty much have
14 to keep up with what other people are doing.
15 So you see if they make breakthroughs and that
16 may affect what you do or give you a different
17 perspective. So I, basically, was familiar
18 with the whole field, yes.

19 Q Okay. And what changes did you see
20 across the field as a whole as a result of the
21 passing of the Controlled Substances Act?

22 A Well, when I was a graduate student,
23 there were no really controls. We just put
24 them into a -- in a laboratory drawer. We
25 didn't have to really worry about that. Then,

1 when I got to Purdue and I had to get a
2 Schedule I license, that involved an inspection
3 of my facilities, random inspections of my
4 inventory at various times.

5 Over the period of time that I was
6 at Purdue for 38 years, the regulations became
7 more stringent. When I first got my Schedule I
8 license, you simply had to register with the
9 DEA. And then, they changed the procedures
10 later on. They wanted to know the experiments
11 you were going to do, how much you were going
12 to use. And then they changed the procedures
13 so that they have to get another review by
14 someone, I believe, at the Food and Drug
15 Administration. They started inspecting more
16 often.

17 So, in the beginning, the
18 regulations were more flexible. You didn't
19 really have to specify how much you needed at
20 any point in time. I don't remember that I had
21 to do that. But later on, you really -- they
22 wanted to know how much you were going to use,
23 how many animals you were going to use. You
24 had to justify the amount you were going to use
25 by a number of animals and the drug per dose,

1 so really a lot more regulation in terms of the
2 drugs.

3 And even drugs, for example, I have
4 a Schedule I license for working with
5 mescaline, which is like one of the oldest
6 psychedelics. That's isolated from the peyote
7 cactus. Typically, the amounts that I would
8 need for my lab would be 20 or 30 milligrams
9 for rat studies or mouse studies. Whereas, the
10 human dose would be 200 or 300 milligrams. So,
11 even though I had trivial amounts of the
12 mescaline, I still had to keep the same
13 records.

14 Q And outside of your own research,
15 how did those changes in the regulations impact
16 the broader landscape of the study of the
17 structure activity relationships of psychedelic
18 agents?

19 MR. MANN: Objection, Your Honor.
20 This witness is not being offered as an expert
21 in research or the broad spectrum of research
22 that's going on. He can only speak about his
23 own experiences.

24 MR. PHELPS: That's a total
25 mischaracterization of his expertise. It is

1 the study of the structure activity
2 relationships of psychedelic agents, not his
3 own personal study.

4 JUDGE SOEFFING: So overrule the
5 objection. He may answer

6 BY MR. PHELPS:

7 Q Dr. Nichols, how did the broader
8 landscape of this type of research, how was it
9 impacted by these changing regulations?

10 A Well, I, over the years, met many
11 other scientists. I was considered a
12 neuroscientist, and I met many other
13 neuroscientists. And when I -- when they would
14 find out that I was working on psychedelics, a
15 lot of the times, they were, I would say,
16 somewhat envious.

17 And they would say things like,
18 well, that sounds really interesting, but it's
19 too much of a headache to get into that field,
20 or it's too hard to get money for that field; I
21 don't want to get into it. So there was
22 any -- any impediment to research really
23 affected anybody who wanted to work in this
24 field.

25 You know, you may not know much

1 about academics, but if you're an academic,
2 when you start off as an assistant professor,
3 you have basically five years to get a grant
4 for your research most places. If you don't
5 get a grant, you don't get a -- you don't get
6 tenure and promotion, and so you'd look for
7 another job.

8 So it was a risky field. I was one
9 of the very few that was doing any research on
10 psychedelics. I knew a lot of people that had
11 an interest in the field, and they were
12 somewhat envious. Like, you know, boy, that's
13 a lot of work; how did you get into that field,
14 and why are you doing it, and so forth, and so
15 on. And I knew a lot of people personally that
16 would say --

17 MR. PHELPS: Your Honor, I'm sorry
18 to interrupt the witness. I'm trying to keep
19 my thoughts composed here, and I keep being
20 distracted by the talk at the other table. If
21 we could just have some direction there,
22 please?

23 JUDGE SOEFFING: Okay. Well, I
24 think they're doing their best. There are a
25 lot of people involved in this case, and you

1 are going off the -- a lot of this is not
2 covered in the prehearing statement.

3 So I can see why Government counsel
4 needs to consult with each other because you're
5 talking a lot about the history of the changes
6 that happened when the Controlled Substances
7 Act was implemented, and I don't see that in
8 the prehearing statement. So I can kind of
9 understand why the Government counsel needs to
10 consult. I think they are trying to be as
11 quiet as possible.

12 MR. PHELPS: Okay. Well --

13 JUDGE SOEFFING: I'll again say, you
14 know, if we could try to keep the whispering to
15 a minimum. I'm sorry that it's been
16 distracting to you, but I will give that
17 instructions.

18 Mr. Mann, you had something to say?

19 MR. MANN: Yeah, may I be heard,
20 Judge? And I'm sorry about the distraction.

21 He has been qualified as an expert
22 in the study of the structure activity
23 relationships of psychedelic agents. I really
24 fail to see how that makes him an expert on the
25 entire scope of research activity involving

1 these two controlled substances. I don't see
2 there how there is any connection between those
3 two.

