

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	:	

Tuesday,
November 12, 2024

700 Army Navy Drive
Arlington, Virginia

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

BEFORE:

THE HONORABLE PAUL E. SOEFFING,
Administrative Law Judge

APPEARANCES:

On Behalf of the Government:

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KAYLA L. KREINHEDER, ESQ.
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On Behalf of the Science Policy Counsel,
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ALSO PRESENT:

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

CONTENTS

Opening Statements	
Government	.26

WITNESS	DIRECT	CROSS	REDIRECT	RECROSS
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Government

HEATHER ACHBACH	31	44	51
DR. THERESA CARBONARO	54	144	

EXHIBIT NO.	MAKR	RECD
-------------	------	------

ALJ

1-71	12
------	----

Government

1	Declaration of Heather Achbach	12	36
2	Notice of Proposed Rulemaking from December 13, 2023	12	39
3	Electronic comments for the rulemaking	12	43
4		12	58
5		12	76
6		12	80
7		12	82
7A		12	85
8		12	139
9		12	93

Petitioners

1-5	12
8-13	12
16-22	12
24-26	12
28, 32, 33,	12
35-42,	12
46	12
49-55,	12
57	12
61-71	12
73-87	12

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

2 9:02 a.m.

3 JUDGE SOEFFING: All right, we are on
4 the record In the matter of Schedules of
5 Controlled Substances: Placement of
6 2,5-dimethoxy-4-iodoamphetamine, (DOI) and
7 2,5-dimethoxy-4-chloroamphetamine (DOC) in
8 Schedule I, Docket No. 24-24.

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

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

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

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

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

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

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

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

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

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

1 The issue in this case is whether
2 2,5-dimethoxy-4-iodoamphetamine, which I will
3 refer to throughout these proceedings as DOI,
4 should be listed in Schedule I of the Controlled
5 Substances Act, pursuant to 21 USC Sections 811
6 and 812(b)(1), and, whether
7 2,5-dimethoxy-4-chloroamphetamine, which I will
8 refer to throughout these proceedings as DOC,
9 should be listed in Schedule I of the Controlled
10 Substances Act, pursuant to 21 USC Sections 811
11 and 812(b)(1).

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

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

22 Let me get appearances with office
23 addresses, please.

24 Government?

25 MR. MANN: Your Honor, Frank Mann,

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

5 MS. ATTANASIO: Good morning, Your
6 Honor. Alexis Attanasio for the Government.
7 Address: 870 -- 8701 Morrisette Drive,
8 Springfield, Virginia 22152.

9 MS. KREINHEDER: Good morning, Your
10 Honor. Kayla Kreinheder for the Government. Our
11 address is 8701 Morrisette Drive, Springfield,
12 Virginia 22152.

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

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

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

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

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

24 MR. MANN: Yes.

25 JUDGE SOEFFING: Okay. Thank you, Mr.

1 Mann.

2 Counsel for SSDP?

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

7 JUDGE SOEFFING: Your office address.

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

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

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

15 JUDGE SOEFFING: Okay. Very good.
16 Mr. Rush?

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

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

22 MR. RUSH: Yes, he is.

23 JUDGE SOEFFING: Okay. Very good.
24 Welcome, Dr. Ramos.

25 Okay. This morning the tribunal

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

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

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

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

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

12 JUDGE SOEFFING: You do? Okay, very
13 good.

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

16 MR. PHELPS: We did, Your Honor.

17 JUDGE SOEFFING: Okay.

18 MR. RUSH: Yes, Your Honor.

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

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

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

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

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

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

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

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

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

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

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

1 in accordance with 21 CFR Section 1316.59(f), I'm
2 including in the record as ALJ Exhibits 1 through
3 71.

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

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

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

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

18 (Whereupon, the documents were marked
19 as Petitioners' Exhibit Nos. 1 through 5, 8
20 through 13, 16 through 22, 24 through 26, 28, 32,
21 33, 35 through 42, 46, 49 through 55, 57, 61
22 through 71, and 73 through 87 for
23 identification.)

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

1 are not offered will not be forwarded to the
2 Administrator.

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

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

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

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

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

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

23 Mr. Mann?

24 MR. MANN: A couple of issues.

25 First of all, you mentioned a number

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

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

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

9 JUDGE SOEFFING: No.

10 MR. MANN: All right. So --

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

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

16 JUDGE SOEFFING: I will -- okay.
17 Right.

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

20 JUDGE SOEFFING: Let me just see --

21 MR. MANN: Okay.

22 JUDGE SOEFFING: -- questions on
23 procedure first --

24 MR. MANN: Okay.

25 JUDGE SOEFFING: -- and then, I'll

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

3 Any questions about process or
4 procedures? Mr. Phelps?

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

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

17 MR. PHELPS: Okay. Thank you.

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

20 MR. RUSH: No, Your Honor.

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

1 sequestration of witnesses is necessary for this
2 case.

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

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

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

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

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

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

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

9 MR. PHELPS: Yes, he's here.

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

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

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

20 JUDGE SOEFFING: Okay.

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

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

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

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

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

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

1 least for that part of the case.

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

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

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

15 Mr. Phelps, do you have a response?

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

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

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

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

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

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

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

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

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

9 JUDGE SOEFFING: Okay. So, I will --

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

14 JUDGE SOEFFING: Okay. Thank you, Mr.
15 --

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

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

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

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

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

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

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

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

23 MR. PHELPS: Okay.

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

1 take written briefs now.

2 MR. PHELPS: Okay. Thank you, Judge.

3 JUDGE SOEFFING: Okay.

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

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

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

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

21 JUDGE SOEFFING: Okay. Very good.
22 Thank you.

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

1 Thank you, Mr. Phelps.

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

4 MR. MANN: Your Honor, Panacea -- the
5 Government would argue that Panacea has now
6 waived its right to participate in this hearing.
7 1301.43(d) says that, if such person so files and
8 fails to appear at the hearing, such person shall
9 be deemed to have waived their opportunity to
10 participate in the hearing unless such person
11 shows good cause for such failure.

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

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

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

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

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

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

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

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

3 Mr. Mann?

4 MR. MANN: No, Your Honor.

5 JUDGE SOEFFING: Okay. And, Mr.
6 Phelps?

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

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

12 MR. PHELPS: Yes.

13 JUDGE SOEFFING: -- you call your
14 first witnesses?

15 MR. PHELPS: Yes, Your Honor.

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

18 MR. PHELPS: Thank you.

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

21 MR. MANN: Thank you, Your Honor.

22 May it please the Court.

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

1 don't fall into the wrong hands.

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

7 This scheduling action is about
8 2,5-dimethoxy-4-iodoamphetamine, also known as
9 DOI, and 2,5-dimethoxy-4-chloroamphetamine, also
10 known as DOC. These are hallucinogenic
11 substances, also known as psychedelics, a word
12 that means mind manifesting. They are defined as
13 of, relating to, or being drugs capable of
14 producing abnormal psychic effects, such as
15 hallucinations and sometimes psychotic states.

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

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

1 Alexander Shulgin.

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

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

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

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

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

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

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

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

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

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

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

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

8 Thank you.

9 JUDGE SOEFFING: Thank you, Mr. Mann.

10 Mr. Mann, you may call your first
11 witness.

12 MS. KREINHEDER: The Government will
13 call Heather Achbach.

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

16 JUDGE SOEFFING: Very good.

17 (Pause.)

18 Ms. Achbach, can you hear me?

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

21 JUDGE SOEFFING: Yes.

22 Mr. Reporter, can you hear the
23 witness?

24 COURT REPORTER: Yes, Your Honor.

25 JUDGE SOEFFING: Okay. All right.

1 Ms. Achbach, please raise your right
2 hand.

3 WHEREUPON,

4 HEATHER ACHBACH
5 was called for examination by Counsel for the
6 Government, and having been first duly sworn, was
7 examined and 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: My name is Heather
12 Achbach. The first name is H-E-A-T-H-E-R. Last
13 name is A-C-H-B-A-C-H.

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

19 THE WITNESS: Yes, I do.

20 JUDGE SOEFFING: Okay.

21 Counsel, you may inquire.

22 DIRECT EXAMINATION

23 BY MS. KREINHEDER:

24 Q Good morning, Ms. Achbach.

25 A Good morning.

1 Q Who are you currently employed by?

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

4 Q And --

5 A -- under their Diversion Section.

6 Q And how long have you been at the DEA?

7 A I've been at the DEA since August of
8 2012.

9 Q What previous assignments have you had
10 with the DEA?

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

15 And then, I transferred to
16 Headquarters as the Lead Staff Coordinator in
17 2021, and then, converted to a Policy Analyst
18 last year.

19 Q And what is your current title?

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

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

25 A Of course. So, the Regulatory

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

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

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

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

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

10 Q Great. Thank you.

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

14 A Yes. I have that in front of me.

15 Q Okay. Do you recognize this document?

16 A Yes, I do.

17 Q And what is it?

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

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

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

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

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

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

18 A Yes, it -- yes, it is.

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

21 A Yes, it is.

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

25 JUDGE SOEFFING: Any objection, Mr.

1 Phelps?

2 MR. PHELPS: No objection, Your Honor.

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

7 It's in. You may use it.

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

11 BY MS. KREINHEDER:

12 Q You can close that document now.

13 A Okay.

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

18 A I was one of two Federal Register
19 Liaisons.

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

22 A Yes, it was.

23 Q What was your involvement in that
24 publication?

25 A I was not involved in the actual

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

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

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

12 MR. PHELPS: Okay. Thank you.

13 JUDGE SOEFFING: Okay.

14 BY MS. KREINHEDER:

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

17 A Scott Brinks.

18 Q And who is Scott Brinks?

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

23 Q And who replaced Scott Brinks when he
24 left?

25 A I am currently his acting replacement.

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

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

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

9 A Yes. Open.

10 Q Do you recognize this document?

11 A Yes, I do.

12 Q And what is that?

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

17 Q And what agency issued this notice?

18 A This is issued by the Drug Enforcement
19 Administration.

20 Q Who signed off on the notice?

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

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

1 2023?

2 A Yes, it is.

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

5 A Yes, it is.

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

8 JUDGE SOEFFING: Mr. Phelps, any
9 objection?

10 MR. PHELPS: No objection, Your Honor.

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

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

23 It's in. You may use it.

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

1 identification was received in evidence.)

2 BY MS. KREINHEDER:

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

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

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

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

16 Q What was the stated comment period in
17 the notice?

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

22 Q And what purpose do these comments
23 serve?

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

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

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

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

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

1 Q How did you receive the comments?

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

6 Q And how many comments were there?

7 A A hundred and fifty-one.

8 Q Were any comments received after the
9 comment period?

10 A Not to my knowledge.

11 Q And what did you do next with the
12 comments?

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

17 Q Were any alterations made?

18 A No.

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

22 A Yes, I have it open.

23 Q Do you recognize this document?

24 A Yes, I do.

25 Q What is it?

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

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

7 A Yes, it is.

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

10 A Yes.

11 MS. KREINHEDER: Your Honor, I'd like
12 to offer this exhibit as Government's Exhibit No.
13 3.

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

16 MR. PHELPS: No objection, Your Honor.

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

21 It's in. You may use it.

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

25 BY MS. KREINHEDER:

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

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

9 Q So, has DEA responded to these
10 comments yet?

11 A Not to my knowledge.

12 Q Okay. Thank you.

13 MS. KREINHEDER: I have no further
14 questions.

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

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

20 CROSS-EXAMINATION

21 BY MR. PHELPS:

22 Q Good morning, Ms. Achbach.

23 A Good morning.

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

1 for Sensible Drug Policy.

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

5 A Yes, that's correct.

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

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

13 Q And what exactly did that position
14 entail?

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

21 Q And what drugs did you investigate?

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

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

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

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

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

13 A I do not recall dealing with analogue
14 substances.

15 Q Okay.

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

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

20 So, you may proceed. Overruled.

21 BY MR. PHELPS:

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

25 A I am not aware of investigations.

1 That is outside of my purview.

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

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

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

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

11 BY MR. PHELPS:

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

16 A I was in charge of the electronic
17 comments.

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

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

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

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

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

12 A That is correct, yes.

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

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

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

21 A I am not aware of that information.

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

25 A For this?

1 Q No, in --

2 A Please clarify, please.

3 Q In general.

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

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

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

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

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

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

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

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

3 Q And what would be a compelling reason?

4 A That would be a decision above my pay
5 grade.

6 Q Fair enough.

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

9 A I have been with DPW since August of
10 2021.

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

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

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

19 A I know that there was a publication.

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

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

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

3 A No.

4 Q Thank you.

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

7 JUDGE SOEFFING: All right. Thank
8 you.

9 Government, any redirect?

10 MS. KREINHEDER: Yes, Your Honor.

11 REDIRECT EXAMINATION

12 BY MS. KREINHEDER:

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

15 A Uh-hum.

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

18 A Yes.

19 Q -- those real quickly?

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

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

10 Q Thank you.

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

13 A No, we do not.

14 Q Okay. Thank you.

15 MS. KREINHEDER: No further questions.

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

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

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

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

25 THE WITNESS: Thank you, sir.

1 JUDGE SOEFFING: All right. Good day.

2 THE WITNESS: Good day.

3 (Witness excused.)

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

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

8 JUDGE SOEFFING: Okay. Good morning,
9 Doctor.

10 DR. CARBONARO: Good morning.

11 JUDGE SOEFFING: Please raise your
12 right hand.

13 WHEREUPON,

14 DR. THERESA M. CARBONARO
15 was called for examination by Counsel for the
16 Government, and having been first duly sworn, was
17 examined and testified as follows:

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

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

23 JUDGE SOEFFING: Counsel, you may
24 inquire.

25 DIRECT EXAMINATION

1 BY MR. MANN:

2 Q Good morning, Dr. Carbonaro.

3 Do you have a business address?

4 A Yes. 8701 Morrisette Drive, Silver
5 Spring, Maryland 2252.

6 Q That's your business address? Or?

7 A That's the mailing address.

8 Q Okay.

9 A But Headquarters, 600 Army-Navy Drive.

10 Q Okay.

11 JUDGE SOEFFING: Would that be
12 Springfield or Silver Spring?

13 THE WITNESS: Springfield. My
14 apologies.

15 JUDGE SOEFFING: Springfield. Okay.

16 THE WITNESS: Yes. Sorry.

17 BY MR. MANN:

18 Q Are you currently employed?

19 A Yes.

20 Q And where are you employed?

21 A The Drug Enforcement Administration.

22 Q In what capacity are you employed?

23 A As a pharmacologist.

24 Q Is that your job title here --

25 A Yes.

1 Q -- at DEA?

2 A Yes.

3 Q And how long have you been employed at
4 DEA?

5 A Since September of 2018.

6 Q And did you start off as a
7 pharmacologist?

8 A Yes.

9 Q Now, you're being offered as the
10 Government's expert in this case, and I want to
11 ask you a few questions about your background,
12 experience, and education.

13 First of all, do you hold any academic
14 degrees?

15 A Yes. I have a bachelor of arts in
16 psychology and a PhD in biomedical sciences with
17 a specialization in neuroscience and
18 pharmacology.

19 Q And where is that bachelor of arts
20 from?

21 A The University of Texas in Arlington.

22 Q And the PhD?

23 A The University of North Texas Health
24 Science Center, in Fort Worth.

25 Q Okay. Do you recall when you acquired

1 your bachelor of arts?

2 A May 20, 2006.

3 Q And your PhD?

4 A December of 2012.

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

7 A Yes.

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

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

15 Q And to acquire your PhD, what was
16 required?

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

25 Q And do you hold any professional

1 licenses?

2 A I do not.

3 Q Okay. If the witness could please be
4 shown what's been marked as identification --
5 marked for identification as Government Exhibit
6 4, please?

7 A Thank you. Okay.

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

10 A Yes.

11 Q And what is it?

12 A It is my curriculum vitae.

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

15 A Yes. I updated it every couple of
16 quarters.

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

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

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

1 of abuse.

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

5 A No. Just hallucinogens in general.

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

10 A Yes.

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

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

16 MR. PHELPS: No objection, Your Honor.

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

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

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

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

3 THE WITNESS: Yes.

4 BY MR. MANN:

5 Q Did you concentrate on any particular
6 area in psychology?

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

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

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

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

21 A Yes.

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

25 A Yes. I investigated mechanisms of

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

6 Q Do they have abbreviations?

7 A Yes, DMT for dimethyltryptamine and
8 DiPT for diisopropyltryptamine.

9 Q DMT?

10 A Yes.

11 Q And the other is?

12 A DiPT.

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

15 A Yes.

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

18 A Yes.

19 Q All right. So is it safe to assume
20 that you attained your PhD, or doctorate, in
21 2012?

22 A Yes.

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

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

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

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

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

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

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

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

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

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

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

1 it can produce hallucinogenic effects.

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

7 A Yes.

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

12 A Yes.

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

17 A I did.

18 Q For what time period?

19 A January 2017 through September 2018.

20 Q And what did you do there?

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

1 left.

2 Q Any work with controlled substances?

3 A It was specific to nicotine.

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

6 A Yes.

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

9 A Yes.

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

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

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

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

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

10 A Yes.

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

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

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

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

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

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

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

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

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

24 A Yes.

25 Q And can you summarize for the Court in

1 what capacity did you serve as an expert?

2 A So, I have served as an expert in the
3 Analogue Act provision. So, I've submitted Rule
4 16s, or rules of opinion, for various drugs, as
5 they are compared to the pharmacological effects
6 of Schedule I or II substances. And then I also
7 provided testimony in a case earlier this year
8 relating to the sentencing of tapentadol versus
9 what was argued to be -- or it should be
10 sentenced similar to morphine or tramadol as
11 Schedule IV substance.

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

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

19 Q I'm sorry.

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

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

4 A I have not.

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

7 A Yes.

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

10 A Yes.

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

14 A Yes.

15 Q And --

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

19 MR. MANN: Yes.

20 JUDGE SOEFFING: You're still --

21 MR. MANN: I have one more question.

22 JUDGE SOEFFING: Okay, all right.

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

1 THE WITNESS: Yes.

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

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

9 MR. PHELPS: Just one second, Your
10 Honor.

11 (Pause.)

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

16 JUDGE SOEFFING: Very good. You may
17 proceed.

18 MR. PHELPS: Good morning, Dr.
19 Carbonaro.

20 THE WITNESS: Good morning.

21 VOIR DIRE EXAMINATION

22 BY MR. PHELPS:

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

1 A More or less, yes.

2 Q Okay. Have you received any formal
3 training in the field of epidemiology?

4 A As part of courses, I've taken
5 statistics and epidemiology classes.

6 Q Was -- and when did you take those?
7 Was that in -- what part of your --

8 A During undergrad.

9 Q Okay, so you took some undergrad
10 statistic classes on epidemiology?

11 A And statistics, also, in graduate
12 school.

13 Q Okay. Beyond those courses, any other
14 formal training in epidemiology?

15 A I mean, I have published on databases
16 that are epidemiology in nature. I've used them,
17 I've evaluated them. When I was working at
18 Hopkins, we would use databases such as the
19 National Survey of Drug Use household use. So, I
20 have training from working with Roland, as well,
21 in how he would use them.

22 Q Okay. Could you point to where in
23 your CV that those publications are, that work
24 is?

25 A Yes. During the survey on the single

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

7 Q And did you personally analyze those
8 epidemiological data sets?

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

13 Q Okay.

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

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

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

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

1 A Not those surveys, no.

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

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

6 Q The ones that you're talking about.

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

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

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

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

24 A No.

25 Q Okay. And do you have any formal

1 training in epidemiological criminology?

2 A I do not.

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

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

13 MR. MANN: She was not offered, no.

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

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

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

23 MR. PHELPS: That is correct, Your
24 Honor.

25 JUDGE SOEFFING: Okay. All right, the

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

8 You may proceed, Mr. Mann.

9 BY MR. MANN:

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

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

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

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

6 A Okay.

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

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

14 Q And pages three through 35 of
15 Government Exhibit 5?

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

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

22 A Yes.

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

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

3 MR. PHELPS: No objection, Your Honor.

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

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

10 JUDGE SOEFFING: Yes.

11 MR. PHELPS: Okay.

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

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

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

22 MR. MANN: That's fine.

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

25 MR. PHELPS: Thank you, Your Honor.

1 (Whereupon, the above-entitled matter
2 went off the record at 10:26 a.m. and resumed at
3 10:45 a.m.)

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

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

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

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

1 JUDGE SOEFFING: Okay.

2 MR. PHELPS: -- Court's consideration.

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

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

8 JUDGE SOEFFING: Okay.

9 MR. PHELPS: -- about phone use.

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

12 MR. PHELPS: Thank you, Your Honor.

13 JUDGE SOEFFING: You may proceed, Mr.
14 Mann.

15 BY MR. MANN:

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

19 A I do.

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

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

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

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

6 A Generally speaking, yes.

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

10 A Yes.

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

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

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

18 A Yes.

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

21 A Yes.

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

25 JUDGE SOEFFING: Mr. Phelps, any

1 objection?

2 MR. PHELPS: No objection.

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

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

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

12 BY MR. MANN:

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

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

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

23 A This letter, yes.

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

1 A Yes.

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

5 A Yes.

6 Q And this is from HHS, correct?

7 A Yes.

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

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

13 BY MR. MANN:

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

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

19 Q And what's the date on that?

20 A August 2021.

21 Q And this is something that you
22 created, correct?

23 A Yes, yes.

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

25 A Yes.

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

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

7 MR. MANN: Yes, yes.

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

10 MR. PHELPS: No objection.

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

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

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

20 BY MR. MANN:

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

23 A Seven?

24 Q Yes.

25 A August 2021.

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

3 A October 2023.

4 Q Well, the question is -- okay, I'll
5 ask the question. What is the date on Government
6 7A?

7 A October 2023.

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

10 A Yes.

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

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

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

18 A Sure. So the one that is dated August
19 2021 was with DEA's action to -- NPRM to control
20 DOI and DOC that occurred in 2022. However, that
21 notice was withdrawn.

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

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

3 A Yes.

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

6 A Yes.

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

11 JUDGE SOEFFING: We have copies.

12 MR. MANN: Okay.

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

15 MR. MANN: I sent it to you.

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

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

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

22 JUDGE SOEFFING: Mr. Phelps, any
23 objection?

24 MR. PHELPS: No objection, Your Honor.

25 JUDGE SOEFFING: Okay. Government

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

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

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

9 BY MR. MANN:

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

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

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

24 A Yes.

25 Q Now does Government Exhibit 7A contain

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

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

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

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

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

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

18 Q And what is that?

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

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

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

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

12 A Yes, that is correct.

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

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

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

1 have many reports of non-controlled substances.

2 Q You use the term cutters?

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

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

12 A Yes.

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

15 A Correct.

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

19 A They're hallucinogenic substances.

20 Q Are they natural substances?

21 A They're synthetic.

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

24 A Yes, they're similar to
25 2,5-dimethoxy-4-methamphetamine or DOM. I may

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

3 Q Both of them are similar to that?

4 A Yes.

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

8 A Yes, they work through the Serotonin
9 2A receptors specifically.

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

13 A So serotonin is one of the
14 neurotransmitters in the body. And serotonin, I
15 believe, has 17 different receptors throughout
16 the body. It is believed that binding and
17 activity through the specific receptor Serotonin
18 2A is necessary but not sufficient to cause
19 hallucinogenic effects.

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

22 A Yes.

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

1 cause?

2 A Yes.

3 Q And what are they?

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

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

14 A Yes.

15 Q Depression?

16 A Yes.

17 Q Violent outbursts?

18 A Yes.

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

22 A I believe they're controlled in
23 Florida.

24 Q How about any other countries that you
25 know of?

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

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

8 A Yes.

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

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

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

17 A Yes.

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

20 A Yes, it is.

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

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

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

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

6 A Yes, on the top.

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

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

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

13 A That is --

14 Q -- to the best of your knowledge?

15 A -- a member of the treaty that we then
16 must regulate it in a way that would meet the
17 1971 convention.

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

21 A Yes.

22 Q If it met its obligations under the
23 treaty?

24 A Yes.

25 MR. MANN: The Government would move

1 Government Exhibit 9 into the record, please.

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

4 MR. PHELPS: No objection, Your Honor.

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

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

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

14 BY MR. MANN:

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

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

20 Q Yes.

21 A Okay, yes.

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

24 A Yes.

25 Q And this goes to DEA?

1 A Yes.

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

4 A Yes.

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

7 A Correct.

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

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

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

22 A Okay.

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

25 A Yes.

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

3 A I don't believe so.

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

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

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

17 A Yes.

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

20 A Correct.

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

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

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

1 the first factor on page 3?

2 A Yes.

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

5 A Yes.

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

11 A Yes.

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

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

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

21 A Yes.

22 Q And what was your conclusion regarding
23 that?

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

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

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

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

11 A Yes.

12 Q And they are currently being made and
13 manufactured --

14 A Yes.

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

17 A Yes.

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

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

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

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

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

7 Q And what did you determine?

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

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

17 A No.

18 Q Recommending this drug?

19 A Not to my knowledge.

20 Q Prescribing this drug?

21 A Not to my knowledge.

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

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

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

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

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

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

21 A Yes.

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

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

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

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

17 A Because DOM is a Schedule I substance.

18 Q And that you're comparing the two?

19 A Yes, with a similar mechanism of
20 action.

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

24 A In that they can produce
25 hallucinations and hallucinogenic activity and

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

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

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

1 effects relative to that known drug of abuse.

2 Q And the term, in vivo means?

3 A In life.

4 Q So these are --

5 A So it's a whole body system.

6 Q These are studying actual animals?

7 A Yes.

8 Q Not cell studies?

9 A Yes.

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

15 A Yes.

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

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

1 the stimulants.

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

4 A Yes.

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

8 A Yes.

9 Q Okay. What about DOC?

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

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

15 A Yes, as did HHS.

16 Q And what did you conclude from the
17 anecdotal reports?

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

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

1 and auditory hallucinations, fatigue, headache,
2 gastrointestinal distress, insomnia, and anxiety.

3 Is that consistent with your research?

4 A Yes, and HHS's evaluation.

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

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

17 Q And did he take these drugs?

18 A Seemingly.

19 Q According to his writing?

20 A Yes.

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

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

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

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

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

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

22 A Yes.

23 Q And that came from HHS's
24 recommendation?

25 A Yes.

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

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

14 Q Okay. I'd like to move on to Factor
15 2, scientific evidence of the substance's
16 pharmacological effects. First of all, what does
17 this factor call for you to do?

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

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

22 A To some degree, yes.

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

25 A So in this factor, I start with some

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

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

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

18 Q With respect to DOI, I'd like to
19 direct your attention to the last paragraph on
20 page 5. It says here, DOI had a Kd ranging from
21 .33 to 3.5. Could you tell us what that means?

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

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

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

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

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

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

16 Q So the agonist does something?

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

19 Q And what does the antagonist do?

20 A It would essentially block a response.

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

23 A Yes.

24 Q And what is the antagonist?

25 A It would be naloxone.

1 Q In other words, it blocks --

2 A Yeah, so it would bind to the --

3 Q -- the activity?

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

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

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

13 Q Similar to other Schedule I
14 hallucinogens?

15 A Yes.

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

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

25 Q And again, you concluded that DOI and

1 DOC are similar to DOM or -- also known as STP.

2 Do you concur with that?

3 A Yes.

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

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

11 Q What is a psychopharmacological assay?

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

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

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

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

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

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

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

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

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

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

22 Q It was done?

23 A Yes, with DOI.

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

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

3 Q Okay. I'd like to direct you to page
4 7 of Exhibit 7A. Again, we're talking about
5 discriminative stimulus effects. Is this
6 different than drug discrimination studies?

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

12 Q Are we still talking about animals
13 pushing levers?

14 A Yes.

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

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

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

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

8 A Not amphetamine or methamphetamine.

9 Q Did DOC substitute for MDMA or
10 ecstasy?

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

16 Q Did DOI substitute for DOM and DOB?

17 A DOI?

18 Q DOI.

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

23 Q How about LSD and DMT?

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

1 similar.

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

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

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

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

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

20 A Yes.

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

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

1 Known and Loved.

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

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

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

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

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

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

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

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

23 Q I'm sorry. Is there an antagonist?

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

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

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

13 A Yes.

14 Q Okay. So when something lasts 16 to
15 30 hours and it's an unpleasant experience,
16 that's a very long bad trip, isn't it?

17 A It could be.

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

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

1 Q And you note here the organization
2 known as WHO.

3 A The WHO, yes.

4 Q World Health Organization?

5 A Yes.

6 Q Why is that put in your report?

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

11 Q Does WHO say anything about DOI?

12 A No, it did not evaluate DOI.

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

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

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

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

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

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

6 A Yes.

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

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

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

20 A Yes.

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

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

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

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

7 A Okay.

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

10 A I do not.

11 MR. MANN: May I?

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

14 THE WITNESS: Thank you.

15 BY MR. MANN:

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

18 A Yes.

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

22 A Just on this paper?

23 Q Yes.

24 A Okay.

25 Q Is that --

1 A Yeah, I can draw.

2 Q And then initial your drawing.

3 JUDGE SOEFFING: So in the exhibit?

4 MR. MANN: Yes.

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

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

11 JUDGE SOEFFING: Okay.

12 THE WITNESS: Okay.

13 MR. MANN: Could I get it?

14 JUDGE SOEFFING: Let me see it first.

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

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

20 MR. PHELPS: Thank you, Judge.

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

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

25 JUDGE SOEFFING: Yeah, we'll get a

1 copy.

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

4 BY MR. MANN:

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

11 A Yes.

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

14 A Yes.

15 Q The diagram on the left is --

16 JUDGE SOEFFING: Hold on. Hold on one
17 second.

18 THE WITNESS: Yes.

19 BY MR. MANN:

20 Q The diagram on the left is what?

21 A DOM.

22 Q So what is the difference between DOI
23 and DOM?

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

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

3 Q And your initials, TC?

4 A Yes.

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

7 A Yes.

8 Q Also known as STP?

9 A Yes.

10 MR. MANN: And for the record, I would
11 offer to admit that drawing as part of Exhibit
12 7A.

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

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

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

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

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

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

4 BY MR. MANN:

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

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

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

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

24 Q Dr. Carbonaro, what does IND mean?

25 A Investigational New Drug.

1 Q And what is that? What does that
2 mean?

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

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

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

13 Q And what does the abbreviation NDA
14 mean?

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

18 Q And are there any NDAs for any other
19 hallucinogens?

20 A Not currently.

21 Q So the IND generally comes first,
22 correct?

23 A Yes.

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

1 A There is not.

2 Q Is there any IND for DOC?

3 A Not to my knowledge for either one of
4 them.

5 Q And the same for NDAs? There's no NDA
6 for either drug?

7 A No. There was an NDA that was
8 submitted for MDMA. But it was not approved.
9 And so there was one submitted, but it doesn't
10 have approval.

11 Q I'm asking, though, is there any NDAs
12 for DOC?

13 A No.

14 Q Or DOI?

15 A No.

16 Q Okay. So next, let's talk about
17 Factor 4. The history and current pattern of
18 abuse, how do you analyze that under Factor 4?

19 A So here we look at any law enforcement
20 data that we have. And if there were clinical
21 trial information about that, we'd include it.
22 If not, then we do look at anecdotal evidence of
23 its use.

24 Q Now you explained what NFLIS means
25 earlier, correct?

1 A Yes.

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

5 A Yes.

6 Q And what did you conclude?

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

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

13 A Phenethylamines.

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

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

25 Q And has DOI and DOC been found in

1 these forms?

2 A Yes.

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

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

12 MR. PHELPS: Objection. Speculation.

13 JUDGE SOEFFING: Sustained.

14 BY MR. MANN:

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

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

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

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

7 A Yes.

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

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

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

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

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

1 A From the WHO report.

2 Q And that relates to DOC?

3 A Yes.

4 Q Did you see any evidence where DOC has
5 been seized in any other countries?

6 A I don't recall specifically.

7 Q How about at the bottom of that
8 paragraph?

9 A That's specific to DOC. And in those
10 countries, there were seizures from Sweden, the
11 United Kingdom, France, Norway, Italy, Belgium,
12 Ireland, et cetera.

13 Q Now looking at Factor 5, the scope,
14 duration, and significance of abuse, how is that
15 -- first of all, how is that different than the
16 history and current pattern of abuse?

17 A This one, we looked more for trends
18 with a NFLIS drug.

19 Q All right. And looking at page 10,
20 you have a chart there. Can you explain for the
21 Court what this chart shows?

22 A Yes, it's a chart that shows the
23 summary of the NFLIS drug encounters in the
24 United States for both DOI and DOC.

25 Q And when you say an encounter, what's

1 your understanding of what an encounter is?

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

7 Q So the drug has been found by law
8 enforcement.

9 A Yes.

10 Q And it's been tested.

11 A Yes, by a local --

12 Q And it's tested positive for DOI?

13 A Yes.

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

16 A Yes.

17 Q And 40 reports since 2005, correct?

18 A Yes.

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

21 A Yes.

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

25 A Yes.

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

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

12 Q So you saturate a piece of paper?

13 A Yes.

14 Q Take a pair of scissors and cut it up?

15 A Yes.

16 Q And every little piece is a separate
17 dose?

18 A Yes.

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

21 A Not on paper, no.

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

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

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

3 MR. PHELPS: Sure.

4 BY MR. MANN:

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

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

9 Q All right. If we could look at page
10 11 of your report, I'd like you to explain. You
11 talked about five submissions of DOI and two
12 submissions of DOC reported in the Microgram
13 Bulletin since 2006. Explain for the Court what
14 is the Microgram Bulletin.

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

20 Q And does this relate to DEA activity?

21 A Yes, generally speaking.

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

1 consulted?

2 A Yes.

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

5 A Yes.

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

10 A Yes.

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

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

16 Q And where were they analyzed?

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

20 Q And has DOC been found on blotter
21 paper?

22 A Yes.

23 Q Where's that? Where was it found?

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

1 Bureau of Investigations, West Region Laboratory.

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

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

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

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

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

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

1 Hallucinogens.

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

4 A Yes.

5 Q And would these be considered adverse
6 health effects?

7 A Yes.

8 Q Were there any adverse health effects
9 associated with DOC?

10 A Yes.

11 Q And what were they?

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

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

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

1 A Yes, more or less.

2 Q And could you explain the other term?

3 I think you pronounced it --

4 A It's --

5 Q Say the term again.

6 A Rhabdomyolysis.

7 Q Okay. What is that?

8 A It's essentially, like, muscles being
9 broken down and then entering the blood stream.

10 And that can cause hepatic -- renal -- kidney
11 failure or kidney toxicity.

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

14 THE WITNESS:

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

16 BY MR. MANN:

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

19 A One was a 2014 report where a
20 37-year-old man had a history of methamphetamine
21 abuse was found dead in his home. He was found
22 partially decomposed. But he was found laying
23 face side with a book entitled Psychedelic
24 Chemistry in his hand. And the only thing that
25 was positive in his blood was DOC and caffeine.

1 Q And the final one regarding DOC?

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

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

11 A Yes.

12 Q What is that?

13 A It's rapid breathing.

14 Q How do you pronounce it?

15 A Tachypnea, I believe.

16 Q It's rapid breathing?

17 A Yes.

18 Q All right.

19 A I believe so.

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

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

1 admitted.

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

4 BY MR. MANN:

5 Q Do you see this two-page exhibit?

6 A Yes.

7 Q And do you recognize this?

8 A Yes.

9 Q And what is it?

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

14 Q And who created these charts?

15 A My section.

16 Q Your section did?

17 A Yes.

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

20 A Yes.

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

23 A Yes.

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

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

3 MR. PHELPS: No objection, Your Honor.

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

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

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

13 BY MR. MANN:

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

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

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

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

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

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

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

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

25 A There is evidence based on people

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

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

12 A No, not necessarily.

13 Q It could be repeated over and over
14 again?

15 A Yes.

16 Q Based on the psychic --

17 A Yes.

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

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

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

25 A They also note that these

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

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

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

11 Q And does DOI fit that --

12 A No.

13 Q -- profile?

14 A No.

15 Q Does DOC fit that profile?

16 A No.

17 Q So this factor does not apply --

18 A Correct.

19 Q -- in your opinion?

20 A Correct.

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

24 A Yes.

25 Q Is there substantial evidence of DOC's

1 relative potential for abuse?

2 A Yes.

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

6 A Relating to Factor 2?

7 Q Yes.

8 A Yes.

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

11 A Yes.

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

19 A Yes.

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

23 A Yes.

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

1 A Yes.

2 Q Does it tell you they are similar to
3 DMT?

4 A Yes.

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

10 A Yes.

11 Q And what is your opinion, yes or no?

12 A Yes.

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

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

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

21 A It's the same.

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

24 A Yes.

25 Q Is there evidence of a history and

1 pattern of abuse regarding DOC?

2 A Yes.

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

8 A Yes.

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

12 A Yes.

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

16 A Yes.

17 Q And what is that opinion?

18 A That DOI has evidence of significance
19 of abuse.

20 Q How about DOC?

21 A That it also has evidence of abuse.

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

25 A Yes.

1 Q And what is your opinion in that
2 regard?

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

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

10 A Yes.

11 Q And what is your opinion?

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

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

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

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

21 A Yes.

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

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

3 A Yes.

4 Q And that is based on what?

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

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

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

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

21 A Yes.

22 Q And what does that mean?

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

1 certain way.