4 He's offering an opinion about all
5 of the other people who are researching DOI and
6 DOC, presumably. And his expertise is confined
7 to an ability for the Tribunal to understand
8 the structure activity relationships of
9 psychedelic agents. I just don't get it.

10 MR. PHELPS: And Your Honor, if I
11 could respond?

12 JUDGE SOEFFING: Certainly.

13 MR. PHELPS: The expertise is
14 specifically in the study of the structure
15 relationships of psychedelic agents. He has
16 been involved in the study of those since 1969,
17 and his history, his understanding of the
18 history of the study of these substances,
19 that's what he's an expert in.

20 It's not saying he's an expert in
21 testing, or -- he's an expert in the study of,
22 which to say that being an expert in the study
23 of a particular field does not include the
24 history of the study in that field and the
25 context in which the study of these structure

1 activity relationships of psychedelic agents
2 take place is -- I mean, the study of something
3 is includes the history and the context in
4 which that research and studying is taking
5 place.

6 He's not testifying. He's not -- he
7 hasn't been admitted as an expert in his own
8 lab expertise or his own personal ability to do
9 different things with structure activity
10 relationships. He is an expert in the study of
11 this. And every sentence of his testimony has
12 been directly related to the study of the
13 structure activity relationships of psychedelic
14 agents.

15 JUDGE SOEFFING: Mr. Mann?

16 MR. MANN: Yes, Judge. I think a
17 more suitable analogy here is that this is like
18 a trigonometry professor trying to act as an
19 expert in education. He is a -- of the study
20 of activity relationships with psychedelic
21 agents. Of course, none of that is
22 meant -- none of that is expounded upon in the
23 prehearing statement. But that's what he's
24 been accepted as an expert in.

25 He's not an expert in research

1 techniques, research patterns, research
2 behavior, and research history. If he was
3 going to testify about that, he should've been
4 qualified as an expert in those areas, and that
5 was not disclosed to the Government.

6 MR. PHELPS: I'm just baffled at
7 what the Government's understanding of what the
8 study of something entails, Your Honor.

9 JUDGE SOEFFING: So here's
10 what -- okay. I think he has talked about the
11 fact that he needed to keep up on other areas
12 of research, what other researchers were doing,
13 so that he knew what the effect or potential
14 effect would be on his own research. So,
15 again, I'm going to give some leeway here.

16 I do think that because of the
17 prehearing statement and what he's been
18 accepted as an expert in, the Tribunal is most
19 interested in what he has to say about the
20 structure activity relationships. We have
21 heard from other witnesses, and I expect we'll
22 hear more about general research activity, so,
23 you know, I --

24 MR. PHELPS: Well, and I'm sorry to
25 interrupt, Your Honor. The reason I'm

1 specifically trying to go through this is
2 because it's my understanding that the Court is
3 fairly familiar, at this point, with these
4 granular level details of the study of these
5 substances. And so, Dr. Nichols provides a
6 very unique particular expertise within this
7 study that's beyond what we've been hearing
8 about for the last four days.

9 So, if you'd like him to talk
10 chemistry and those kind of things, we can go
11 down that road, but I thought it would be most
12 helpful for this Court to have a broader
13 understanding of the historical context in
14 which this study is taking place, and really
15 the what everything we've heard in the last
16 four days is taking place in.

17 JUDGE SOEFFING: Well, I'm not
18 seeing a lot of the history. Like the stuff
19 he's talking about from 1969, 1970, when the
20 Controlled Substances Act was first enacted and
21 how that changed things, I don't see that in
22 the prehearing statement.

23 MR. PHELPS: Your Honor, at the
24 bottom of page 26, he does say he will testify
25 to the great difficulty to obtain a license to

1 work with Schedule I substances. And I think
2 that's exactly what he's testifying about right
3 now.

4 JUDGE SOEFFING: Well, I take that
5 to be current, the difficulty to get a license
6 today, a registration today to work with
7 Schedule I substances, not what was going on in
8 1969, 1970. I think this is about contemporary
9 issues and what's going today with the DEA and
10 whether these should be scheduled and not what
11 was happening in 1969, 1970.

12 So, I mean, a little bit of that is
13 fine to lay some background, but you're
14 spending a lot of time on it. I don't see that
15 in the prehearing statement, so I do understand
16 the Government's frustration on that. But you
17 know, as you see, my practice is to give some
18 leeway to people on things.

19 MR. PHELPS: Certainly. We don't
20 have to do an entire history lesson. I
21 understand the Court's direction, and we can,
22 yeah, not a problem.

23 JUDGE SOEFFING: Okay. That'd be
24 appreciated. Thank you.

25 MR. PHELPS: Certainly.

1 JUDGE SOEFFING: You may ask your
2 next question.

3 MR. PHELPS: Thank you.

4 So, Dr. Nichols, what do you know
5 about the difficulty of obtaining a Schedule I
6 license today?

7 THE WITNESS: It's more difficult
8 than it was when I started my work. I saw it
9 evolve over the period of time I was at Purdue
10 as the regulations and oversight became more
11 and more onerous; I'll use that word.