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

4 A It is.

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

8 A Yes.

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

11 A No.

12 Q Why is that?

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

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

18 A That is correct.

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

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

24 Q How about DOC?

25 A For neither substance.

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

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

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

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

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

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

18 Q And what scientific evidence are we
19 talking about?

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

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

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

1 Q The third factor in -- I think it was
2 812 -- is there is a lack of accepted safety for
3 use of the drug under medical supervision. What
4 are your conclusions with respect to that?

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

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

19 A Not to my knowledge.

20 Q What about DOC?

21 A No.

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

25 A Not to my knowledge.

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

4 A Yes.

5 Q Is there anything you would like to
6 add?

7 A I mean, I know that they are
8 investigated in research, usually basic research,
9 and that DOI more so than DOC. And that data is
10 important to DEA. But generally for these eight
11 factors, we generally rely on the abuse potential
12 data that is available for these, if there's any
13 safety studies in animals.

14 Like, a safety study in an animal
15 would not necessarily be sufficient to say that
16 it would be safe for use in humans without those.
17 And saying that we have to just look at the data
18 specific for DOI and DOC specifically and not for
19 other -- not for other drugs that may -- like,
20 for abuse potential when we are comparing them,
21 like, head to head. But we can't use data that
22 is not comparing them in a similar fashion. So
23 we try to stick to the data that is available
24 related to abuse potential for these drugs.

25 Q Is LSD a Schedule I controlled

1 substance?

2 A Yes.

3 Q Is it being researched?

4 A Yes.

5 Q Is MDMA a Schedule I controlled
6 substance?

7 A Yes.

8 Q Is there research going on with MDMA?

9 A Yes.

10 Q Would placing DOI in Schedule I shut
11 down research?

12 A I don't believe so.

13 Q Why not?

14 A So as part of my duties in the
15 section, I also handle the Schedule I researcher
16 program as a backup since I started. And then I
17 was the primary point of contact for some time.
18 And now I just kind of consult.

19 And so I am familiar with the Schedule
20 I researcher process, how those applications come
21 in through DEA, how we review them, how we work
22 with HHS. I also -- so understanding that
23 process, also working with Schedule I substances
24 in essentially every step of my career before
25 joining government, understanding those from,

1 like, also a researcher standpoint and using DOI
2 in research before joining DEA that with my
3 experience of being a researcher and in DEA that
4 research can still be done under the Schedule I
5 researcher program. And many of the studies --
6 even many of the studies that were included as
7 evidence are done in labs that have Schedule I
8 researcher registrations.

9 MR. MANN: Just one moment, Your
10 Honor. I pass the witness.

11 JUDGE SOEFFING: Okay. Thank you, Mr.
12 Mann. Mr. Phelps, would you like to start your
13 cross examination or break for lunch?

14 MR. PHELPS: I think a break for lunch
15 now would be great, Your Honor.

16 JUDGE SOEFFING: Okay. We will break
17 for lunch. We will return at 1:15. Let's go off
18 the record for a moment.

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

22 JUDGE SOEFFING: All right, we're back
23 on the record.

24 Dr. Carbonaro, I'll remind you you are
25 still under oath. Mr. Phelps, you may begin your

1 cross-examination.

2 MR. PHELPS: Thank you, Your Honor.

3 And with the Court's permission, would it be
4 allowable for me to conduct it here at the table
5 still standing, rather than at the lectern?

6 JUDGE SOEFFING: Oh, if that's easier
7 for you, that's all right.

8 MR. PHELPS: I think it would, I think
9 it would be easier.

10 JUDGE SOEFFING: Okay.

11 MR. PHELPS: Thank you, Your Honor.

12 Sorry, I want to get this plugged in
13 so my screen's not going black. Okay.

14 Whenever you're ready, Judge.

15 JUDGE SOEFFING: Ready.

16 MR. PHELPS: Thank you.

17 Good afternoon, Dr. Carbonaro, welcome
18 back. So, I'd first like to point your attention
19 to Government's Exhibit No 6.

20 THE WITNESS: Thank you. Okay.

21 CROSS-EXAMINATION

22 BY MR. PHELPS:

23 Q And this is the -- this is the letter
24 signed by Brett Giroir, correct?

25 A Yes.

1 Q Okay. And in the third paragraph of
2 that letter, the first sentence says, FDA and
3 NIDA, N-I-D-A, have also considered the abuse
4 potential of DOI and DOC. And it goes on from
5 there.

6 Those -- the FDA and the NIDA
7 analysis, are those -- is that publicly available
8 information?

9 A FD -- I mean, I think it's in totality
10 with the Eight Factors of Analysis that were
11 submitted with the submissions of the NPRMs. And
12 my understanding is that the FDA sends that to
13 NIDA, and they have a communication within
14 themselves about concurrence. I'm not aware of
15 that being public knowledge, the communication
16 between FDA and NIDA.

17 Q Okay. And do you -- do you, in
18 compiling your reports, did you review any of
19 that NIDA analysis?

20 A I reviewed the Eight Factor Analysis
21 that was submitted to me on behalf of HHS that
22 NIDA concurred on.

23 MR. PHELPS: Okay.

24 JUDGE SOEFFING: Hold on a second.

25 Mr. Reporter, are you able to pick up

1 Mr. Phelps?

2 COURT REPORTER: Yeah, I am, it's just
3 kind of pointed towards his shoulder and not his
4 mouth.

5 MR. PHELPS: Okay, not a problem,
6 yeah.

7 JUDGE SOEFFING: Put that mic a little
8 closer.

9 MR. PHELPS: That's never been a
10 problem for me in court before, so thanks for --
11 thanks for letting me know.

12 Okay, so it's your understanding that
13 NIDA just reviewed and concurred on what was
14 already provided in the other Eight Factor
15 Analysis.

16 THE WITNESS: Based on what this
17 letter says, and personal communications, yes.

18 BY MR. PHELPS:

19 Q Okay, okay, thank you. So I'd like to
20 walk through with you the Eight Factors and some
21 of your previous testimony about those. So
22 Factor One is about the potential for abuse. How
23 did -- you say that this is the DEA's definition
24 for abuse. Is this the only definition for drug
25 abuse?

1 A It is DEA's definition of abuse.
2 There may be other definitions. But it is the
3 one that has been used previously in legislative
4 history.

5 Q Okay. And specifically in the
6 legislative history, they go through the four
7 factors that are analyzed here?

8 A Yes.

9 Q Okay. And in your previous work prior
10 to being employed by the DEA, was that how you
11 and your colleagues defined drug abuse?

12 A I mean, to some degree, yes, but not
13 as specific to some of these points.

14 Q Okay, and what -- which of those
15 points? What do you see different?

16 A That's a good question. Actually,
17 upon looking at them, I feel like this would
18 still mirror my definition of abuse.

19 Q Would this mirror Dr. Roland
20 Griffith's definition of abuse?

21 A I'm not sure.

22 Q Because you, when you were working
23 with him at Johns Hopkins, you dealt with issues
24 of drug abuse, right?

25 A We assessed abuse liability.

1 Q Okay. And so you don't know if that
2 -- if the abuse studies you were doing there used
3 the same definition or something different?

4 A Oh, we measured like abuse liability
5 metrics. But I don't know what his definition is
6 or was.

7 MR. PHELPS: Okay. So Factor A says,
8 There is evidence that individuals are taking the
9 drug or other substances in amounts sufficient to
10 create a hazard to their health or the safety of
11 other individuals or to the community. Oh, I
12 apologize, the 7, 7A mixup has -- which one is?

13 Oh, oh, oh, thank you. Thank you, yes.

14 JUDGE SOEFFING: Yeah, so we're looking
15 at 6, is what I'm looking at.

16 MR. PHELPS: Yes, okay.

17 JUDGE SOEFFING: And what the witness
18 has. It's Government Exhibit 6.

19 MR. PHELPS: Yes, I apologize, Your
20 Honor. We're finished with that now. We're going
21 to work through the Eight Factor Analysis
22 provided in Government's Exhibit 7A.

23 THE WITNESS: So I'll give this one
24 back.

25 BY MR. PHELPS:

1 Q Okay, and can you please go to page 3
2 of that report, Dr. Carbonaro?

3 A Okay, I'm on page 3.

4 Q Okay, and you see what's the
5 subparagraph A there?

6 A Yes.

7 Q Okay, that there's evidence that
8 individuals are taking the drug or other
9 substances in amounts sufficient to create a
10 hazard to their health or to the safety of other
11 individuals or to the community.

12 So how do you define sufficient
13 amount?

14 A I think any evidence that produces a
15 psychological or a psychoactive effect that the
16 drug induces. And if there's evidence to show
17 that there are harms associated with it. The
18 sufficient amount is going to be relative to that
19 drug.

20 We know DOI and DOC are very potent.
21 I think 1-3 milligrams can have an effect. So a
22 small amount of this drug would -- could be very
23 likely to cause significant harm.

24 Q Okay, so you're specifically referring
25 to the dosage amount that an individual is taking

1 --

2 A And --

3 Q In that --

4 A In what I just said, yes.

5 Q Yes, okay, okay. And so, and you said
6 that for DOI or for DOC, something in the amount
7 of several milligrams could be considered a
8 sufficient amount?

9 A Yes, because it's been shown to cause
10 hallucinogenic properties.

11 Q Okay, and in any of the law
12 enforcement data, NFLIS, any of the other
13 evidence that you've provided, has any of that
14 shown the amount that people are taking?

15 A In the public forums and in like the
16 PiHKAL by Shulgin, there are doses that are
17 mentioned of what would cause a strong
18 psychoactive hallucinogenic effect.

19 Q Okay, and what about in any of the law
20 enforcement data?

21 A In some of that law enforcement data,
22 there are amounts that can provided within
23 NFLIS-Drug, but it's not necessarily saying how
24 much any one person is using.

25 Q So that's the amount that is

1 encountered, right, or seized?

2 A Or at least tested.

3 Q Or the amount tested. But it says
4 nothing about the amount that an individual
5 consumed.

6 A Correct, but it is showing that it is
7 encountered by law enforcement.

8 Q Okay. So how do you know that people
9 are consuming these substances at a sufficient
10 amount?

11 A For this factor, I relied on HHS's
12 evaluation, saying that they are used, that
13 individuals are using them in sufficient amounts.
14 But also based on public forums, it does indicate
15 that people are using them in a way that would
16 cause hallucinogenic effects.

17 Q And HHS's analysis of that was based
18 on the same anecdotal reports, right?

19 A I believe so,

20 Q Okay.

21 A And others. Like on Erowid, not just
22 PiHKAL.

23 Q Okay. And is -- does that sufficient
24 amount have anything to do with the amount of
25 times that somebody takes a drug, or it's only a

1 specific dosage on a single use?

2 A It's not even a specific dosage, and
3 it's -- it just shows the evidence that people
4 are using it. It's not specific to a -- any
5 duration of time of use.

6 Q Okay, okay. Okay, I'd like to just
7 take, if we turn the page there, to page 4,
8 subsection B.

9 A I'm sorry, which subsection?

10 Q Or the subparagraph B there.

11 A Okay.

12 Q It says there's -- so this is the
13 factor of if there's significant diversion of the
14 drug or substance from legitimate drug channels.

15 A Yes.

16 Q And to be -- what is your -- according
17 to DEA's findings, there's no evidence of
18 diversion from legitimate channels, correct?

19 A We could not find any evidence, but it
20 doesn't mean that there is no evidence. Like the
21 -- it doesn't happen, we just, we didn't find it
22 in our evaluation.

23 Q Okay. How broadly do you -- do you
24 evaluate that to make that determination?

25 A In this case, I mean, we're kind of

1 limited to what's available online and through
2 some like court prosecutions. But it's very
3 limited. But as I noted in this factor, I said
4 this characteristic of abuse potential is not
5 applicable.

6 Q Okay. So as far as you know, there's
7 been no criminal prosecutions for that either.

8 A Not that I'm aware of.

9 Q Okay. And then down to Part C,
10 paragraph C.

11 A Okay.

12 Q Individuals are taking the substance
13 on their own initiative rather than on the basis
14 of medical advice from a practitioner licensed by
15 law to administer such substance.

16 So this is where you mentioned about
17 people being able to buy this on the street,
18 right?

19 A Yes.

20 Q And during your previous testimony,
21 you testified that people purchase DOI and DOC
22 online for recreational use.

23 A It seems that way, yes.

24 Q Where do they purchase it?

25 A I don't know if I said online

1 specifically, but there -- people are purchasing
2 it based on having drug encounters with DOI and
3 DOC.

4 Q Okay, but are you aware of -- are you
5 aware of anywhere that people can purchase these
6 drugs online for recreational use, as you
7 testified?

8 A I mean, there are many websites where
9 you can purchase DOI and DOC and other chemicals
10 online.

11 Q Okay. You can purchase them online
12 for research purposes, right?

13 A No, for a recreational drug. There
14 are many websites on the Clearnet and Darknet
15 where you can buy substances.

16 Q Okay, and does the DEA have any
17 evidence of sales of DOI and DOC online?

18 A I'm not aware of any.

19 Q Okay. So any testimony that it could
20 be done is purely speculative.

21 A Yes.

22 Q Okay.

23 A But they are found on the street in
24 blotter paper. Like there are ways that people
25 are using them. So there is evidence of people

1 using them and reporting online about their
2 effects.

3 Q With that, I think I'd like to take a
4 look at Exhibit 8 with you, Doctor.

5 A Okay.

6 Q So the first page of this exhibit is
7 specifically about DOI. And you just testified
8 that people are out there buying it and using it.
9 Can you tell me how many people, based on your
10 own data, bought or used DOI in the year 2005,
11 when this study began?

12 A It's not a study per se, it's just
13 data that were collected. So I wouldn't call it
14 necessarily a study, it's just data that we're
15 able to pull from our database. And again, this
16 is just based on encounters, it's not necessarily
17 based on like specific number of users.

18 Q Okay. But based on -- based on the
19 data that you collected, you're right, it's not a
20 study. Thank you for correcting that. How many
21 encounters were there with DOI in 2005?

22 A One.

23 Q And in 2006?

24 A Seven.

25 Q Seven for the year?

1 A Yes.

2 Q That would be three in Kansas and four
3 in Wisconsin?

4 A Yes.

5 Q Okay. How about 2007?

6 A Five.

7 Q Two thousand and eight?

8 A Two.

9 Q Two thousand and nine?

10 A Twelve.

11 Q Two thousand and ten?

12 A One.

13 Q Two thousand eleven?

14 A Three.

15 Q Two thousand and twelve?

16 A Three.

17 Q Two thousand thirteen?

18 A One.

19 Q Two thousand fourteen?

20 A One.

21 Q Two thousand and fifteen?

22 A Two.

23 Q Two thousand and sixteen?

24 A I don't believe any.

25 Q Two thousand seventeen?

1 A One.

2 Q Two thousand and eighteen?

3 A One.

4 Q Two thousand nineteen?

5 A Zero.

6 Q Twenty twenty?

7 A None.

8 Q Twenty twenty-one?

9 A None.

10 Q Twenty twenty-two?

11 A None.

12 Q And twenty twenty-three?

13 A None.

14 Q Okay. So would you say that numbers
15 like that indicates that there's a lot of sales
16 going on of this?

17 A NFLIS numbers, like I said, NFLIS-Drug
18 is a voluntary database. What drugs are tested
19 for and confirmed for and reported back to DEA
20 can vary for different reasons, based on
21 priorities of labs and other caveats.

22 Just because like these numbers, maybe
23 there are no reports between 2019 and 2024, it
24 doesn't mean that they're not there. It just
25 means they were not recorded into NFLIS.

1 And these numbers for, especially for
2 non-controlled drugs, tend to be lower than ones
3 that are controlled. And then labs will start
4 testing them. And those numbers will increase
5 once they are controlled.

6 So since they are uncontrolled, it is
7 very likely these numbers are under-reported.
8 But it shows that there is evidence of them in
9 law enforcement encounters.

10 Q And how do those numbers compare to
11 other substances you may see in the same type of
12 data?

13 A It varies from drug to drug.

14 Q Well, how about some of the other
15 drugs you've testified about today? MDMA?

16 A It's higher. But it's also a
17 controlled substance. So if it's positive and if
18 a lab finds MDMA, which is a controlled
19 substance, they may stop testing for other
20 controlled substances or non-controlled
21 substances. So I would expect MDMA, LSD, and
22 psilocybin to all be higher than these
23 noncontrolled substances.

24 Q So what you're saying is this data may
25 not even accurately reflect what's happening out

1 there with these substances in terms of public --

2 A It just shows that there's evidence
3 that they are being encountered in seizures.

4 Q Okay. And you mentioned other than --
5 other than this data, the other basis that you're
6 using to come to this conclusion about the
7 potential harms of this drug is anecdotal
8 reports, right?

9 A Based on HHS's evaluation, yes.

10 Q Okay. And where did those reports
11 come from? You mentioned a few different places
12 today.

13 A HHS's mostly came from Erowid and also
14 cited PiHKAL's book.

15 Q Okay. And do you have any information
16 about -- well I guess did you personally review
17 any of the Erowid posts?

18 A I did.

19 Q Okay, and do you know the dates of
20 when those were posted?

21 A Not off the top of my head.

22 Q Okay. Did you find anything on -- do
23 you know who made the posts?

24 A Online users.

25 Q Okay. Any identifying

1 characteristics?

2 A Not more than they put out there. Some
3 of them put age, gender, stuff like that. But
4 not any individual information.

5 Q Okay. So is there -- were you able
6 to, in reviewing those Erowid posts, was there
7 anything in them to indicate that they were
8 reliable, scientifically speaking?

9 A We routinely review Erowid posts,
10 Reddit posts for, looking for what effects a drug
11 might have on a person. Because it's unethical
12 to give them to humans in a clinical trial to
13 assess abuse liability without the right
14 parameters. So to some degree, we rely on them
15 to see what people are saying.

16 They did indicate, many of them, that
17 the drug lasted a long time. And that would be
18 not like LSD or other substances that might be
19 similar. So it does give some indication that if
20 it was DOI or DOC, it was something similar to
21 it.

22 Q Well, anyone who's read PiHKAL would
23 know that this is a long-lasting substance,
24 right?

25 A Yes.

1 Q So the fact that they said that
2 doesn't make the -- doesn't make this information
3 inherently reliable, scientifically speaking.

4 A It's still available, the evidence
5 that we have --

6 MR. MANN: Objection. The witness is
7 not able to establish reliability on that basis.

8 JUDGE SOEFFING: Overruled.

9 MR. PHELPS: Is there any way in any
10 of these posts to verify the veracity of what
11 people are saying?

12 THE WITNESS: I again relied on HHS's
13 evaluation. It's one of their prongs when they
14 assess post-market surveillance information. And
15 they understand that there are issues with
16 relying on anecdotal evidence. But I did rely on
17 them to review them and I gave them credence in
18 my evaluation.

19 BY MR. PHELPS:

20 Q Okay. And what makes -- I'm just
21 trying to figure out how do you know that it was
22 even a human that wrote that?

23 A I suppose I don't. But again, I defer
24 to HHS on this, on this factor.

25 Q Okay.

1 A For this evaluation of the anecdotal
2 data.

3 Q Okay. And what was it about HHS that
4 made it more reliable than analyzing it yourself?

5 A Well, I concurred with them after I
6 reviewed the posts as well. But because they are
7 the ones that drafted the medical and scientific
8 evaluation, I do give credence to what they
9 review.

10 Q Okay.

11 A And what they submit to us.

12 Q But they didn't -- they didn't have
13 any additional information regarding the veracity
14 of what's on Erowid, right?

15 A Not that I'm aware of.

16 Q Okay, and anyone with internet access
17 can go on Erowid and post whatever they want,
18 right?

19 A True.

20 Q Okay.

21 A But I did see a new Reddit post that
22 was published last month about DOI and about the
23 use of the DOI. And there was an indication that
24 in a, some sort of large group gathering that DOI
25 was used by some two to three hundred people in

1 this one gathering. So there is other more
2 current evidence that DOI is being used.

3 Q And was there anything in that post
4 that indicated these people knew they were taking
5 -- that what they were taking was DOI?

6 A They seemed to, based on the posts
7 that they were saying that DOI was specifically
8 given to two to three hundred people at this
9 gathering. That other people, again, I go back
10 to what I noted earlier about the individual who
11 read a scientific paper in rodents and then
12 sought to get DOI and then gave it to his mother
13 or gave it to their mother to treat rheumatoid
14 arthritis.

15 So there is some indication that
16 people are seeking it for one thing or another.
17 In the deaths there was, they thought that they
18 took DOI. It turned out to be DOC in one of
19 those cases. So there is some evidence that
20 people are seeking out DOI.

21 Q Okay. Did that post describe any kind
22 of analytical chemistry, any kind of testing to
23 actually verify that that's what it was?

24 A In the large gathering?

25 Q Yes.

1 A No, it was just a comment on Reddit.
2 But they seemed to know exactly what it was,
3 because it was in relation to is that the drug
4 that DEA is trying to schedule. That's not used
5 by a hundred people. And they're like no, there
6 was a report of it to two to three hundred
7 people. Again, this was just published online.

8 Q Okay. And other than that, other than
9 that post, do you have any proof that that story
10 is real and not something somebody just made up?

11 A No, but again, we do -- it is often
12 used to assess abuse liability to see what people
13 are saying about it. Because it would be
14 unethical to give it to a human to ask them what
15 the effects are without knowing how safe or
16 effective it would be.

17 Q Okay, yeah, that was just a yes-or-no
18 question. Do you have any proof that that story
19 is real?

20 A No.

21 Q Thank you. And some of your other
22 anecdotal reports that you mentioned were
23 emergency room reports, right?

24 A Yes.

25 Q Okay. And did any of those ER reports

1 include people who were admitted for only
2 consuming DOI or DOC?

3 A The DOC was DOC plus caffeine. So
4 essentially just DOI. The person attributed it
5 to DOC specifically.

6 Q Okay. You -- so let's talk about
7 caffeine for a second then. What are some of the
8 psychopharmacological effects of caffeine on the
9 human body?

10 A It had stimulant effects.

11 Q Okay, and the issues that these people
12 were presenting for at the -- at the emergency
13 room were consistent with the side effects of the
14 stimulants, right?

15 A I believe -- let me look at that
16 factor. Hold on one second. I think the one
17 that was DOC and caffeine was -- he was found
18 dead. And the medical examiner made the
19 conclusion that it was related to the effects of
20 DOC.

21 Q Okay. So in that case, do you know
22 how long the individual had been dead?

23 A I do not recall from the paper.

24 Q Okay. You did testify, though, that
25 his body was already decomposed, right?

1 A It was partially decomposed, yes.

2 Q So that would not immediate.

3 A There was some time. I don't remember
4 if he said how long or gave an estimate.

5 Q And so can you definitively say that
6 there weren't other substances in his body that
7 had already -- that had already decomposed along
8 with the rest of him, the metabolites had broken
9 down where they weren't testable?

10 A I know that they tested for a whole
11 number of drugs. But I'm not sure, I'm not a
12 toxicologist.

13 Q Okay. So yes, it could have been
14 possible that at the time of his death, there was
15 more than just those two substances.

16 A They didn't seem to think that was the
17 case. The authors of the papers seemed to --

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

19 A Repeat your question, please.

20 Q Can you say yes or no that it's
21 possible that there was other substances that he
22 consumed at the time before he died?

23 A Presumably.

24 Q Okay. And so the people who presented
25 still alive at the ER --

1 A Yes.

2 Q None of those had only DOI or DOC,
3 right?

4 A Correct. One was MDMA and DOC and the
5 other was DOC with other drugs.

6 Q Okay. So can you attribute the
7 adverse health effects that they were suffering
8 strictly to DOI or DOC? It's a yes-or-no
9 question.

10 A Not necessarily.

11 Q Okay. And the fast-beating heart, the
12 breathing issues, those are also potential
13 adverse health effects of MDMA, right?

14 A Yes, and DOC as well. And other
15 hallucinogens that work in the 2A receptor.

16 Q Okay. I'd like to take us back to
17 Exhibit 7A, please. And move on to page 4,
18 paragraph D. Can you please just read the first
19 two lines of that?

20 A Of which paragraph?

21 Q What's listed as Section D in italics
22 at the bottom of the page.

23 A The first two lines?

24 Q Actually just the whole first
25 sentence, please.

1 A The drug is a new drug, so related in
2 actions to a drug or other substance already
3 listed as having a potential for abuse to make it
4 likely that the new -- that the drug substance
5 will have the same potential for abuse as such
6 drugs, thus making it reasonable to assume that
7 they may be significant diversion from channels,
8 significant use contrary to or without medical
9 advice, or that it has substantial capability of
10 creating hazards to the health of the user or the
11 safety of the community.

12 Q Okay. So isn't it true then that that
13 factor specifically applies to new drugs?

14 A I'm not sure that there's an
15 operational definition of a new drug.

16 Q Okay. Well, that's what's in your --
17 that's what's in your standard that you're using
18 here, right?

19 A Right, but like a new drug may not be,
20 well, it may be like a current -- it could just
21 be a drug that's not controlled and it's being
22 evaluated for that. We use this also for the
23 same Eight Factor Analysis for drugs that go into
24 2 through 5.

25 And so it just may be like a drug that

1 has been around for a while but is now going
2 through that process. New is relative.

3 Q New is certainly relative. So how
4 does the DEA define a new drug then?

5 A We just use it broadly to assess any
6 drug that we're reviewing.

7 Q Okay, so it means it's new to you.

8 A It's a new drug of concern, yes.

9 Q Okay. When was Shulgin describing his
10 experiences with DOI? Now when it was published.
11 What were the dates that he was talking about in
12 his lab?

13 A I don't recall the specific dates.

14 Q Do you know when the book was
15 published?

16 A I believe -- I don't recall off the
17 top of my head.

18 Q Nineteen ninety-one sound right?

19 A I believe it was in the 90s, that
20 sounds about right.

21 Q Okay, 1991 according to your
22 citations.

23 A Yes.

24 Q And in your understanding of that,
25 when Alexander Shulgin published that book, he

1 had already been working on these substances for
2 decades, right?

3 A I believe so.

4 Q Okay. So it's safe to say that he's
5 referring to when he first synthesized DOI and
6 DOC, sometime decades before 1991?

7 A It seems likely.

8 Q And that to the DEA is what qualifies
9 as a new drug?

10 A Again, I don't know that we have a
11 definition of new being temporal. That it has to
12 be within a certain time period for it to be new.
13 It's just the language that was put forward in
14 the CSA and we have used it since.

15 Q If it's not temporal, what is new?

16 A Again, I think it could just be the
17 drug that is what they've called to be under
18 evaluation. There are many drugs that go through
19 the FDA process that have been around for decades
20 and are now being tested for medical use, and we
21 use that same language.

22 Q That's under the NDAs that you
23 referred to earlier?

24 A Not during the NDAs, because we only
25 receive it after the NDA has been approved. And

1 then we get an Eight Factor Analysis and
2 recommendation from HHS at that time.

3 Q Okay. So it would -- so even though
4 it was synthesized maybe 50 years ago, it was
5 first brought to the public's attention in 1991,
6 say, widely, that still constitutes in your
7 understanding a new drug?

8 A Yes.

9 Q Okay. Would this factor still apply
10 to something that's not a new drug?

11 A Yes.

12 Q This factor D that specifically says
13 the drug is a new drug?

14 A Yes, we still do this factor analysis
15 for drugs that may have been around longer and
16 may not be considered new based on your seemingly
17 temporal definition.

18 Q So essentially what you're saying is
19 it's only a new drug because DEA's calling it
20 that?

21 A Because the CSA called it -- called it
22 that in our Eight Factor Analysis.

23 Q The CSA doesn't refer to DOI
24 specifically, right?

25 A It does not.

1 Q Okay, so it's strictly your
2 interpretation that makes it -- you and your
3 organization that you're speaking here on behalf
4 of, that makes it a new drug.

5 A Also HHS's. Like this also is
6 promulgated by HHS's evaluation. So it's not
7 just my opinion, it's language that's used by HHS
8 in their evaluation.

9 Q Okay. And you specifically mentioned
10 that DOI and DOC are analogues to DOM, correct?

11 A Yes.

12 Q And DOM is a Schedule I substance?

13 A Yes.

14 Q And can you explain how the DEA
15 prosecutes under the Analogue Act?

16 A Yeah, under the Analogue Act, a case
17 comes to, usually it comes to us, so we are not
18 involved in like the drug seizure or the
19 information. It's after a drug has been seized
20 and they want to take it to court.

21 And our involvement, we have to show
22 that a drug has chemical similarity to a drug,
23 pharmacology similarity, and intended for human
24 use.

25 Q Okay, so, so drugs that are -- that

1 are prosecuted under the Analogue Act come
2 through you from law enforcement seizures.

3 A They come to us from Assistant U.S.
4 Attorneys.

5 Q Okay. So they come to you when the
6 drugs are being used recreationally, not for
7 research purposes.

8 A As far as I'm aware, yes.

9 Q Okay. And has DOI or DOC ever been
10 prosecuted under the Analogue Act?

11 A Not since I -- not to my knowledge
12 since I've joined. I don't know historically.

13 Q Okay. But a AUSA could bring that to
14 you if they had concerns in their community about
15 it being an issue with recreational use.

16 A If there were -- if there was a
17 seizure and they wanted to take it forward, they
18 could, yes.

19 Q Okay. So according to the data that
20 you have, that couldn't have been done in the
21 last five years?

22 A To DOI or DOC?

23 Q To DOI.

24 A It could be possible because not every
25 -- again, it's voluntary, so not every lab gives

1 us that information.

2 Q I'm just saying, based on the
3 information that you have.

4 A Right, I'm just -- and I'm saying that
5 it's still could have happened and just not
6 reported to NFLIS-Drug.

7 Q Okay, it could have. I'd like to go
8 to the next page of Exhibit 7A, to factor two.

9 So you testified previously that drug
10 discrimination is a significant indicator of
11 abuse potential, correct?

12 A For hallucinogens, yes.

13 Q But not other drugs?

14 A It is also an indicator for other
15 drugs. But for hallucinogens, it is, it weighs a
16 significant bearing.

17 Q Okay. Can you just explain a little
18 bit more about how the assays in drug
19 discrimination studies are conducted? What would
20 be the -- what would be kind of your first steps
21 in carrying out a study like that?

22 A So again, it would depend on the
23 species. But since these were done in rats, I'll
24 stick to rats. Obviously acquiring the rats,
25 giving them some time to habituate to, you know,

1 having traveled. And then once you have them,
2 you have to train them to press a lever to get a
3 food reinforcer or some other reinforcer, which
4 is in most of these studies sugar pellets.

5 Q Okay. So how is the drug
6 administered?

7 A It depends on what the researcher
8 wants. It can vary. These cases, there were all
9 intraperitoneal injections.

10 Q Okay, and does the -- so they're
11 injected directly into the -- into the rodent,
12 whatever the species is?

13 A Yes.

14 Q Okay. So the animals are not choosing
15 to take the drug of their own volition.

16 A They're not.

17 Q Okay. They're essentially having the
18 drugs forced on them by a scientist and then they
19 get a reward after they get that drug.

20 A They get a reinforcer, yes.

21 Q Okay. So they're not self-selecting
22 to consume those drugs.

23 A No, and it's not intended to do that
24 in this type of study.

25 Q Okay, it's just a yes or no. So if

1 the drugs are being administered to them by
2 humans, how do you determine that it's being
3 abused?

4 A We are comparing it to drugs of --
5 that have known abuse potential. And if the
6 animal substitute -- so an animals has learned to
7 press a lever after they've received that drug.
8 There is an effect that's going on in that drug
9 that is tied to pressing a lever.

10 And then after ten lever presses, say,
11 they'll get a sugar pellet for some time period.
12 And if the animal, let's say DOM was trained, if
13 then you give DOI and it produces all lever
14 presses on the DOM lever, then it's said to have
15 substituted. And based on DOM's known abuse
16 potential, then it can be inferred that DOI would
17 also have abuse potential.

18 Q Okay, so there's nothing about, other
19 than -- other than that inference, so you're
20 making the leap that's saying this drug is like
21 the other one that we say is potentially abused,
22 there's nothing about the rat pressing the lever
23 itself that's indicative of abuse.

24 A I mean, it's saying that it's similar
25 to that effect. But this is also something

1 that's like, people have been doing since like
2 the 70s and 80s. This a well-established study
3 paradigm.

4 Q Absolutely. And are there other
5 interpretations of this drug discrimination
6 paradigm, other than how you phrased it?

7 A So it can be used to assess mechanisms
8 of action. And drug discrimination is usually
9 drugs will substitute for drugs that have a
10 similar mechanism of action. So you can do other
11 things with this assay.

12 You can give an antagonist to see if
13 that blocks the cues of the drug that you've
14 trained or the drug you're testing. You can also
15 do time, like an effect of time with drug
16 discrimination. You can do a lot of things with
17 it.

18 Q Okay. And were -- were drug
19 discrimination studies created to show drug
20 abuse?

21 A I'm not sure about the creation of
22 drug discrimination, about the history of the
23 creation of it.

24 Q Well, you spoke earlier about how it's
25 been done for many, many decades.

1 A That's good, but I don't know the
2 inception of drug discrimination, what it was
3 initially like.

4 Q Okay. So you can't say that it was
5 definitively developed for testing drug abuse.

6 A But that is how it's being used today.
7 I don't know how it was used when it was first
8 inception.

9 Q Okay, and that's not the only way that
10 it's used.

11 A Again, you can assess mechanism
12 action, so yes. It is an assay that NIDA uses.
13 They've had contracts for over 30 years to assess
14 abuse liability. FDA has contracts with drug
15 discrimination to assess abuse liability.

16 Any new drug that might have abuse
17 potential, almost all of them have drug
18 discrimination data. It is an accepted paradigm
19 to assess abuse liability.

20 Q So without that inference correlating
21 it to something you're previously tested, is
22 there anything about these drug discrimination
23 studies that show potential for abuse?

24 A It shows that they're similar to known
25 drugs of abuse, a number of them.

1 Q And you mentioned that it's -- that
2 it's used to, that these studies are used to show
3 psychological dependence and subjective effects.

4 A I don't use drug discrimination to
5 show psychological dependence.

6 Q So you don't recall testifying about
7 that earlier?

8 A I said -- I quoted the data again,
9 saying that because it's similar that it's likely
10 to have psychological dependence. But I didn't
11 say that drug discrimination necessarily was an
12 assay to test psychological dependence.

13 Q Okay, but that's how you're -- that's,
14 as you just said, you're still linking those
15 things, the psychological dependence based on the
16 -- based on the drug discrimination.

17 A Because we know DOM, LSD, and
18 psilocybin have psychological dependence and we
19 know that they have effects that are similar too,
20 yes.

21 Q So can you measure the psychological
22 aspects of the human experience through rodents?

23 A Drug discrimination actually has
24 really good parallel validity.

25 Q It's just a yes-or-no question.

1 A Repeat your question, please.

2 Q Can you measure psychological aspects
3 of the human experience through rodents?

4 A Not specifically.

5 Q Okay, that's a no?

6 A Not specifically. I don't know what
7 a rodent is feeling.

8 Q Okay. So you said that drug
9 discrimination is the gold standard for measuring
10 abuse potential, those were your exact words,
11 right?

12 A And hallucinogens, yes.

13 Q Are there other ways to measure abuse
14 potential in animals?

15 A I believe you're getting to
16 self-administration.

17 Q So who -- is that another, that is
18 another way to measure abuse potential,
19 self-administration?

20 A Yes, but -- yes.

21 Q Okay. Can you explain how
22 self-administration tests work?

23 A Yeah, so generally a cannula is
24 inserted into generally a rodent but it could be
25 a nonhuman primate. And then in that case the

1 animal responds on a lever, a nose poke to
2 receive additional infusions of a drug.

3 Q And so those are -- and so can you
4 explain kind of how that's carried out to show
5 potential, abuse potential?

6 A An animal usually has to press a lever
7 an increased amount of time to receive another
8 administration. And so by them pressing the
9 lever sometimes hundreds of times for a long
10 period of time, will show that as a drug is being
11 self-administered based on the effects that is
12 being produced.

13 Q Okay, so self-administration studies
14 don't require inferences to other substances.
15 It's a direct.

16 A Self-administration data can be
17 misinterpreted. Lots of things could change an
18 animal's behavior in self-administration.

19 Q Okay, but it was -- it was a yes-or-no
20 question. When you're conducting a
21 self-administration study, that doesn't require
22 you to make inferences about drugs, other than
23 the drug being provided to the animal.

24 A I'm not sure I can give you a
25 yes-or-no answer.

1 Q You said that self-administration can
2 be misinterpreted. Is it possible that drug
3 discrimination studies can be misinterpreted?

4 A There are potential for false
5 positives and false negatives. There have been
6 reports of that. But again, in -- for DOI and
7 DOC, they were compared to a number of other
8 hallucinogens. So it's not just relying on one
9 study, it's multiple studies from different labs.

10 Q And how can drug discrimination
11 studies be the gold standard for testing for
12 potential for abuse when the animals are not
13 self-administering the drugs?

14 A It's pretty well known that drugs that
15 work for the serotonin 2A receptor don't produce
16 self-administration. It's been published and
17 cited many times. HHS is aware of it.

18 Again, in their policy document for
19 assessing abuse potential, they specifically note
20 that hallucinogens don't, generally don't cause
21 self-administration. And they say -- they make a
22 note of drug discrimination specifically in their
23 industry document.