12 My son is also a researcher at
13 Louisiana State University of Health's Medical
14 School. He got a Schedule I license to work
15 with compounds, and that was more recent. That
16 was 2007, I think, around then. And I watched
17 his frustration as they bungled his inspection
18 the first time. It took him a long time to get
19 his license. He expressed his frustration to
20 me.

21 Other people have told me the same
22 thing. In New York University, where they use
23 psilocybin for treating patients, the local DEA
24 comes in and inspects their safe very regularly
25 to see if any is missing.

1 MR. MANN: Objection, Your Honor.
2 None of this has been disclosed in the
3 prehearing statement, and it's all hearsay.

4 MR. PHELPS: Again, this is exactly
5 what the Court was asking to give context to
6 this today. This is in the study of his
7 labeled expertise. This is entirely relevant.

8 JUDGE SOEFFING: Well, it is
9 hearsay. I have accepted that previously.
10 He's making certain characterizations about how
11 DEA conducted its investigations. I'm not
12 likely to give a lot of weight to this. It's
13 not specifically laid out.

14 Certainly, you talk about he will
15 testify to the difficulty to obtain a Schedule
16 I registration, but prehearing statements were
17 supposed to give some more detail and not just
18 the subject matter you cover, but what the
19 testimony would be. So I would ordinarily
20 expect to see a little more detail in there.
21 I'll sustain the objection in light of that.
22 Ask your next question.

23 MR. PHELPS: So, Dr. Nichols, how
24 many Schedule I licenses have you personally
25 been involved in applying for or helping others

1 apply for since 1969?

2 MR. MANN: Objection. Compound
3 question.

4 JUDGE SOEFFING: Sustained as to the
5 form of the question. If you could, break that
6 up.

7 MR. PHELPS: Yes. Dr. Nichols, how
8 many Schedule I licenses have you obtained for
9 your own personal research over the course of
10 your career?

11 THE WITNESS: I had one Schedule I
12 license which was expanded to include 15
13 specific controlled substances.

14 BY MR. PHELPS:

15 Q And that was the original?

16 A Yes. You renew the license
17 regularly.

18 Q Okay. And have you maintained that
19 license since that time?

20 A I did until my retirement from
21 Purdue in 2012. The lab I work in now has a
22 different license, so I work in that lab.

23 Q Okay. And approximately how many
24 licenses have you assisted other researchers in
25 obtaining over the course of your career?

1 A I've probably had discussions with
2 half a dozen or so people who got licenses when
3 they would ask for, you know, my hints, what do
4 you think I should do; should I do this; what
5 do I need to do?

6 Unfortunately, I don't have
7 notarized documents from all of those people to
8 tell you, so I can't tell you specifically.
9 But I did help just because I had a license.
10 People knew I had a license, and they would
11 come to me and say how do we do this, how hard
12 is it, what do I need to do? So I counseled a
13 number of people. I would guess at least half
14 a dozen, maybe even ten.

15 Q Now, Dr. Nichols, I'd like to talk a
16 little bit about your historical experience
17 with laboratory safety and diversion
18 prevention. You said that there's historically
19 been changes in how laboratory safety and
20 diversion prevention --

21 MR. PHELPS: Let me take those one
22 at a time, Your Honor. They're listed together
23 in the supplemental prehearing statement, but
24 we can take those one at a time.

25 Dr. Nichols, could you tell us about

1 your historical experience with laboratory
2 safety, particularly within the context of the
3 study of psychedelics?

4 THE WITNESS: Laboratory safety?
5 Well, psychedelics are very safe molecules, so
6 it was never a safety issue. Basically, we
7 just had to do things in a way that was
8 acceptable to the Drug Enforcement
9 Administration, which meant keeping records.
10 People that were authorized to obtain Schedule
11 I substances, I had a list of those people.

12 We had to keep the track of how much
13 they took out and when they took it out and
14 that sort of thing, so regular inventories, and
15 then the DEA would come in randomly at various
16 times to check and see if your inventory was up
17 to snuff.

18 BY MR. PHELPS:

19 Q Can you tell us a little bit about
20 your historical experience with diversion
21 prevention
22 in the study of psychedelic agents?

23 A Once the CSA was passed in 1970,
24 then I started Purdue in 1974. As of that
25 point, I had to apply for a license. I had to

1 have a specific secure storage area. I
2 happened to be in an office that had an outer
3 chamber where the secretary was, so that door
4 was locked; my inner door was locked. We
5 didn't have alarms. It was just controlled
6 just by whoever had access to the room. And
7 all of the controlled substances were locked up
8 in the safe in my office.

9 Q And you testified previously that,
10 based on your understanding, it was this
11 diversion prevention was a main concern in the
12 passing of the Controlled Substances Act?

13 A I don't know the motivations at that
14 point, but the DEA's goal is to prevent
15 diversion of controlled substances, so I was
16 aware of that.