24 Q Okay. So drugs like, well, so DOI and
25 DOC are in self-selection -- in

1 self-administration studies, you're saying that
2 they aren't producing abuse liability in a valid
3 scientific assay?

4 A I'm saying that for hallucinogens,
5 self-administration is not necessarily a valid
6 scientific study, based on published data for
7 this drug class.

8 Q Okay, but they're valid for other
9 classes of drugs, right?

10 A That have a different mechanism of
11 action, yes.

12 Q Okay. And what is -- why is this
13 considered not valid?

14 A Again, it's been published many times
15 that they don't produce self-administration.
16 It's not one that's relied on for hallucinogenic
17 substances.

18 We know people, when they administer,
19 and they may not administer them the same way
20 like they would like an opioid, but it doesn't
21 mean they don't have abuse liability. Just their
22 pattern of abuse is different.

23 Q Just because they don't choose to keep
24 taking it, right?

25 A Depends on the drug.

1 Q DOI, specifically. When given the
2 opportunity, an animal in a self-administration
3 setting would not choose to continually take the
4 drug itself. Yes or no?

5 A I'm not aware of a study with
6 self-administration with DOI.

7 Q Okay. So why is it then that you
8 interpret that as it's not a valid test rather
9 than maybe that's not indicative of potential for
10 abuse?

11 A Again, based on HHS's document on how
12 to assess abuse liability specific to, they have
13 a note specific to hallucinogens. And they say
14 that it's well known that self-administration is
15 not reported in hallucinogens that work in the
16 serotonin 2A receptor.

17 Q So wouldn't another reasonable
18 conclusion of the studies be that they in fact
19 aren't -- don't have the same potential for abuse
20 as other drugs?

21 A Again, we compare it to a drug that is
22 similar to it and we know that LSD and psilocybin
23 have abuse potential.

24 Q But specifically, specifically
25 regarding self-administration, isn't it true that

1 one interpretation of that data could be that
2 based on self-administration, it does not show an
3 abuse potential?

4 A I don't believe so. Because we know
5 LSD is used and abused. Just because it doesn't
6 work in self-administration doesn't mean that
7 then it does not have abuse liability.

8 Q Isn't the gold standard of whether
9 something is addictive is if animals will keep
10 taking it if you give it to them?

11 A Addiction is not specifically noted in
12 the Eight Factor Analysis. A drug does not have
13 to cause addiction for it to be -- have abuse
14 potential.

15 Q Excuse me, I misspoke. Abuse
16 potential. Is -- are there any other classes of
17 drugs that don't have -- that aren't
18 self-administered by animals when given the
19 opportunity?

20 A I believe there are some
21 benzodiazepines that are not self-administered.

22 Q Okay.

23 A In rodent studies.

24 Q Any other Schedule I substances?

25 A Again, like I don't believe psilocybin

1 and DMT are self-administered. And in some
2 studies, MDMA I think was marginal
3 self-administration. But again, it's not -- it's
4 only one component of the Eight Factors Analysis.

5 Q So what about -- what about DOM?

6 A I believe there was one study, and it
7 did not produce self-administration that was
8 significant.

9 Q So are there -- are you aware of any
10 studies with any hallucinogens showing a
11 self-administering effect?

12 A I believe there was some
13 self-administration with MDMA.

14 Q Okay. Does MDMA work as a 2A agonist?

15 A No, it's through a different
16 mechanism. But I also know from personal
17 communications with some individuals that were at
18 Hopkins, there is a tryptamine that produced
19 self-administration in low amounts.

20 Q So of all the -- of all the drugs that
21 substitute for DOI and DOC in drug discrimination
22 studies, are there any of those who have shown
23 self-administration effects?

24 A Not that I'm aware of off -- off the
25 top of my head.

1 Q Okay, so if not a single one of those
2 shows self-administration, what was -- and that's
3 the gold standard for potential of abuse, and
4 everything else is being analogized to those,
5 what was the first drug that they started with
6 that then they linked all these other ones up to?

7 A Are you talking about
8 self-administration or drug discrimination? I
9 feel you, you bounced.

10 Q Well, it's two parts, because you're
11 saying that DOI and DOC show a potential for
12 abuse because they are substitutable in the drug
13 discrimination studies with other hallucinogens.

14 A Correct.

15 Q And not a single one of those other
16 hallucinogens that it substitutes for show
17 self-administration.

18 A Correct, but we wouldn't expect them
19 to.

20 Q So where did you -- so where did you
21 -- what was the first substance that then you can
22 start analogizing all of these under drug
23 discrimination?

24 A We just took them off of studies that
25 were published, we didn't pick the drug that they

1 were compared to.

2 Q Okay. So just we've kind of gone
3 around and around and so I just want to be clear
4 to finish. So of all the drugs that can
5 discriminate for DOI and DOC that they can
6 substitute out for, not a single one of those has
7 shown potential for abuse through
8 self-administration studies. Yes or no?

9 A Not that I'm aware of. I feel like
10 DOM may have had like a little bit of
11 self-administration.

12 Q Okay, but nothing significant that you
13 could say?

14 A No.

15 Q Thank you. And so you testified that
16 a large reason, one of the significant factors
17 that you were -- that DEA is considering when
18 determining to make these due to schedule -- into
19 Schedule I is due to their hallucinogenic
20 properties, correct?

21 A Yes.

22 Q Okay. You also testified earlier
23 today that -- about the drug dextromethorphan.

24 A Yes.

25 Q And what is that again?

1 A It's generally prescribed or used as
2 a cough suppressant, but at high doses it can
3 cause hallucinogenic effects.

4 Q Is it prescribed?

5 A It might be in some prescription
6 products.

7 Q Okay, but it's -- do you -- let me
8 rephrase the question. Do you need a
9 prescription to purchase dextromethorphan?

10 A No.

11 Q And dextromethorphan when taken in
12 large amounts acts as a hallucinogen.

13 A It can, yes.

14 Q It can. So if hallucinogenic
15 properties of a drug are a major consideration
16 for whether it should be scheduled, why isn't
17 dextromethorphan in Schedule I?

18 A Well, first, it has a currently
19 accepted medical use. So if it was controlled,
20 it wouldn't be placed in Schedule I, it would be
21 placed in Schedule II through V.

22 Q Okay. Why isn't it controlled at all?

23 A When it was approved, FDA deemed that
24 it didn't have abuse potential, that it didn't
25 need to be controlled. And we could evaluate it

1 today to see if that is still the case or not.

2 Q Do you know at the time they made that
3 determination they were aware of its use as a
4 recreational hallucinogen?

5 A No.

6 Q Okay. Because part of what you said
7 earlier is that the hallucinogenic qualities
8 require these drugs to be put into the
9 scheduling.

10 A It's also a different mechanism of
11 action. You're talking about a whole different
12 system. And like we're talking about it being
13 specific to the serotonin 2A receptor, which that
14 is not.

15 Q Is it because of the mechanism of
16 action that DEA thinks this is such a dangerous
17 substance, or is it because of the effects that
18 it causes?

19 A The effects that it causes, but it has
20 a shared mechanism of action.

21 Q Okay, but it's not about what it binds
22 to in your brain that makes it dangerous, right?
23 It's the fact that it, according to DEA, it makes
24 you hallucinate.

25 A Correct.

1 Q Okay. But dextromethorphan can also
2 make you hallucinate, and that's not considered
3 currently by DEA a drug of concern.

4 A I'm not going to say it's not a drug
5 of concern, but it's not a -- it's not in the
6 scheduling action.

7 Q Okay. Because DXM can still cause
8 delirium, right?

9 A It can.

10 Q And violent outbursts?

11 A It can.

12 Q And psychotic features?

13 A It can.

14 Q And the DEA is moving to schedule
15 these substances because those issues are of
16 grave concern to the agency, right?

17 A Correct.

18 Q So --

19 A That's my understanding.

20 Q So is DEA taking any action regarding
21 the scheduling of DXM when it has these same
22 dangerous qualities?

23 A I'm not sure I can comment on any
24 active scheduling actions or considerations.

25 MR. PHELPS: Your Honor, if I could

1 just confer with my co-counsel for just a moment
2 and we'll resume.

3 JUDGE SOEFFING: Certainly.

4 MR. PHELPS: Okay, thank you for that,
5 Your Honor.

6 Dr. Carbonaro, we're going to come
7 back to our other factors, but I'd like us to go,
8 take a look at the analysis for Factor 5. That's
9 going to be starting on Page 10 of Government's
10 Exhibit 7A.

11 So, Factor 5 is the scope, duration
12 and significance of abuse, correct?

13 THE WITNESS: Correct.

14 MR. PHELPS: So, it says, according to
15 the NFLIS data in the U.S. there has been
16 significant availability, trafficking and abuse
17 of DOI and DOC. How does the DEA define
18 significant?

19 MR. MANN: Your Honor, Counsel is
20 mischaracterizing what's written here. It says,
21 significant availability, trafficking and abuse
22 of a number of phenethylamines hallucinogens,
23 including DOI and DOC.

24 MR. PHELPS: Fair enough. That is the
25 full sentence there.

1 BY MR. PHELPS:

2 Q But this is specifically about the
3 significance of abuse for DOI and DOC in today's
4 proceeding, correct Dr. Carbonaro?

5 A Yes. But that's just a summary
6 statement specific to the whole class of
7 phenethylamines hallucinogens.

8 Q Okay. But this is an analysis of the
9 significance of abuse of these two substances?
10 That's what's in the title of Factor 5.

11 A Yes.

12 Q Okay. So I'm asking you, how does
13 you, or your office, or your agency, define
14 significant?

15 A Oh, I think that varies from
16 drug-to-drug.

17 Q I --

18 A I'm not sure we have one definition of
19 significance.

20 Q So you just determine what's, you
21 don't have a standard for what's considered
22 significant availability, trafficking and abuse?

23 A I mean, we're just looking for
24 evidence of them in NFLIS drug. And for this part
25 right here. Yes.

1 Q So any evidence, in your analysis, any
2 evidence of these drugs being seen is -- counts
3 as significant abuse?

4 A I mean, I would say in totality of
5 these two substances, over 800, reports it's
6 pretty significant compared to some of the other
7 drugs in NFLIS-Drug. And again, this is a
8 voluntary basis. And it's likely largely under
9 reported for both substances.

10 Q So, if we can't go off the data that
11 you've given us, and you don't have a firm
12 definition of what's significance, would it be
13 accurate to say that a drug becomes significant
14 when you decide to schedule it?

15 A I would say that the NFLIS numbers
16 would likely increase after a drug is controlled
17 because of it being controlled, and more labs
18 will test for it. So like, the numbers may go up
19 after it. But again, it's based on NFLIS
20 numbers, but also other evidence.

21 Q The other evidence is the anecdotal
22 reports, right?

23 A Correct. That HHS provided.

24 Q Okay. Do you know how many anecdotal
25 reports that looked at?

1 A Oh, my apologies. The anecdotal
2 report really comes into Factor 6. This is based
3 on other DEA data that were about the seizures
4 and in the microgram report specifically.

5 Q Okay. But all you have to, I
6 understand you've said it several times that this
7 data can be under reported, but that's, the NFLIS
8 data is all we have to go on, right?

9 A That there is evidence of these two
10 drugs, yes.

11 Q Okay.

12 A And in many states.

13 Q So would you say that since 2019 there
14 has been significant availability trafficking and
15 abuse of DOI based on the NFLIS data that you're
16 using for your own analysis?

17 A It's in totality not necessarily
18 specific to a specific period.

19 Q That, I'm asking specifically since
20 you said you don't have a, you don't have a
21 definition of what's new, that's not tied to
22 time. You don't have a definition of what's
23 significant. I'm asking you, in your scientific
24 analysis would you say that the NFLIS data
25 provided from 2019 to 2023 shows significant

1 availability, trafficking and abuse, yes or no?

2 A There are no reports since 2019 for
3 DOI.

4 Q So is that significant, is that a
5 significant amount zero?

6 A If you limit it to those years it is
7 not.

8 Q Okay.

9 A But we don't limit it to those years
10 we look at it in totality from when it was first
11 encountered.

12 Q So if you're looking at 40 total
13 seizures over the last 20 years, would you say
14 that two encounters a year is significant?

15 A Again, that's in totality of the
16 reports and --

17 Q I'm asking based on the numbers that
18 you have provided.

19 A I think any evidence is significant.

20 Q Any evidence?

21 A Yes.

22 Q If there had been one seizure in the
23 last 20 years you would say that that shows
24 significant availability, trafficking and abuse?

25 A It shows that there is evidence of it.

1 Yes.

2 Q So any evidence to you is what you
3 consider significant?

4 A Personally I think. Yes.

5 Q So that qualifier has no meaning to
6 you, significant?

7 A I think it's only one part of the
8 analysis and it's in totality. And the numbers
9 we know are under reported.

10 Q Do you have an estimate on how under
11 reported they are?

12 A No. It varies from drug-to-drug and
13 the availability of referenced standards and
14 other things.

15 Q And so you talk about the availability
16 of reference standards. Do you know how these
17 states are testing these alleged DOI substances?

18 A It varies from state-to-state and from
19 lab-to-lab.

20 Q But when you're compiling your data
21 and putting this out here as data that you think
22 is extremely relevant in regards to scheduling,
23 do you know how all these states are testing
24 these drugs?

25 A There are reports that go into

1 NFLIS-Drug. And they do have their SOPs involved
2 in, and they are confirmed clauses for those
3 drugs.

4 Q Have you reviewed the SOPs for all of
5 these labs?

6 A No.

7 Q Are there nation-wide standards that
8 match up to the DEA standard for identifying
9 drugs?

10 A Again, it's a voluntary system. Like,
11 anyone could report whatever they tested,
12 whatever they confirmed. There may be DOI or DOC
13 in samples that they didn't test for numerous
14 reasons.

15 Q Have you ever seen a state and their
16 laboratory testing regime and said that testing
17 isn't up to snuff for the DEA?

18 A I don't believe so.

19 Q Okay.

20 A I'm not aware.

21 Q Okay. So if they're whole method for
22 testing these things was to ask the guy who got
23 seized with it what it was and that was their SOP
24 and they followed their standard operating
25 procedures, you would still include that in your

1 data?

2 A I don't follow your question.

3 Q I guess my question is, do you have
4 any scientific standards that these other labs
5 have to follow?

6 A No. When I say standards it's not a
7 standard operating procedure it's actually the
8 chemical that they have to have in the laboratory
9 to confirm that that is the drug.

10 Q And --

11 A This is not a controlled substance,
12 it's likely that not all labs have it in the
13 death report. They actually said that they don't
14 usually test for such a substance. And they
15 indicated that we, good to test for.

16 Q Okay. So the standard that we're
17 talking about, that's the reference data to see
18 if it actually matches up. Did you validate that
19 data yourself?

20 A I did not.

21 Q Okay. So it's possible then that
22 without being able to review ever single test
23 that's done it's actually possible that there
24 could be potentially false positives for DOI and
25 DOC?

1 A I don't believe that to be true.

2 Q Why not?

3 A Because they are confirmed positive
4 for each lab. And those data reports are
5 submitted for external review so I don't believe
6 that we have false positives.

7 Q They're confirmed by who?

8 A By our contractor.

9 Q So when they have a positive sample
10 they send it off to someone from DEA that then
11 tests it?

12 A No. We don't test the sample again,
13 we review the report.

14 Q Okay. So you would say there is
15 absolutely zero possibility that there could be a
16 false positive for one of these substances?

17 A Of my understanding of NFLIS, yes.
18 For these drugs.

19 Q So each of these labs have their own
20 reference standards, right?

21 A Yes.

22 Q Okay. And how do they, how do they
23 test those? Can you just explain how you test
24 what a drug is?

25 A There are different techniques that

1 labs will use, but for these ones, because they
2 are law enforcement encounters they have to be
3 confirmed positive for that drug. It's not just
4 like a radar test that, or not, I don't think
5 it's radar, like a test that one might use at the
6 border to see if it's positive for something.
7 These are actually tested in labs using various
8 methods that are established that would confirm
9 that drug.

10 Q And can you describe what some of
11 those methods might be?

12 A I am not a chemist so I would prefer
13 not to.

14 Q Does a reference standard ever expire
15 over time?

16 A It could. Depending on the drug.

17 Q Okay. And in, and DEA's protocol or
18 review, is that something that you're checking in
19 their data?

20 A Again, I am not checking the data, I
21 am relying on the contractors to check it. You
22 get different peaks. And so if you had a
23 reference standard you would, for some of the
24 data you would be able to confirm that is the
25 drug. There are ways to confirm that you're

1 referencing are just still accurate.

2 Q Briefly I'd like to take a look at
3 Exhibit 7 together with Exhibit 7A please.

4 A Thank you.

5 Q Okay. And could you go to Page 10 of
6 both exhibits?

7 A Okay.

8 Q And looking at DOI, in Exhibit 7
9 that's the old data, right, from 2021?

10 A Correct.

11 Q How many total reports of DOI
12 encounters were there then?

13 A Forty.

14 Q And in what states did those
15 encounters occur?

16 A Colorado, Florida, Iowa, Indiana,
17 Kansas, Maine, Minnesota, Missouri, North
18 Carolina, Ohio, Pennsylvania, Tennessee, Texas
19 and Wisconsin.

20 Q Okay. And then that data was updated
21 for Exhibit 7A, right?

22 A Yes.

23 Q And can you tell me how many total
24 reports of DOI encounters there were in the 2023
25 report?

1 A Forty.

2 Q And can you tell me the states where
3 DOI was encountered there?

4 A It was the same states, with the
5 addition of Nevada.

6 Q So can you explain how there was an
7 additional state where this was encountered and
8 no more total encounters?

9 A I believe the, it's possible that when
10 I made the list the first time that I left off
11 Nevada. I think it was just a correction when I
12 updated the report.

13 Q So there actually weren't any new
14 states where it was encountered between 2021 and
15 2023?

16 A Just a new state that I noted to be
17 encountered.

18 Q Okay. But that was something that had
19 already occurred?

20 A I believe so.

21 Q So there weren't actually any new
22 encounters between 2021 and 2023?

23 A That is correct. But we know that
24 during COVID there was a significant reduction in
25 NFLIS reports. So during the years of 2021

1 through 2023 some of the reports did go down.

2 Like total reports.

3 Q And remind me again what year was it
4 that COVID hit?

5 A It started in December of 2019, but
6 March 2020.

7 Q Okay.

8 A And data for 2023 are still
9 incomplete.

10 Q Okay. But there was no data in 2019,
11 right?

12 A I believe that's correct.

13 Q Before COVID. And in 2018 there was
14 one, right?

15 A I believe that is correct.

16 Q And in 2017 there was one?

17 A I believe that is correct.

18 Q And in 2016 there was zero, right?

19 A I believe so.

20 Q Okay. So any drop there from one to
21 zero, I mean, there was zeros all the way, could
22 that be attributed to COVID?