17 Q Okay. Have you, in your years of
18 experience since 1969, seen evidence of
19 diversion of DOI?

20 A No. I don't think that DOI ever
21 became popular.

22 On my -- you know, I would read
23 Microgram sometimes, and you would see news
24 reports. Lots of things had been confiscated
25 in underground labs. I can't recall ever

1 seeing an incidence of DOI. My impression is
2 it wasn't a very popular drug because it was
3 very long-lasting.

4 Q And when you were at Purdue doing
5 your work, who was -- where did you receive
6 your funding for the study of psychedelics?

7 A That grant was funded by the
8 National Institute on Drug Abuse.

9 Q And could you explain a little bit
10 about how that grant worked?

11 A When I first got the grant, I had it
12 for 28 years. I first got it was the study of
13 structure activity relationships of
14 psychedelics. So not a -- there wasn't much
15 known about psychedelics. We knew that there
16 was LSD or mescaline, psilocybin, but there
17 wasn't much known beyond that.

18 And so, I was focused on
19 understanding the kinds of drugs that would
20 have similar properties and what their targets
21 were in the body. And I used rats, mice,
22 isolated tissues, receptor-binding assays to
23 really understand the interface between the
24 chemicals and the biology.

25 Q Have you stayed up to date on the

1 current study of psychedelic research since
2 your retirement in 2012?

3 A Yes. After I retired, I moved to
4 Chapel Hill and was granted the courtesy
5 appointment in the laboratories of
6 Dr. Bryan Roth. He's had an extensive program
7 to study crystal structures of psychedelics
8 bound through receptors. I've consulted. I
9 did some chemistry myself here. I'm also the
10 co-founder of a startup company that's studying
11 psychedelics as anti-inflammatory agents.

12 So I've been continuously involved
13 in this research area since my retirement from
14 Purdue in 2012. And I continue to publish. I
15 have four papers now in press this year having
16 to do with psychedelics.

17 Q Dr. Nichols, how did the DEA's
18 scheduling of hallucinogens originally, when
19 this happened more than 50 years ago, impact
20 the discovery of the medical utility of
21 psychedelics?

22 MR. MANN: Objection. Not disclosed
23 in the prehearing statement.

24 MR. PHELPS: Your Honor, if you look
25 at the second to last paragraph on page 26, we

1 will specifically testify how DEA's scheduling
2 of hallucinogens more than 50 years ago
3 significantly hindered discovery of their
4 medical utility.

5 MR. MANN: I'm sorry. I withdraw
6 the objection.

7 JUDGE SOEFFING: It's withdrawn.

8 You may answer the question, Doctor.

9 THE WITNESS: Can you restate the
10 question?

11 BY MR. PHELPS:

12 Q Yes. So you would consider yourself
13 up to date on the latest psychedelic research?

14 A Yes.

15 Q And without going into too much
16 detail because we've heard a good bit about it,
17 what have been some of the recent discoveries
18 that you're aware of in your review of the
19 literature?

20 A So what most people are aware of is
21 the fact that psychedelics -- in particular,
22 psilocybin has been used -- can reverse the
23 symptoms of treatment-resistant depression. A
24 single treatment can provide profound relief
25 from depression in patients who have not

1 responded to conventional treatments like
2 SSRIs.

3 LSD has been used to show that a
4 single treatment with LSD can reverse anxiety
5 and depression. DMT has been used in the form
6 of ayahuasca, also as just DMT, to show that it
7 can reverse depression. These are novel
8 treatments for depression and anxiety
9 disorders.

10 It's been shown that psilocybin can
11 attenuate alcohol-seeking behavior in humans
12 who have alcohol use disorder. And psilocybin
13 therapy can disrupt smoking addiction. A paper
14 which has not been published has shown that
15 psilocybin can reverse the symptoms of
16 obsessive-compulsive disorder.

17 A paper done at the University of
18 Alabama at Birmingham, by Peter Hendricks, has
19 shown -- has been published that has shown that
20 psilocybin can reverse addiction in persons who
21 are addicted to cocaine. They're finding lots
22 and lots of things. This has all been since
23 about 2016 when the first papers came out.

24 So psychedelics have been shown to
25 have tremendous potential in treating central

1 nervous system disorders, depression, anxiety,
2 and substance use disorders. And we've
3 discovered and start basis for our company that
4 psychedelics are useful in treating depression
5 and anti-inflammatory -- and inflammatory
6 conditions.

7 In fact, a company has been founded
8 called 2A Biosciences, which is focused
9 specifically on studying psychedelics as anti-
10 inflammatory agents. None of this work
11 would've happened were these agents -- it
12 would've happened much sooner had these not
13 been controlled substances.

14 Q So, in your expert opinion, how did
15 the DEA's scheduling of these psychedelics more
16 than 50 years ago hinder the discovery of their
17 medical utility?

18 MR. MANN: Objection. This is not
19 within his scope of his expertise.

20 MR. PHELPS: This is --

21 JUDGE SOEFFING: Overruled. He may
22 answer.

23 THE WITNESS: I should mention that
24 I have written several papers on the history of
25 psychedelics and psychiatry. I'm well aware of

1 the history of all this.

2 So what I started to say before was
3 if you're an assistant professor, you have five
4 years to get a grant, or you'll lose your
5 position.