23 A I mean, it is potential for that. But
24 also, this is data that HHS had in their
25 evaluation and still made a determination that it

1 has significance of abuse.

2 Q You said that the NFLIS reporting in
3 general was down in 2020?

4 A 2021 and 2020. 2020 as well.

5 Q Okay. Do you know if the number of
6 encounters for Fentanyl decreased during that
7 time?

8 A I don't know off the top of my head.

9 Q Okay. I'd like to talk for just a
10 minute about the microgram bulletin. Can you
11 just remind microgram bulletin is?

12 A These were reports put together by
13 DEA's Office of Forensic Sciences based on the
14 detection analysis of suspected drugs, controlled
15 and non-controlled.

16 Q Is that a peer reviewed publication?

17 A I believe they go through an internal
18 peer review process.

19 Q Okay.

20 A But I'm not sure. These predate my
21 time at DEA.

22 Q So they no longer produce the
23 microgram bulletin?

24 A Correct.

25 Q Do you know why that is?

1 A I do not.

2 Q And in all the labs that are mentioned
3 in the microgram bulletin claiming to have tested
4 for certain substances, do you know anything
5 about those labs testing protocols?

6 A I do not. But our Office of Forensic
7 Sciences would, and they're the ones that
8 published it.

9 Q And you mentioned in your earlier
10 testimony discussing a microgram bulletin, that
11 it mentioned specifically that sometimes these
12 drugs were encountered in powder form, right?

13 A Yes. At least one.

14 Q And my colleagues over here, he asked
15 you that the fact that it was in powder form was
16 evidence of its dangers, correct?

17 A Potentially. Yes.

18 Q What is it about a drug being in a
19 powder that makes it inherently more dangerous or
20 more subject to abuse than a pill?

21 A Well, it usually is in reference to an
22 FDA approved product that would come in a pill
23 form. And the FDA, to my knowledge, doesn't have
24 a compound that's been approved to be
25 administered as a powder form. So finding it in

1 a powder form shows evidence that it's likely to
2 be an illicit substance.

3 Q Cocaine is an FDA approved substance
4 in certain circumstances, right?

5 A Yes.

6 Q Cocaine is typically a powder drug?

7 A When it's used illicitly, yes.

8 Q Okay. So you're not aware of any
9 prescribed scheduled drug that is in a powder
10 form, in capsules?

11 A I mean, in capsules, yes. But they're
12 encapsulated so you would find a capsule not just
13 powder.

14 Q Okay. But it doesn't just appear as
15 a powder in the capsule, right?

16 A It has a capsule around it, and then
17 powder within the capsule.

18 Q Okay. But it starts out as just the
19 powder on its own?

20 A Yes.

21 Q Okay. And so, and at that point, so
22 just the fact that a drug is in a powder form at
23 that point doesn't necessarily speak to its
24 inherent danger?

25 A It just usually suggests that it was

1 intended for illicit use. Is my understanding.

2 Q Does encapsulation of powder
3 substances mean that those drugs aren't abused?

4 A No. Someone can take the powder out
5 of the capsule and abuse it. But if it's in a
6 capsule as an FDA approved product, then there
7 would have been safety and efficacy studies
8 related to that specific formulation and deemed
9 safe and effective.

10 Q Okay.

11 A But a powder can be smoked, snorted
12 and not ingested orally as intended.

13 Q In any of the seizures of DOI, was it
14 ever found in a capsule?

15 A I believe so.

16 Q Okay. So does that make it inherently
17 less subject to abuse because it's not in a
18 capsule?

19 A No, because it's not an FDA approved
20 product. So finding it, generally speaking,
21 would suggest that there would be harm related to
22 any use of it.

23 Q Okay. So being in a capsule or being
24 in a powder, based on what you just said, doesn't
25 necessarily indicate that something is subject to

1 abuse?

2 A I think being in a powder does show
3 evidence that it can be used and abused.

4 Q Other research drugs, research
5 chemicals that are ordered from the same types of
6 labs where researchers are getting DOI and DOC,
7 those also come in powders, right?

8 A Often times, yes.

9 Q Okay. And so, does the fact that
10 those drugs come in powders when they're getting
11 sent to labs, is that indicative of significant
12 abuse or potential for abuse?

13 A No. They're in adequately labeled
14 bottles and packaging with information about
15 their chemical nature. And generally
16 pharmacology data that is available for those
17 drugs.

18 Q So the microgram bulletin that you're
19 going off of that refers to these being found in
20 a powder, did it say what the powder was in?

21 A I don't recall.

22 Q It didn't say that it wasn't in a
23 labeled, sealed bottle?

24 A I don't recall.

25 Q So NFLIS could report an encounter of

1 DOI if they walked into a university laboratory
2 and saw a labeled bottle of powder DOI in the
3 safe?

4 A I'm not sure I'm following. Like
5 agents don't necessarily go into safes looking
6 for drugs to then seize.

7 Q Okay. Well let's, yes, let's, the
8 drugs that are seized, do you know anything about
9 the context in which they're seized?

10 A Sometimes. But not always.

11 Q Okay. Of the 40 seizures of DOI since
12 2005, do you know the context of, let me rephrase
13 that question.

14 Just because something is reported as
15 an encounter doesn't mean, on its own, that the
16 drug, that the substances are being used in an
17 illegal way, yes or no?

18 A I suppose not.

19 Q Okay. And just because it says that
20 it was found in a powder without any other
21 information about what that powder was contained
22 in, you don't have any knowledge other than it
23 was a powder?

24 A Sometimes there are other item level
25 details about that encounter specifically.

1 Q Okay. But in general it's not
2 required?

3 A Again, it's, everything in NFLIS is
4 voluntary.

5 Q Okay. And right now these, well, can
6 you say with certainty that possession of a
7 substance means that it's been consumed?

8 A I mean, if it's ceased and it hasn't
9 been consumed, correct?

10 Q Or that it's going to be consumed?

11 A Not necessarily.

12 Q Okay.

13 A But often times it seems that way.

14 Q Okay. But just based on the fact that
15 it was encountered doesn't tell you anything
16 about consumption?

17 A No but it, not specifically but it
18 does show that it is encountered, and we can see
19 other drugs that it's encountered with. And we
20 can get some evidence from NFLIS in that regard
21 as well.

22 Again, these are law enforcement
23 seizures so they're from state, local and federal
24 labs. So often times they are meant for
25 consumption.

1 Q So when drugs are seized that's
2 because they're illegal substances, right?

3 A Not necessarily.

4 Q So what basis is required for law
5 enforcement to seize a legal substance?

6 A I'm not a law enforcement agent, I
7 don't know.

8 Q Okay. So do you know how they're, how
9 these drugs get seized if they're not illegal?

10 A I know that different like local,
11 state, federal law enforcement seize them at
12 different parts. It could be border entry, it
13 could be in different, different instances. And
14 they're assessed for what the drugs are.

15 Q Okay.

16 A Or presume to be.

17 Q And so, since these drugs are
18 currently legal to possess, right?

19 A Yes. They are not controlled
20 currently.

21 Q Okay. So the fact that it was seized
22 doesn't necessarily indicate that that individual
23 was doing anything illegal?

24 A Again, that would be case specific.

25 Q Okay. But in general, just the fact

1 that it was seized doesn't tell you anything,
2 doesn't tell you anything about the broader
3 context of how they came to be seized?

4 A It would, again, depend on the seizure
5 and the case.

6 JUDGE SOEFFING: Mr. Phelps, is now a
7 good time to take our afternoon break?

8 MR. PHELPS: Yes, Your Honor.

9 JUDGE SOEFFING: Okay. Let's go ahead
10 and take a 15 minute recess for our afternoon
11 break.

12 (Whereupon, the above-entitled matter
13 went off the record at 3:03 p.m. and resumed at
14 3:25 p.m.)

15 JUDGE SOEFFING: Okay, we are back on
16 the record.

17 Dr. Carbonaro, I remind you you're
18 still under oath.

19 THE WITNESS: Okay.

20 JUDGE SOEFFING: And Mr. Phelps, you
21 may continue with your cross examination.

22 (Pause.)

23 MR. PHELPS: Yes, thank you, Your
24 Honor, and Dr. Carbonaro.

25 BY MR. PHELPS:

1 Q I just wanted to follow up or clarify
2 on a couple of points you mentioned before. Do
3 you know specifically where DOI is available to
4 purchase?

5 A There are companies that sell it for
6 research purchases such as Cayman Chemical or
7 others, but also there are other online websites
8 that can be purchased from.

9 Q Let's focus on the Cayman and those --
10 those type. What exactly is Cayman Chemicals?

11 A It's a company that sells substances
12 that are generally used for research to -- to
13 labs.

14 Q Okay. And is it the -- is it the only
15 business of that type or are there other similar,
16 similar companies that do the same --

17 A There are similar companies.

18 Q Okay. Any estimate on how many of
19 those may be available?

20 A The number of companies available?

21 Q Yes.

22 A I'm not sure off the top of my head.

23 Q Okay. And Cayman Chemicals, do they
24 have a DEA license?

25 A Yes.

1 Q And is a DEA license for selling
2 chemicals different than the types of licenses
3 you've described before regarding the research?

4 A Yes.

5 Q And what specifically goes into a
6 company like Cayman getting that -- that license?
7 What do I have to do if I want to start a lab and
8 sell chemicals?

9 A There are regulations put forward in
10 the CSA to follow those. I don't deal with
11 registrations related to companies.

12 Q Okay. Do you know as part of them --
13 well, that license is not permanent, correct? It
14 can be taken away?

15 A Correct.

16 Q And with this license, who is Cayman
17 able to sell to?

18 A In theory, anyone that purchases from
19 their website or from their online source.

20 Q So does the DEA have any protocols in
21 issuing licenses to control who companies like
22 Cayman can sell to?

23 A I'm sure they do. Again, that's
24 outside my scope, so I don't know what those are.

25 Q Can they sell to people to use

1 recreationally?

2 A In theory, yes.

3 Q Would that be a violation of their
4 license?

5 A If it's a non-controlled substance,
6 then it wouldn't be a violation because it's not
7 a controlled.

8 Q So it's the DEA's position that if
9 Cayman Chemical posted on these Reddit forms,
10 hey, guys, we've got your DOI, come get it, the
11 DEA would have no problem with that?

12 A Again, that's not something --

13 MR. MANN: Objection, Your Honor. I
14 don't know where this is going, but it seems way
15 outside the scope of direct.

16 JUDGE SOEFFING: I agree. I sustain
17 the objection. Is there --

18 MR. PHELPS: Yes, yes. I was using
19 that for demonstration purposes.

20 BY MR. PHELPS:

21 Q They're sold for research, right?

22 A From Cayman Chemical --

23 JUDGE SOEFFING: So I'm going to
24 sustain the objection just to be clear on that.
25 You're talking about DEA registrations. We've

1 been talking about licenses, but you're talking
2 about DEA registrations, that was really not any
3 part of the direct and I think she said that she
4 doesn't handle DEA registrations. So if you
5 could wrap it up and move on.

6 MR. PHELPS: Yeah, certainly, Your
7 Honor.

8 BY MR. PHELPS:

9 Q I just want to contrast to -- you
10 testified before that there's other places that
11 people who want to use DOI recreationally can
12 purchase DOI, right?

13 A Yes, based on my evaluation over time,
14 yes.

15 Q Okay. And what are those places?

16 A I'm not sure that I can say what those
17 websites are. They're internationally recognized
18 as websites that sell companies, but I don't feel
19 conformable naming companies that sell illicit
20 substances.

21 Q So they're out there, but you can't
22 tell us who they are?

23 A Again, I don't feel comfortable giving
24 names of those companies.

25 Q In all the data and discovery that was

1 provided, was there any numbers about how much is
2 being sold at these places that you can't tell us
3 about?

4 A Again, that's outside my scope. That
5 would be related to an agent or a diversion
6 investigator.

7 Q Well, your analysis relates to the
8 significant trafficking, so this would be part of
9 -- that would be considered part of the
10 significance of the trafficking, right?

11 MR. MANN: Objection, there's no term
12 significant trafficking used in direct.

13 JUDGE SOEFFING: I'm going to sustain.
14 I'm not sure what you mean by trafficking. I'll
15 sustain the objection. You can rephrase.

16 MR. PHELPS: Absolutely, Your Honor.
17 Give me just one second and I can read it right
18 off the -- on Page 10 of Government's Exhibit 7A,
19 beginning of Factor 5, the significance of abuse.

20 Do you have that there, Doctor?

21 THE WITNESS: Yes.

22 BY MR. PHELPS:

23 Q Okay. It says according to NFLIS-Drug
24 in the U.S. there has been significant
25 availability, trafficking, and abuse of a number

1 of phenethylamine hallucinogens including DOI and
2 DOC?

3 A Correct.

4 Q Okay. So my question then and the
5 point I'm trying to get at is if you're stating
6 here that there is significant availability in
7 trafficking, can you give us any numbers about
8 what's being trafficked out there in these places
9 that you can't tell us about?

10 A Again, that was a summary statement,
11 not specific to just DOI and DOC, but the
12 phenethylamine hallucinogens in totality and DOI
13 and DOC make up a part of that total.

14 Q Do you have any idea how much of that
15 totality DOI and DOC make up?

16 A It's just a general introduction
17 statement. I don't have a number to reference.

18 Q In general, based on the seizure data
19 that you have, do you know how significant DOI
20 and DOC are in the broader hallucinogen seizure
21 data?

22 A I know there are others that are in
23 Schedule I that have a higher number of reports.
24 But again, they're Schedule I, so more like to be
25 reported into NFLIS.

1 Q Certainly, because you mentioned that
2 the number of seizures is indicative of usage,
3 right?

4 A It is a component of it, yes.

5 Q Okay. And you also said that if DOI
6 and DOC were moved in Schedule I that the number
7 of seizures would go up, right?

8 A Likely, yes.

9 Q So does that mean that scheduling
10 these substances, by your own words, would lead
11 to an increase in usage?

12 A Not necessarily, just an increase of
13 reports that may have been missed previously.

14 Q Okay, but you said the numbers of
15 reports are indicative of the amount of usage?

16 A I'm not sure I said that.

17 Q Okay. We can move on. Those are the
18 ones that I wanted to follow up on just a little.

19 I'd like to go to Page 8 of Government
20 Exhibit 7A, Factor 3. Factor 3 is the state of
21 current scientific knowledge regarding the
22 substance and just wanted to be clear, the CAS
23 number for DOA, or excuse me, DOI, is 42203-78-1,
24 correct?

25 A I believe so.

1 Q Okay. And the CAS number for DOC is
2 123431-31-2, correct?

3 A I believe so.

4 Q Okay. Would you say that accuracy is
5 important in scientific testing?

6 A Yes.

7 Q Okay. And does the form of a compound
8 determine its pharmacological properties?

9 A The form does not, but the route of
10 administration would, which would vary by form.

11 Q Can the -- so the pharmacological
12 properties can change based on the form of the
13 compound?

14 A And route of administration, yes.

15 Q Okay. Does the salt form of a
16 compound alter its solubility?

17 A Yes.

18 Q How does solubility alter
19 pharmacokinetic properties?

20 A It again would depend on the solvents
21 that's used and having a salt form would
22 solubilize in saline more easily, but it would
23 depend on what the solvent is. And that solvent
24 could have different pharmacological activity.

25 Q So the form, if it's a salt or a free

1 base, that is important in regards to its
2 pharmacokinetic properties?

3 A Yes.

4 Q Okay, and the cited CAS number for
5 DOI, do you know is that the CAS number for the
6 salt or the free base form?

7 A It might be for the salt. I'm not
8 sure.

9 Q Okay. And the molecular weight that
10 you listed there, the 321.16 grams per mole, is
11 that the molecular weight for the salt form or
12 the free base form?

13 A I am not a chemist. I'm not sure. I
14 also -- we have chemists that reviewed this and
15 wrote this part of this document.

16 Q Okay. So did you review this prior to
17 sending it out?

18 A I reviewed it.

19 Q Okay. And did you review specifically
20 the numbers of the molecular weight for DOI?

21 A I did not. I deferred to the chemists
22 in my section.

23 Q Okay. And --

24 A It also may have come from HHS's
25 evaluation. Sometimes they put in different CAS

1 numbers. I'm not sure.

2 Q So you don't even know where this
3 number came from?

4 A Again, a chemist writes that section
5 for us, so I'm not sure.

6 Q Okay.

7 A I'd have to go back and look at the
8 HHS evaluation.

9 Q Okay. So you wouldn't know whether
10 that 321.16 is the free base weight or the salt
11 weight?

12 A I do not. I defer to the chemists.

13 Q And do you know in the studies that
14 are cited about DOI whether they're using the
15 salt or the free base weight?

16 A Generally, the salt version.

17 Q Do you know what the difference is in
18 the free base versus the salt weight?

19 A HCl does not have a large weight, but
20 I don't know what that number is.

21 Q Okay. Because what's listed here is
22 --. Okay. So what's described here as the DOI
23 salt in this analysis, right?

24 A The melting point, specifically, yes.

25 Q Okay, okay. The CAS number that's

1 listed there, do you know if that's for the salt
2 or the free base of DOI?

3 A Again, I do not.

4 Q Okay. And you don't know the
5 difference between the weights there?

6 A I don't know the weight of HCl.

7 Q Okay. So could that be possibly why
8 the CAS number describes the DOI salt, but the
9 weight given is, in fact, the free base weight?

10 A Again, I defer to the chemists in this
11 portion.

12 Q Okay, but you've adopted the chemists'
13 findings here as your own, right?

14 A I adopt -- I mean they are in this
15 document. This document is reviewed by other
16 people outside of me, as well.

17 Q Okay. And so do you know, did the DEA
18 get it wrong here with the salt CAS number and
19 the free base weight?

20 A Again, I defer to the chemists, but if
21 you're saying that that CAS number is for the
22 salt and the weight is for the free base, then
23 yes.

24 Q Okay. And those two different forms
25 could significantly alter the pharmacokinetic

1 effects, right?

2 A But this is relating just to the
3 chemical information of it. It has nothing to do
4 about the pharmacological activity of it.

5 Q Certainly. Okay, thank you for
6 breaking that down for us, Doctor.

7 (Pause.)

8 Okay, I think that's all on -- well,
9 I guess one other -- one other question regarding
10 Factor 3. This is the state of current
11 scientific knowledge regarding the substance,
12 right?

13 A Correct.

14 Q And how would the -- does the DEA have
15 a definition for what they consider current
16 scientific knowledge?

17 A This section usually is left for
18 chemical activity -- sorry, chemical knowledge of
19 it and largely any medical use that's associated
20 with it. But it could be open to other things,
21 but generally, it's limited to a couple of items.