6 Many people that I have met
7 personally -- and I don't have documentation of
8 all of them -- many people have said I wish I
9 could work in this field but it's too much
10 trouble. I'd have to get a license. There's
11 no money. The government still doesn't fund
12 research with psychedelics. Most of the
13 research has been funded by philanthropists.
14 Even to the present time, there's only one or
15 two grants that have been funded to study
16 psychedelics.

17 So this idea that they're dangerous
18 substances and their regulation by the DEA, in
19 my opinion, has been a disinhibiting effect.
20 It's kept people out of the field for more than
21 50 years. These discoveries could have been
22 made years ago if these drugs had been more
23 available for researchers.

24 The claim is that by regulating
25 them, it doesn't keep legitimate researchers

1 out of the field, but it does, in fact. And if
2 you talk to anyone in the field, they'll tell
3 you. Having to get the safe, having your
4 records inspected all the time, the application
5 procedures, it's a disincentive for people to
6 be in this field.

7 Now, I don't know how much sooner
8 these things would've been discovered had there
9 not been such regulation, but I don't think it
10 would've taken 50 years to discover some of the
11 things that we know now about them.

12 Q And so, just to zoom out a little
13 bit, how would you say that everything you just
14 described affected public health?

15 A Well, we have a desperate need for
16 treatment --

17 JUDGE SOEFFING: Hold on, Doctor.
18 Hold on a second, Doctor. There's an
19 objection.

20 Mr. Mann?

21 MR. MANN: This has not been
22 disclosed in the prehearing statement.

23 MR. PHELPS: It -- specifically
24 medical utility, I think is relevant to public
25 health.

1 JUDGE SOEFFING: Overruled. That
2 seems pretty similar to the last question you
3 asked, but there's more to the answer.
4 Overruled.

5 MR. PHELPS: Fair enough.

6 So what would you say the scheduling
7 of these substances 50 years ago, what would
8 you say was their impact on public health in a
9 broader sense?

10 THE WITNESS: Terribly damaging, in
11 my opinion.

12 BY MR. PHELPS:

13 Q And in your expert opinion, what is
14 the potential risk to public health of
15 scheduling -- of placing DOI into Schedule I?

16 A Placing DOI in Schedule I, I think,
17 would be a disaster. It's the only substance
18 that acts at these types of receptors that's
19 available for researchers to use that don't
20 have a Schedule I license.

21 Q Just a couple more questions,
22 Mr. Nichols, and we'll wrap it up.

23 Are you familiar with the chemist
24 named Alexander Shulgin?

25 A Yes. He and I were colleagues.

1 Q And are you familiar with
2 Dr. Shulgin's work on DOI?

3 A I don't know specifically because he
4 worked on a lot of different compounds. I'm
5 sure that he has said something about it in one
6 of his books, but that wasn't the focus. That
7 was a main focus of his -- of his work.

8 Q Okay. You said that you were
9 colleagues with Dr. Shulgin?

10 A He was the only other person who was
11 working in this field, and as a result, I met
12 him early on because that's the research I was
13 doing, and he was the only other person doing
14 research in this field. So I communicated with
15 him regularly.

16 Q And through your personal working
17 with him, were you familiar with Dr. Shulgin's
18 assessment of the dangerousness of psychedelic
19 substances?

20 MR. MANN: Objection. Your Honor, I
21 don't see where this is in the prehearing
22 statement.

23 JUDGE SOEFFING: Mr. Phelps?

24 MR. PHELPS: We'll withdraw the
25 question, Your Honor.

1 JUDGE SOEFFING: Okay. Question is
2 withdrawn.

3 BY MR. PHELPS:

4 Q One last question for you,
5 Dr. Nichols. In your expert opinion, why
6 shouldn't these compounds be placed in Schedule
7 I?

8 A What we know is that psychedelics
9 work by activating a receptor in the brain
10 called the Serotonin 2A Receptor. We now know
11 today that that receptor is extremely important
12 in controlling things like addiction,
13 depression, end-of-life anxiety, et cetera.

14 If you want to study that receptor,
15 there are very few tools. They are all
16 psychedelics, and the only psychedelic that's
17 not controlled is DOI. There are over 800
18 publications that DOI was used, where DOI was
19 used as a chemical tool to study that receptor.

20 And if I can be permitted, I'll tell
21 you a specific example of a case where I know
22 that the regulation of DOI as a Schedule I
23 substance would have destroyed an area of study
24 that's currently ongoing. Am I allowed to
25 talk?

1 Q Yes.

2 MR. MANN: Objection.

3 JUDGE SOEFFING: You may complete
4 your answer, Dr. Nichols.

5 THE WITNESS: Does that mean I can
6 give the specific example?

7 JUDGE SOEFFING: Yes, you may.

8 THE WITNESS: So my son is a
9 pharmacologist at Louisiana State University in
10 New Orleans. He was there when Katrina hit and
11 destroyed all the samples he'd brought with him
12 from his post-doctorate fellowship at
13 Vanderbilt. He wanted to study psychedelics,
14 but everything he had brought, all his samples
15 were destroyed.

16 When he got his lab back up and
17 running again, he wanted to work in this field,
18 but he didn't have a Schedule I license. And
19 he contacted me and said, is there any
20 substance that's an agonist that acts at the
21 Serotonin 2A Receptor, a psychedelic that's not
22 a controlled substance?

23 And I said, there's only one. It's
24 called DOI. He said, do you have one; do you
25 have any? I sent him the DOI because I had

1 developed a method for synthesizing it.

2 He had a post-doctoral fellow he had
3 recently recruited that was looking at cardiac
4 damage, and he had some cells, aortic smooth
5 muscle cells that he'd grown up. And he wanted
6 to test them because he was going to have to
7 discard them because they had grown up, and
8 they were almost in contact with each other,
9 and you can't use cells once they start
10 contacting each other.

11 He asked my son, do you have a
12 compound that I could test? My son had the
13 bottle of DOI on the bench, and he said, can I
14 test this DOI against these cells? My son
15 laughed because he said DOI is a psychedelic,
16 and we're looking at it for anti-inflammatory
17 effects.

18 And this post-doc, a Chinese fellow,
19 said, yes, I know, but I have to destroy these
20 cells. Do you mind if test DOI on these cells?
21 My son laughed and said go ahead.

22 He came back a week later, very
23 excited. He said that compound, DOI, is the
24 most potent anti-inflammatory I've ever seen.
25 It has a concentration where it's effective of

1 20 times 10 to the minus 10th molar, 20
2 picomolar. I've never seen anything that
3 potent before.

4 My son didn't believe him. And so,
5 he ran the assays himself and reproduced that
6 value. That was his first publication on
7 psychedelic as an anti-inflammatory.

8 Two companies have been founded now.
9 One called Eleusis, which has been merged with
10 another company, and then the compound I'm
11 currently involved with, 2A Biosciences,
12 developing specifically anti-inflammatory
13 agents based on psychedelics.

14 Had DOI been a controlled substance
15 then, we would not have discovered they have
16 the anti-inflammatory properties, and this
17 whole other field of investigation would not
18 have occurred if DOI had been Schedule I.

19 It was an accidental discovery. He
20 didn't expect it to happen. He got some DOI,
21 which was not a controlled substance, and
22 tested it. If it had been a controlled
23 substance, he wouldn't have gotten it. This
24 discovery never would've occurred.

25 That's a specific example that I'm

1 familiar with of where if DOI had been Schedule
2 I, it would've killed this whole area of
3 investigation, which has been the basis for two
4 startup companies and the current company I'm
5 with now.

6 These anti-inflammatory agents are
7 more potent than any known anti-inflammatory
8 agents, including steroids and the standard
9 anti-inflammatory agents like ibuprofen, et
10 cetera. It's a whole new area of investigation
11 that was only discovered because DOI was not a
12 controlled substance.

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

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

17 Mr. Mann?

18 MR. MANN: Yes. Thank you.

19 Good afternoon, Dr. Nichols.

20 THE WITNESS: Afternoon.

21 CROSS-EXAMINATION

22 BY MR. MANN:

23 Q I just want to clarify something.
24 You said that DOI is the only 2A receptor and
25 agonist that is not controlled?

1 A Agonist. Yes.

2 Q That's the only one that's not
3 controlled, no others?

4 A That's the one at the time when he
5 was doing his work, yes.

6 Q And what time was that?

7 A What's that?

8 Q When was that?

9 A 2007.

10 Q Now, you testified about that you
11 used to keep your psychedelic drugs in bottles
12 in drawers; is that correct?

13 A When I was a graduate student, yes.

14 Q Okay. And you don't like the idea
15 that you have to lock them up now; is that
16 correct?

17 A Well, that's the regulation. That's
18 what you have to do to work with them.

19 Q And you don't agree with that, do
20 you?

21 A No. If they're a controlled
22 substance, they should be locked up. I
23 understand the way they're --

24 Q Okay. So you agree there -- you
25 agree there's a reason why the drugs should be

1 locked up, correct?

2 A To prevent diversion, yes.

3 Q All right. And you described the
4 record-keeping requirements as onerous; is that
5 true?

6 A I believe they are, yes.

7 Q So you disagree with the idea that
8 the Controlled Substances Act requires people
9 who work with psychedelics to actually keep
10 records of where those psychedelic drugs are
11 coming from, where they went, how they were
12 used, how they were disposed of, whatever; is
13 that correct?

14 MR. PHELPS: Objection. Your Honor,
15 that's a mischaracterization of his testimony.

16 JUDGE SOEFFING: Overruled. He can
17 give the answer that he wants to give.

18 THE WITNESS: You've asked a very
19 broad question that goes to the heart of
20 rulemaking and lawmaking. I'm not a
21 legislator. I'm not in the Senate or the
22 House. Those are the regulations that people
23 have to follow. But they're onerous because it
24 disincentivizes people who want to get into the
25 field.

1 BY MR. MANN:

2 Q Okay. So, as someone who has worked
3 with psychedelics, do you feel like you
4 should've been able to obtain and use
5 psychedelics without keeping any records for
6 anyone to inspect; is that correct?