22 Q Okay, but how do you -- when you're
23 talking current, how current are we talking?

24 A In theory it could be any information
25 that's available about the substance.

1 Q Okay. So the -- as far as current
2 research -- what was the most recent research
3 that was considered as part of this 2023
4 analysis?

5 A In Factor 3? I don't have any paper
6 studies, any papers cited.

7 Q Just in general.

8 A I'm not sure.

9 Q Okay. How do you ensure that you're
10 up to date on current scientific knowledge?

11 A I routinely read papers that are
12 published in scientific journals related to drugs
13 of abuse.

14 Q Okay. So current is what's known to
15 the DEA. It's not necessarily what's the most
16 absolutely up to date research?

17 A I mean DEA would know about like
18 current research that has been published.

19 Q Okay. Was any other research that's
20 been done on DOI in the last five years included
21 in this evaluation?

22 A Likely not --

23 Q This assessment? Likely not? So,
24 current, under the DEA's definition means at best
25 five years old?

1 A No. When I drafted this section, I
2 relied on what HHS provided us in their section
3 and I mirrored this very closely to their
4 recommendation. And since I relied on them for
5 scientific and medical evaluation, if they didn't
6 feel inclined to put it in theirs, I didn't take
7 a step further to add it into ours.

8 Q Okay, so are you aware of medical
9 research around DOI and DOC that HHS wasn't
10 interested in including?

11 A I am aware of scientific research with
12 DOI and DOC -- DOI.

13 Q Okay. And research that's more up to
14 date than five years old, correct?

15 A I am of research that has been
16 published.

17 Q Okay. But you chose not to include
18 that as part of your analysis on it?

19 A Yes, I deferred to what HHS put it in
20 their Eight Factor Analysis.

21 Q Okay. Is that because the research
22 that you're aware of personally conflicts with
23 the desired outcome of HHS?

24 A No. I don't believe that it does
25 conflict.

1 Q Okay. I'd like to go to the next page
2 here. We can use the updated 7A. This is the
3 one with your drawing on it.

4 So these are two-dimensional diagrams,
5 right?

6 A Yes.

7 Q And these substances exist in a
8 three-dimensional world, right?

9 A Yes.

10 Q So this is a pretty gross
11 simplification of what a molecule actually looks
12 like, right?

13 A It's a small molecule. I mean sure
14 it's gross, but it's not unfair. Again, I'm not
15 a chemist, but this is generally how chemists
16 draw their structures.

17 Q And you were comparing the DOI and the
18 DOC to DOM in your drawing, right?

19 A Yes.

20 Q And it was one -- it was a minor
21 change between the DOI and the DOC and the DOM,
22 right?

23 A Correct.

24 Q But isn't it true in chemistry that a
25 minor adjustment to one element of a compound

1 like this can have significant impacts on the
2 pharmacological effects of that substance?

3 A Yes, this is why we have to assess
4 each drug.

5 Q Okay. So just because a non-scientist
6 like myself may look at these and say wow, those
7 look awfully similar, that doesn't necessarily
8 mean that they couldn't have vastly different
9 effects?

10 A Correct.

11 Q Okay. Because you could make another
12 minor change to this DOI molecule and yield
13 amphetamines, correct?

14 A It would be three changes, so not as
15 minor.

16 Q Okay. So three versus one, but that
17 would change it into something that is an FDA-
18 approved chemical?

19 A Yes.

20 Q Okay.

21 A But I could also make another very
22 small change and turn it into a 2C series of
23 substances and those are Schedule I substances by
24 removing a carbon.

25 Q Okay. So could changing one element

1 of this chemical render it non-psychoactive?

2 A It could.

3 Q So there's a lot of things that a
4 small change could do to these chemicals here?

5 A Correct.

6 Q Okay. And not all of those would
7 necessarily lead to other controlled substances
8 or even psychoactive substances?

9 A I believe so.

10 Q Okay. So the last part of Factor 3 is
11 -- actually, we'll move on from that.

12 Okay, moving on to Factor 4, we've
13 covered some of this, but I want to address a few
14 things that we haven't gotten to. And that is
15 the WHO report. Can you describe what that
16 report was?

17 A Yes. DOC was up for potential
18 international control, so as part of that, the
19 WHO gets -- collects information from United
20 Nations what is available in their countries and
21 will combine data and publish a report related to
22 what data is available internationally.

23 Q Okay, did that WHO report include
24 anything about DOI?

25 A I believe there may have been a

1 mention to it, but it was not largely focused on
2 DOI.

3 Q Okay. And this is information across
4 all of Europe, correct, many countries?

5 A The U.N., not just Europe.

6 Q Okay. So a couple hundred countries,
7 give or take?

8 A I don't know the number.

9 Q Okay. And across all those countries,
10 there was indicated -- well, I guess first of
11 all, do you know anything about the U.N.'s
12 toxicology portal?

13 A I know that it exists.

14 Q Okay, do you know how it functions?

15 A I don't. It's not a database that I
16 often use.

17 Q Okay. Is it comparable to the NFLIS?

18 A I believe that there are international
19 reports within it. There are other people in my
20 section that use it more so than I do.

21 Q Okay. In that they said that across
22 all of the U.N. countries in a ten-year span,
23 2008 to 2017, there was 16 non-fatal
24 intoxications, correct?

25 A That's what the report said.

1 Q Okay. Do you know, what is a
2 non-fatal intoxication?

3 A It just means that someone likely
4 received, like, emergency care but did not result
5 in a death.

6 Q Could it be anyone that tested
7 positive for the substance? Does it have to have
8 been an emergency room?

9 A It does not have to. Again, would
10 depend on that data.

11 Q Okay. So without further data, we
12 don't know anything about those 16 non-fatal
13 intoxications other than they were recorded in
14 somebody's bloodstream?

15 A I would have to go back to the WHO
16 report. I don't remember anything specific.

17 Q Okay.

18 A There may be specific case information
19 related to those.

20 Q And why is -- this is about scheduling
21 DOI and DOC here in the United States, right?

22 A Yes.

23 Q So why is the U.N.'s input on this
24 significant?

25 A So that we meet treaty obligations.

1 Q Okay. And can you explain how those
2 treaty obligations work?

3 A Other than if it is controlled by the
4 U.N. and we have like the treaty obligations -- I
5 don't know specifics. I just know that we have to
6 -- if they vote to control something, we have to
7 act in kind and regulate it.

8 Q Okay. And that's supposed to be --
9 that's not specific to DOI or DOC, right?

10 A The treaty obligations?

11 Q Yes, ma'am.

12 A No.

13 Q Okay. It includes all the substances
14 that the U.N. schedules?

15 A Yes.

16 Q Okay. The U.N. schedules cannabis,
17 right?

18 A Yes.

19 Q And it's Schedule I?

20 A It is -- the U.N.'s Schedules don't
21 necessarily mirror our Schedules. Like where
22 they put it in theirs, may not be the same place
23 where we put ours. Their Schedules are
24 independent.

25 Q Okay. So because DOC is in Schedule

1 I in the U.N. doesn't mean that you couldn't
2 recommend it be Schedule IV or V?

3 A Except that it has no medical use.

4 Q Okay.

5 A So there is no other place to put it
6 other than Schedule I.

7 Q Okay. The reason that I ask -- so the
8 United States isn't -- doesn't have to follow
9 these identically?

10 A Yeah, whether it's Schedule I or II in
11 the U.N. is not the same as Schedule I or II or I
12 through V for the United States.

13 Q Okay. And that's how the DEA is able
14 to get around those treaty obligations in regard
15 to rescheduling cannabis?

16 A I have no comment on that.

17 MR. MANN: Objection, Your Honor, way
18 outside the scope.

19 JUDGE SOEFFING: Sustained.

20 MR. PHELPS: We'll move on.

21 BY MR. PHELPS:

22 Q So, you testified that you are
23 familiar with the issuing of research licenses
24 through the DEA, right?

25 A Schedule I researcher registrations.

1 Q Schedule I researcher registrations,
2 and you testified earlier that a Schedule --
3 moving DOI into Schedule I wouldn't inhibit
4 research because researchers could get these
5 licenses, right?

6 A Correct.

7 MR. MANN: Objection, that was not her
8 testimony. I think the question was will it halt
9 research.

10 JUDGE SOEFFING: The transcript will
11 reflect what it was, but she's answered the
12 question, so overruled.

13 BY MR. PHELPS:

14 Q Can you tell us a little bit about
15 what -- if I wanted to apply for a Schedule I
16 researcher license, what would I need to do?

17 A The regulations are put forward in the
18 CSA, but you would have to, depending on the type
19 of study, there's special -- certain information
20 that would need to be submitted to DEA, no
21 different than doing a research, a bona fide
22 research study itself.

23 So, that would be things like name,
24 address, a protocol, the amount of drug, where
25 the drug is coming from, institutional approval,

1 a CV and papers among other things, and then
2 there are -- there would be state and other
3 regulations that would apply as well.

4 Q Would I have to have a very specific
5 research project in mind or could I get a
6 Schedule I license for exploratory research?

7 A It depends how you wrote your
8 protocol.

9 Q Do you know approximately the cost of
10 obtaining a Schedule I license?

11 A From a DEA it costs -- an actual
12 registration fee is often waived. For
13 institutions, universities, it usually is private
14 entities that have to pay for one, and it's, I
15 believe, currently less than \$300 for the
16 registration fee.

17 Q Okay, do you have any idea of the cost
18 regarding -- well, I guess, what are the -- you
19 have to do a lot more than just write it out on
20 paper, right? There has to be steps taken within
21 your facility?

22 A As would any bona fide research, yes.

23 Q Okay, but specifically, you have to
24 install specific safes, right, or secure --

25 A Yes.

1 Q -- areas? Okay.

2 A There are safe requirements.

3 Q Okay, and those aren't required as an
4 unscheduled substance, right?

5 A Correct, unless they were controlled
6 by a state and working with them in a state.

7 Q Okay, do you know approximately how
8 long it takes to get a Schedule I license?

9 A From when, like from once it is
10 submitted to DEA through the approval process?
11 Is that your question?

12 Q Yes, ma'am.

13 A It varies from protocol to protocol,
14 but I think currently, we're about under three
15 months for DEA to approve a Schedule I researcher
16 registration.

17 Q So, three months would be the fastest
18 depending on the protocol?

19 A Oh, no, average.

20 Q Average. Okay, do you know how --
21 what the maximum time it could take could be?

22 A Again, that would vary depending --
23 often, when applications come to us, they're
24 incomplete, and we have to reach back and forth
25 with the investigator to get a complete protocol

1 package, because we cannot submit some of our
2 package to FDA for their analysis until it's
3 complete, and so that back and forth with the
4 investigator or them not responding back to us
5 can make that timeline much longer.

6 Q Okay, and then for researchers, if
7 they're doing this type of Schedule I research,
8 they require more licensing beyond just the DEA
9 license, correct?

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

11 Q Like a state-level license?

12 A Yes, usually.

13 Q Usually. And if -- and some type of
14 institutional approval or institutional license?

15 A It's not an institutional license.
16 It's just approval, and oftentimes, if it's
17 coming -- if the institution is reviewing it for
18 ethics, so if it's -- if there -- it's a clinical
19 study and it goes through a university's IRB, or
20 if it's an animal study and it's going through
21 the institutional's IACUC, then that would
22 qualify as the institutional approval.

23 Q Okay, and all of that is outside or on
24 top of the average three months for the DEA
25 processing?

1 A Yes, but any protocol would go through
2 those steps. It's not an addition to DEA's
3 registration to meet DEA's qualifications.

4 Q Well, if it's not scheduled, then you
5 wouldn't have to get a state-level license, would
6 you?

7 A Again, that would vary from state to
8 state, but I'm speaking specifically to the
9 Ethics Board reviews.

10 Q Okay.

11 A Those would be independent and would
12 be needed for any kind of animal or clinical
13 study.

14 Q Not a cell-based study though, right?

15 A No, but the institutional approval
16 that we request is just a letter from somebody in
17 the institution that just says they acknowledge
18 that there is a Schedule I substance in their
19 facility.

20 Q And you did a lot of work in academia
21 before --

22 A Yes.

23 Q -- you went to the DEA, right?

24 A Yes.

25 Q So, when you say it's just a letter,

1 you understand that there's a lot of steps that
2 go into getting just that letter, right?

3 A I never had to achieve such a letter,
4 so I'm not sure, because my PIs both had Schedule
5 I researcher registrations.

6 Q Okay, so you have no personal
7 experience actually applying for one of these
8 licenses?

9 A I have not had to apply for one.

10 Q Okay, do you know, is the DEA required
11 to render a decision within any set time frame
12 for these licenses?

13 A There are some notes within the CSA,
14 yes.

15 Q Do you know what those timelines are?

16 A It's again based on the complete
17 protocol application. The number I told you is
18 in totality of when we receive it and when it's
19 completed, like when it's actually approved, but
20 the date that it's complete may not be day one.
21 It may be several, like, months into it for that
22 to be true. I'm not sure --

23 It varies for whether it's a clinical
24 protocol versus a non-clinical protocol, but
25 again, the number I gave you is in totality, not

1 once an application is deemed complete, and most
2 of them come in incomplete.

3 Q Okay, and that was the three months
4 that you were --

5 A Yes.

6 Q -- talking about? Okay, do you know
7 how many applications are currently pending for
8 Schedule I licenses?

9 MR. MANN: Objection, Your Honor, this
10 is not only outside the scope of direct, but it
11 doesn't relate to any of the eight factors, the
12 five factors, or the three factors.

13 MR. PHELPS: Your Honor, the court has
14 specifically ruled that the research harm is
15 something to be -- that can be considered. She's
16 spoken on her knowledge of issuing licenses.
17 This is again an attempt by the DEA to act like
18 the research harms in this aren't relevant, but
19 this court has already found otherwise.

20 JUDGE SOEFFING: Well, I think the
21 Government did ask about the ability to get a
22 researcher registration, so I don't think it's
23 outside the scope. I did rule and say that, you
24 know, you can present witnesses as to research
25 harm. I don't know how much weight that's going

1 to get because it's not part of the Eight Factor
2 Analysis, but I'll allow you to continue with
3 this line of questioning, so I'll overrule the
4 objection.

5 MR. PHELPS: Thank you, Your Honor.

6 BY MR. PHELPS:

7 Q Dr. Carbonaro, do you know how many
8 applications are currently pending for Schedule I
9 licenses?

10 A For new applications, I do not.

11 Q Do you have any ballpark?

12 A I was in the registration last week,
13 and I think it was that if -- somewhere in the
14 process were maybe 20 new applications.

15 Q And do you know historically, is that
16 low, high, average?

17 A It fluctuates.

18 Q Okay, and do you know what the current
19 wait time is for a license?

20 A I'm not sure I understand your
21 question.

22 Q I think we'll go with three months.
23 That's at least as far as what you've
24 established. So, a couple of questions. You
25 said a lot of the DEA approval has to do with

1 analyzing the protocols of a particular
2 scientific project, right?

3 A I don't think I said that.

4 Q That's something that the DEA is
5 looking at is, what are the protocols for?

6 A We make sure there is a protocol
7 there, yes.

8 Q Okay, and so, if someone was working
9 with an unscheduled substance that then became
10 scheduled and they had to then apply, what
11 happens to their research while they're waiting
12 for that approval?

13 A Their research specific to the drug
14 that's being added, after a final rule is
15 published, there will be an effective date that's
16 published, and so research could continue until
17 that effective date, and if it has not been added
18 to their Schedule I researcher registration or if
19 they don't have one specific to that substance,
20 then it may need to be halted while they're
21 undergoing that process.

22 Q It may be, or it would have to be?

23 A Again, it would depend.

24 Q Well, if a substance is now controlled
25 and they don't have that license, they would not

1 be able to continue legally, right?

2 A I believe there is some discretion if
3 they're working on getting a Schedule I
4 researcher registration. That would be up to the
5 field's discretion, not headquarters, from my
6 understanding.

7 Q Who has that discretion?

8 A I believe the diversion investigators
9 in the fields, the field offices.

10 Q But they would, in fact, be breaking
11 the law at that point, right?

12 A If they are actively trying to get it
13 on their registration, depending on where they
14 are, there may be some discretion. Again, that's
15 outside my scope. I only deal with the part that
16 we see at headquarters.

17 Q Okay, and then once a drug does become
18 scheduled like that, do they then, are they then
19 required to be purchased from specific suppliers?

20 A Yes, they must be purchased from
21 someone that has a DEA registration.

22 Q Okay.

23 A Or they can be synthesized in-house
24 under a Schedule I researcher registration, or
25 can be transferred from one registrant to

1 another.

2 Q Okay.

3 A There are other ways to work within
4 the closed loop of distribution.

5 Q Okay, did you have any personal
6 experience with that type of licensure in your
7 time in academia, the transferring or other than
8 just applying for a straight license, these other
9 options?

10 A Again, I didn't apply for a Schedule
11 I researcher registration. I worked for PIs that
12 had one.

13 Q Okay, so you didn't have any personal
14 experience with these other avenues either?

15 A No, but we have done it for -- from
16 working at DEA, I have helped people figure the
17 information out.

18 Q And then once a substance is in
19 Schedule I, DEA then has discretion over how much
20 of that substance can be produced for research,
21 right?

22 A There will be a quota for it, yes.

23 Q Okay. And the DEA has full discretion
24 in setting those quotas, correct?

25 A That is determined outside of my

1 section. I don't -- that's outside of my
2 purview.

3 Q Okay, but theoretically, the DEA could
4 schedule a substance and then set a quota of zero
5 for that substance, right?

6 A I don't believe so.

7 Q They couldn't do that?

8 A I don't believe there's evidence of
9 that. They look at the available information to
10 them, from my understanding, from personal
11 communications, and make it based on what's
12 available. And quotas are often increased for
13 different substances, so there's a potential if
14 it is too low, that it could be increased.

15 Q Okay, do you know what's considered in
16 making those, setting those quotas at all?

17 A Again, that's outside my scope.

18 Q Okay. Isn't it true that once a drug
19 does become scheduled, it goes from unscheduled
20 to scheduled, that the costs of that for
21 researchers to purchase increases significantly?

22 A Not necessarily. As a matter of fact,
23 DOB and DOM seem to be cheaper than DOI on Cayman
24 Chemical's website, similar or cheaper. One was
25 cheaper. I don't remember the other one.

1 Q Okay. The substances that you were
2 just mentioning, the DOI, do you recall if that
3 was for a research standard amount or for an
4 actual quantity for research purposes?

5 A I believe it was an actual amount for
6 research purposes. I believe it was 50
7 milligrams compared to 50 milligrams.

8 Q Okay.

9 A I believe, but DOI, if a company so
10 chooses to make a reference standard, they could
11 also do that for DOI and it would be an
12 uncontrolled reference sample as they are many
13 other Schedule I substances. But that would be
14 up to the company's discretion.