7 A I didn't say that.

8 Q What did you say?

9 A I didn't say that. I just said the
10 record-keeping was onerous.

11 Just a minute now. This -- didn't
12 have my phone turned off. Sorry.

13 Q So you think there is no public
14 safety reason for requiring someone to keep
15 records of the psychedelics which they obtain
16 and use?

17 A I didn't say that.

18 Q What are you saying? Why are you
19 calling it onerous?

20 A If you understood academics, it's
21 quite often that an academic will get an idea
22 to try something. And if they can buy that
23 chemical from a chemical company and run the
24 experiment, they'll run the experiment, and
25 they'll satisfy the curiosity.

1 That's not possible with
2 psychedelics. If you have an idea about
3 studying the Serotonin 2A Receptor, and you
4 want to get a tool to study it, the only way to
5 do it, if it's controlled, is to go to the DEA,
6 apply for a license, and wait a year -- if
7 you're lucky -- to get your license to do it.
8 By then, most investigators, unless they're
9 dedicated to the field, will have given up and
10 gone in a different direction.

11 Q All right. Let me ask you this. Do
12 you see any public safety benefit in keeping
13 records of the psychedelics which you obtain
14 and use, yes or no?

15 A Do I -- say that -- could you
16 restate your question?

17 Q Do you see any public safety benefit
18 in being required to keep records of the
19 psychedelics which you obtain and use?

20 A I think it's reasonable to keep
21 records.

22 Q All right. Now, you described a
23 situation, and it went by really quickly. You
24 said that somebody attempted to get a DEA
25 registration, and the DEA bungled the

1 investigation.

2 A That was actually my son.

3 Q Okay. And what's your son's name?

4 A Charles Nichols.

5 Q And does Charles Nichols have a DEA
6 registration?

7 A He does now, yes.

8 Q Is it a Schedule I registration?

9 A Yes, it is.

10 Q And how was the investigation
11 bungled?

12 A In the inspection, they lost the
13 results of the inspection, had to come back and
14 reinspect him again. It took him, if I recall,
15 about a year to get a license.

16 Q And you're saying that was the DEA's
17 fault?

18 A Yes, it was.

19 Q Okay. You talked about reading the
20 DEA Micrograms; you're familiar with those
21 then, right?

22 A I used to look at those, yes.

23 Q And do you dispute that some of the
24 Micrograms have been actually entered into
25 evidence in this case and that those Micrograms

1 show seizures of DOI?

2 A I'm not aware of that, but I'm not
3 aware that DOI has ever become that popular.

4 Q You have no reason to dispute those
5 Micrograms that are entered into the record at
6 this time, correct?

7 A I don't know what they say. I can't
8 tell you whether I dispute them or not.

9 Q All right.

10 A If they're simply stating that they
11 found them in a seizure, I can believe that.

12 Q Have you been listening to the
13 Government's case in this matter?

14 A No, I haven't.

15 Q Have you been listening to any of
16 the other witnesses testifying for the
17 Petitioners?

18 A No. No, this is my first --

19 Q Have you talked to anyone -- have
20 you talked to anyone about the testimony from
21 the Petitioners?

22 A No.

23 Q Okay. What were you doing before
24 the passage of the Controlled Substances Act?

25 A I was working with psychedelics

1 doing research as a graduate student and as a
2 post-doc.

3 Q And what were -- were you continuing
4 to work with psychedelics after the passage of
5 the Controlled Substances Act?

6 A That's when I went to Purdue. I had
7 to get a license to work with them.

8 Q So you did not quit your job, did
9 you?

10 A No, because this is an area that I
11 was dedicated to, and I wanted to get into this
12 area.

13 MR. MANN: Just one moment.

14 Thank you, Doctor.

15 JUDGE SOEFFING: Mr. Phelps, you may
16 conduct any redirect.

17 MR. PHELPS: If I can just confer
18 with my co-counsel here?

19 JUDGE SOEFFING: Certainly.

20 MR. PHELPS: Just briefly, Your
21 Honor.

22 Dr. Nichols, oh -- oh, no.

23 MR. GLEASON: He's still on.

24 MR. PHELPS: Oh, he is still on?
25 Okay.

1 THE WITNESS: You can't get rid of
2 me that easily.

3 (Laughter.)

4 MR. PHELPS: Are we good to proceed,
5 Your Honor?

6 JUDGE SOEFFING: Yes, yes.

7 MR. PHELPS: Thank you.

8 JUDGE SOEFFING: The record will
9 reflect there were some slight technical
10 difficulties with the TV screen. You may
11 continue.

12 MR. PHELPS: Thank you.

13 REDIRECT EXAMINATION

14 BY MR. PHELPS:

15 Q Dr. Nichols, you were asked on
16 cross-examination about record keeping in
17 science and in these laboratory settings. In
18 your knowledge and expertise, do scientists
19 keep records of the happenings in their lab
20 regardless of whether those records are related
21 to DEA licensure?

22 A Yes. You have to keep records of
23 your experiments, so somebody could potentially
24 reproduce them in the future.

25 Q Okay. So could you just put that

1 into a little bit of context that -- about the
2 onerousness of the DEA record-keeping versus
3 standard scientific record-keeping?

4 A Well, only my students and post-docs
5 had laboratory notebooks that I could review at
6 various times.

7 With respect to controlled
8 substances, everyone wasn't able to use those.
9 I had to have specific people that were
10 approved to use them, and then I had to make
11 sure that the inventories were taken care of.
12 So it was a different -- it was a different
13 inventory, different type of records.

14 And the other thing I would mention,
15 and I tried to say this at the end of my last
16 statements, I had decided as a graduate student
17 that I really wanted to understand
18 psychedelics. This was my goal in life to do
19 research in this field, so I didn't mind when I
20 had to get a Schedule I license and have to
21 keep the records, et cetera. That's something
22 that I understood came with the territory.

23 What I'm talking about is someone
24 who wasn't devoted to being in this field to
25 studying these. If they wanted to do research

1 or look at the Serotonin 2A Receptor and look
2 at the psychedelics, they would've been
3 disinclined to do it because it would've
4 required additional record keeping. It
5 would've required a safe. It would've required
6 investigation, a background check, listing what
7 they were going to do.

8 And so, there's a different level of
9 paperwork. If you weren't devoted to studying
10 these as a scientific exercise, you wouldn't do
11 that. I did it because that was what I decided
12 I wanted to do with my career was understand
13 these drugs.

14 But if -- there are many
15 pharmacologists who I met who were very
16 interested in but didn't want to do research
17 because they couldn't get a -- they'd have to
18 get a license. It would -- well, ask my son.
19 It took him over a year to get a license to
20 work with a Schedule I substance.

21 In academics, sometimes, you just
22 can't wait. You want to do an experiment, see
23 what happens. Somebody says, well, no, you're
24 going to have to get a license. It's going to
25 take you six months or a year or whatever to

1 get it approved. Sometimes that just isn't
2 compatible with what you want to do.

3 MR. PHELPS: No further questions
4 for this witness, Your Honor. Thank you.

5 JUDGE SOEFFING: Okay. Thank you,
6 Mr. Phelps.

7 Mr. Mann, any recross?

8 MR. MANN: No, Your Honor.

9 JUDGE SOEFFING: All right.
10 Dr. Nichols, thank you. Before we let you go,
11 the court reporter --

12 COURT REPORTER: I don't.

13 JUDGE SOEFFING: You don't? Okay.
14 Never mind. We thought we had something we
15 wanted you to spell for us, but we don't any
16 longer. So, Dr. Nichols, thank you for your
17 testimony. You are excused. I direct you not
18 to discuss your testimony with anyone until the
19 conclusion of the hearing.

20 MR. PHELPS: And we would ask that
21 he be permanently excused, Your Honor.

22 JUDGE SOEFFING: Okay. You don't
23 intend to recall him.

24 Government, any intention to recall
25 this witness?

1 MR. MANN: No.

2 JUDGE SOEFFING: Okay. Dr. Nichols,
3 we're not expecting that you will be recalled
4 in this case.

5 Thank you again for your testimony,
6 and we will disconnect you from the VTC now.

7 THE WITNESS: All right. Thank you.

8 JUDGE SOEFFING: All right. Let's
9 go off the record.

10 (Whereupon, the above-entitled
11 matter went off the record at 3:14 p.m. and
12 resumed at 3:15 p.m.)

13 JUDGE SOEFFING: We're back on the
14 record. We are -- we will take our afternoon
15 break and reconvene in 15 minutes.

16 (Whereupon, the above-entitled
17 matter went off the record at 3:15 p.m. and
18 resumed at 3:53 p.m.)

19 JUDGE SOEFFING: We'll go back on
20 the record. Okay. So, before going back on
21 the record, the Tribunal held a discussion with
22 Mr. Phelps and Mr. Mann.

23 Mr. Phelps has been trying to get a
24 couple of witnesses who were scheduled to be on
25 the VTC today, but there have been technical

1 issues with one and a medical emergency with
2 the patient of another one.

3 So, by the agreement of the parties,
4 and with the Tribunal's permission, we will end
5 today's session just before 4:00 p.m. We will
6 adjourn until 9:00 a.m. on Monday. And at that
7 point, it sounds like there is sufficient
8 lineup of witnesses to proceed with the case of
9 Petitioners.

10 MR. PHELPS: Yes, Your Honor. And
11 with the weekend to kind of line things up, I
12 know it was a little hectic today. We
13 appreciate the Court working with us, but we've
14 got the weekend to get things lined up for
15 Monday, Tuesday.

16 JUDGE SOEFFING: Okay. And
17 Mr. Mann, Government is fine with that,
18 proceeding that way?

19 MR. MANN: Yes, Your Honor.

20 JUDGE SOEFFING: Very well. We are
21 adjourned. Have a nice weekend, everyone. See
22 you on Monday. We're off the record.

23 (Whereupon, the above-entitled
24 matter went off the record at 3:54 p.m.)
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This is to certify that the foregoing transcript

In the matter of: Schedules of Controlled Substances

Before: US Drug Enforcement Administration

Date: 11-15-24

Place: Arlington, Virginia

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