15 Q And you said that you're pretty up to
16 date on the latest research going on with DOI,
17 scientific research?

18 A I have read many studies about DOI.

19 Q And if you had to describe in general,
20 what kind of research is being done on DOI now?

21 A I believe a lot of studies with DOI
22 are using DOI as a reference drug compared to
23 other psychedelics, looking at molecular or
24 mechanisms of action related, like new drugs,
25 comparing them to DOI or just other drugs in

1 general, using that since it is a known 2A
2 agonist with psychedelic properties.

3 There are not just cells, but there
4 are animal studies such as head-twitch that use
5 it, again as a reference standard. There are
6 other studies as well going on with it. I know
7 there was a paper published somewhat recently, I
8 don't remember the year, with DOI may be used as
9 an anti-inflammatory, but again, in rodents.

10 But most of it, all of it is
11 preclinical, so in, I believe, just rodents, and
12 cells, and worms, but I don't think anything -- I
13 don't recall anything in non-human primates or
14 humans in the last -- I don't know, in a long
15 time.

16 Q So, right now, the research is limited
17 to, like you said, preclinical, right? It's not
18 actually on humans?

19 A Correct.

20 Q But the end goal of that research
21 would be to understand how these mechanisms work
22 in humans and related to human diseases?

23 A Potentially, depending on the study.

24 Q There --

25 A Not necessarily.

1 Q They're not just studying it to find
2 out what happens to rats in the long run?

3 A I suppose. I don't -- I'm not sure.

4 Q Okay, and so, in your understanding of
5 general scientific research and how things work,
6 the end goal of this research on serotonin
7 receptors has to do with how it may impact human
8 health, right?

9 A With certain psychedelics, not
10 necessarily with DOI or DOC.

11 Q Okay.

12 A And also non-hallucinogens that
13 activate the serotonin 2A receptor.

14 Q Okay, and so, are you aware of the
15 order or the standard operating procedure that
16 these researchers go through to get from
17 preclinical studies to approved drugs?

18 A Generally speaking, early in the drug
19 development process, you would start with some
20 sort of cellular in vitro like binding assay
21 function and then move up through different live
22 body systems, rodents, what have you, and then
23 after there is some level of understanding
24 relating its potential safety, then it is brought
25 into humans for phase one, two, and three

1 studies.

2 Q Okay, so what begins as preclinical
3 research very oftentimes, or at least the attempt
4 is to get that through all of those steps you
5 just said?

6 A Not necessarily. There are -- I mean,
7 it's possible, but a lot of drugs fail during the
8 preclinical phase and never make it to humans.

9 Q Okay, but every drug that makes it
10 through phase three and is eventually approved
11 begins with preclinical studies, right?

12 A Most of the time. I'm not going to
13 say every time.

14 Q Okay, every is maybe -- I'm sure you
15 could find exceptions, but in general, studies
16 that go through phase three began with
17 preclinical studies?

18 A In general, yes.

19 Q Okay, so would it be reasonable to
20 infer then that preclinical research does, in
21 fact, have value to, ultimately, medical research
22 on humans?

23 A Ultimately, it could.

24 Q Okay.

25 A But it doesn't mean it has medical

1 value, but it could attest to that.

2 Q Yeah, or even at the very least,
3 medical research on humans. Whether that ends up
4 going anywhere or not is --

5 A I wouldn't say necessarily medical
6 research, as I would just call it clinical
7 research.

8 Q Okay, what would you say is the
9 difference between medical research and clinical
10 research?

11 A Medical research usually has some sort
12 of therapeutic metric in mind and they're testing
13 it for some indication. Clinical research may
14 not have that same point. They may just be
15 assessing something else, but not necessarily
16 related to a clinical indication.

17 Q Okay.

18 A That's my personal opinion.

19 Q So, that's not like an industry kind
20 of standard? That's just how you -- that's your
21 personal opinion on those?

22 A I'm not sure what the industry
23 standard is. I'm not in the industry.

24 Q Okay, okay, so there can be some value
25 to preclinical research in terms of medicine and

1 eventually accepted treatment?

2 A Yes, as a stepping stool, yes.

3 Q Okay, and are you aware of any studies
4 out there looking at DOI for its anti-addictive
5 properties in preclinical or clinical?

6 A I'm not sure what you mean by
7 anti-addictive models.

8 Q That it can be used in treating
9 substance abuse disorder?

10 A I am aware of self-administration
11 studies in which DOI was given to animals that
12 learned to respond to other drugs that are
13 administered, if that's what you're referring to.

14 Q Okay, are you aware of any preclinical
15 or clinical studies looking at DOI for its use in
16 treating anxiety?

17 A I know that it has been used in some
18 models, such as, I believe, forced swim tests and
19 other models that might be markers of
20 anti-anxiety.

21 Q Okay, and you mentioned before already
22 that you are aware of some studies looking at DOI
23 and its properties related to its
24 anti-inflammatory qualities, right?

25 A Yes.

1 Q Okay, are you aware of studies looking
2 at DOI for its pain management properties or its
3 understanding of how pain works in the body?

4 A Not specific to DOI. I know that
5 serotonin, especially the 2A receptor, has been
6 investigated, but not specifically with DOI.

7 Q Okay.

8 A Oh, I retract. I am aware of some,
9 yes, and there are some cases where it increased
10 pain and other cases where it reduced pain, and
11 it mattered like where it was administered.

12 Q Okay, how about studies looking at DOI
13 for its potential use in treating cluster
14 headaches?

15 A I am not aware of that off the top of
16 my head.

17 Q Okay, and so, of those studies that
18 you mentioned that you're familiar with, do you
19 have any knowledge of whether those are being
20 conducted through laboratories that have DEA
21 licenses of any type?

22 A Yes.

23 Q Okay.

24 A Most of them. I'm not going to say
25 all of them, but I am aware that these types of

1 studies are being done in Schedule I research
2 labs.

3 Q Okay, some of them are and some of
4 them are not, fair to say?

5 A I have not reviewed all of them in
6 totality to know.

7 Q Okay.

8 A Some of them are also done outside of
9 the United States, so that would be -- that would
10 not be an important factor.

11 Q And this is a pretty wide range of
12 potential medical benefits we just went through,
13 is that accurate?

14 A In preclinical models, yes.

15 Q Okay, and do you know whether that
16 research would have been able to be done if DOI
17 was not currently, if it had always been
18 scheduled back at the same time as DOM or those
19 substances?

20 A Based on my analysis, it looks like
21 most of the labs that are studying DOI are also
22 studying Schedule I substances. There may be
23 some cases where they are not, so it seems likely
24 that it still would be able to continue.

25 Q Okay, but you said you're not aware of

1 the ratio of researchers that are doing with a
2 Schedule I license or not?

3 A I'm not personally aware.

4 Q Okay, are you aware of any companies,
5 pharmaceutical or otherwise, that are looking
6 into DOI research?

7 A I am not, specifically. Like in
8 animals, or in humans, or just generally
9 speaking?

10 Q Both.

11 A I am not. We did confer with HHS, and
12 no one has submitted an IND, so if anything, it
13 would be preclinical.

14 MR. PHELPS: Just one second, Your
15 Honor. Let me confer with my counsel here.

16 (Pause.)

17 BY MR. PHELPS:

18 Q Okay, I'd like to move us now into
19 Factor 7. I'm looking at Government's Exhibit
20 7A. That would take us to page 12. So, this is
21 psychic or physiological dependence liability,
22 correct?

23 A Yes.

24 Q All right, and it's been a long day,
25 so I just want to make sure I've got those two

1 straight. Physiological -- how would you define
2 physiological dependence liability?

3 A Well, it's usually the body has made
4 some adaption so that it needs continued use of
5 the drug to maintain, and then usually there is
6 some notion of tolerance or withdrawal that also
7 pairs with physiological dependence.

8 Q Okay, so it's how it affects your
9 actual body systems?

10 A Yes.

11 Q For example, somebody that's
12 physiologically dependent on alcohol that's
13 coming off could have, like, tremors or that kind
14 of thing? That's what we're referring to in
15 general, right?

16 A Correct.

17 Q Okay, and there's been, according to
18 HHS and the DEA's own data, there's no evidence
19 of physiological dependence liability for DOI and
20 DOC, correct?

21 A Correct.

22 Q And that includes in animals and in
23 humans?

24 A Correct.

25 Q So, DEA's position -- and if we look

1 at -- this is on page two. I think you're going
2 along with us there, right, on Factor 7?

3 A Yes, page two, yes.

4 Q Yes, so it says thus, it is not
5 possible -- well, I'll just read through the
6 whole thing. According to HHS, the physiological
7 dependence liability of DOI and DOC in animals
8 and humans is not reported in scientific and
9 medical literature. Do you know, is that
10 something that they've tried to test for?

11 A I'm not aware of a specific study
12 looking for it.

13 Q Okay.

14 A There have been studies of tolerance
15 related to the 2A receptor being downregulated,
16 but I believe that's as far as it's really been
17 investigated.

18 Q And this kind of ties back into the
19 self-administration studies, right? That could
20 be a way to show physiological dependence?

21 A It could be used that way, but I'm --
22 but it could be used other ways.

23 Q Okay.

24 A Usually, you give -- if it was an
25 animal study, a chronic injection over some

1 period of time, multiple times a day or what have
2 you by the protocol and the drug's kinetics, and
3 then try to precipitate withdrawal or let the
4 animal withdrawal themselves and look at the
5 behavioral effects.

6 Q Okay, and of all of the studies and
7 everything you've seen for DOI and DOC, you
8 haven't seen anyone even trying that or just
9 reporting that it hadn't happened?

10 A I'm not aware of anyone trying it.

11 Q Okay.

12 A But it's also known that hallucinogens
13 of this class don't cause physical dependence, so
14 it wouldn't necessarily be expected that that
15 study would need to be done either.

16 Q Okay, I'm glad you brought that up
17 because that brings me to the very next sentence
18 there. It says, thus, it is not possible to
19 determine whether DOI and DOC produce
20 physiological dependence following acute or
21 chronic administration.

22 So, you wouldn't expect there to be
23 evidence of that physiological dependence, right?

24 A We also don't have to have evidence of
25 physiological dependence to control something.

1 Psychic dependence alone would meet this
2 criteria.

3 Q Okay, and could you define for me
4 psychic dependence?

5 A I generally use it in the way that HHS
6 has reported on it in the past, and that is it's
7 likely to be used, like continued use of these
8 substances even though that they may know that
9 they could cause harm.

10 Q Okay.

11 A That would be things like if the drug
12 caused euphoria or markers of like drug liking.
13 Things like that that have been reported with
14 hallucinogens would meet the criteria for psychic
15 dependence.

16 Q But you testified during direct that
17 in all of your studies and research, almost
18 everyone that takes DOI or DOC only takes it
19 once, right?

20 A No, I did not testify to that. I
21 think I said that some people will take it once,
22 but I don't know how often people take it.

23 Q In the Erowid reports, did people
24 indicate a desire to take it again?

25 A I don't recall all of the Erowid

1 reports specifically, but I know in some reports,
2 people will say that they enjoy it and will seek
3 out a long-acting phenethylamine hallucinogen.

4 Q Okay, so you don't recall testifying
5 that most people only take it once?

6 A I do not.

7 Q Okay, if --

8 JUDGE SOEFFING: Mr. Phelps, is there
9 another question?

10 MR. PHELPS: Yes, Your Honor. We're
11 just -- our whole team had clear notes on this,
12 and I think it's critical in regards to the
13 psychic dependence of Ms. Carbonaro's testimony.
14 I'm just looking at where we're at and where
15 we're at in the day and whether we would need to
16 go back and review the record regarding what she
17 said about that.

18 JUDGE SOEFFING: Well, I mean, she
19 says she doesn't recall testifying that way. The
20 transcript will show whether she did or not and
21 you can make use of it then, but --

22 MR. PHELPS: Certainly, okay.

23 JUDGE SOEFFING: -- as of right now,
24 she says she doesn't remember saying that. I'm
25 not really remembering her saying that either,

1 but the transcript will reflect what she said.

2 MR. PHELPS: Okay, no problem. Yeah,
3 we don't need to go digging that up right now.
4 We can include that in any kind of, yeah,
5 post-hearing briefing.

6 BY MR. PHELPS:

7 Q So, if it was the case that most
8 people took a drug and didn't want to take it
9 again because of its extremely long-lasting
10 effects, would that qualify as psychic
11 dependence?

12 A Yes, because there are reports of
13 people seeking out long-acting phenethylamines
14 such as DOM and other drugs that have long-acting
15 effects, so I think it would still meet that
16 definition.

17 Q So, when you're going through these
18 criteria of psychic dependence or physiological
19 dependence, are you looking at the population as
20 a whole or are you looking at -- does it only
21 take one person to say I really that want to do
22 it again for the whole drug to be classified as
23 creating psychic dependence?

24 A I'm looking at data in its totality,
25 but then also relating it back to what's known,

1 again, the drug discrimination data showing that
2 they're similar to other drugs, and they have
3 known psychic dependence.

4 Q But we did establish that the drug
5 discrimination studies don't show the psychic
6 dependence, correct?

7 A Correct, I'm not saying that the drug
8 discrimination show, studies, sorry, my
9 apologies, the drug discrimination studies show
10 psychic dependence, but they show that they are
11 similar to other drugs that have known psychic
12 dependence, so it would be reasonable to assume
13 that DOI and DOC could then have the same
14 potential for psychic dependence as those
15 hallucinogens.

16 Q And --

17 A And that was a conclusion from HHS
18 that I reiterated, so HHS felt strongly about
19 that statement.

20 Q Okay, but there's been no studies
21 showing actual dependence, right?

22 A Again, there have been no clinical
23 trials with DOI or DOC, and we can only go off of
24 the information that is available and what we
25 know that are similar to other Schedule I

1 substances with the same mechanism of action.

2 Q And, well, what about actual
3 dependence in non-human subjects?

4 A Again, we would confer back to the
5 mechanism of action and how it is similar and has
6 the relative potential for the same for drugs
7 that have the same mechanism of action.

8 Q Doctor, do you have a general
9 definition of dependence outside of the psychic
10 or physiological?

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

12 Q Okay, I guess, what actually
13 constitutes dependence?

14 A Again, that depends on whether you're
15 talking about physiological dependence or psychic
16 dependence.

17 Q Okay, and so, going back to the factor
18 one, the four factors for abuse, would you say
19 that any use of DOI or DOC constitutes abuse?

20 A I mean, based on these four factors,
21 it just shows that we need evidence of it, so I
22 guess my answer is, yes, if they're using it
23 intentionally for hallucinogenic effects.

24 Q And using a drug for hallucinogenic
25 effects could actually have medical benefits,

1 right?

2 A I'm not sure where you're going with
3 that. I don't understand.

4 Q Well, you're saying that any use is --
5 you're saying that it's abuse because they're
6 using it for hallucinogenic properties, right?

7 A And also not under like the guidance
8 of like a medical practitioner, so just use on
9 their own for hallucinogenic use.

10 Q Okay, so in general, right, or if
11 we're looking across other substances, right,
12 just the fact that something has hallucinogenic
13 properties doesn't necessarily mean that that's a
14 bad thing, right? There can be benefits to that?

15 A It's seen as an adverse effect by HHS,
16 a hallucinogen. Whether that's intended or not
17 intended, it's considered an adverse effect.

18 Q Okay, but I'm asking you about your
19 personal opinion as an expert in this field. The
20 fact that a substance is hallucinogenic is not an
21 inherently problematic --

22 A Are you referring to like psilocybin
23 studies and other studies that are going on
24 related to hallucinogens in therapeutic contexts?

25 Q Sure.

1 A Okay, I think that there are certain
2 guardrails in place for those studies to happen
3 in a well-controlled setting. There are a lot of
4 things, inclusion and exclusion criteria that are
5 in place to allow these studies to happen.

6 There are some people that believe
7 that a hallucinogenic effect is important in
8 those therapeutic contexts. There are others
9 that believe activating but not having a
10 hallucinogenic effect would also be important in
11 having a therapeutic effect. I think there's two
12 camps in the hallucinogenic field.

13 Whether a hallucinogenic effect may be
14 useful is still under investigation, especially
15 for psilocybin, like they're undergoing Phase 3
16 studies, but there are harms that also occur in
17 these clinical trials.

18 Q Okay, so in your personal expertise
19 and opinion, which camp do you fall into?

20 A As a researcher, I'm interested in
21 both.

22 Q Okay, and the guardrails that you're
23 referring to, that boils down to what's
24 essentially known as set and setting, correct?

25 A But also the inclusion and exclusion

1 criteria are very stringent on these studies
2 right now. It's not just set and setting. It is
3 also a known dose, a known dose formulation, the
4 route of administration. It's more than just set
5 and setting.

6 Q Okay, what are the inclusion and
7 exclusion factors?

8 A Generally, for exclusion, they have to
9 not come from a family that has a psychosis, like
10 a background of psychosis or other mental
11 conditions largely, other like cardiovascular
12 effects. There are like health things that have
13 to be checked off along the process. Oftentimes,
14 if they're taking other medications, they're
15 excluded from the study, but not always. Again,
16 it depends on the type of study and what the
17 outcome is.

18 Q So, if we could look at page two of
19 Exhibit 7A, there's a quote from you here. Okay,
20 you're on page two there, Doctor?

21 A Yes.

22 Q Okay. On background, the first
23 paragraph, can you read the sentence that starts
24 there on the third line starting with the
25 subjective effects?

1 A The subjective effects of
2 hallucinogens drive their abuse.

3 Q And keep reading the next sentence,
4 please?

5 A The abuse of these substances can lead
6 to a variety of adverse health effects such as
7 paranoia, agitation, depression, and violent
8 outbursts towards self and others.

9 Q And who is cited there?

10 A I am.

11 Q This was a paper that you wrote?

12 A Yes, with other authors.

13 Q You were the lead author on that
14 though, right?

15 A On that paper, I was the first author,
16 yes.

17 Q The first author, yes, ma'am, and do
18 you remember the title of that paper?

19 A It was about challenging experiences
20 with psilocybin mushrooms.

21 Q Was it only challenging?

22 A I mean, it was related to challenging
23 experiences, but there is more in the title if I
24 can find it.

25 Q Okay.

1 A The survey and study of challenging
2 experiences after ingesting psilocybin mushrooms,
3 acute and enduring positive and negative
4 consequences.

5 Q Positive and negative consequences,
6 because what you're cited here in the paper, and
7 generalizing it to all hallucinogens, you're just
8 talking about the negatives, right?

9 A I was referring to the negatives, yes.

10 Q Okay, do you recall what you said in
11 the last paragraph of that paper?

12 A I don't specifically recall.

13 Q The office it cites? If I showed you
14 an excerpt of that, would that help refresh your
15 recollection?

16 A Sure.

17 MR. PHELPS: May I approach, Your
18 Honor, or I can provide this? We just have a
19 quote pulled from the paper that's being cited.

20 JUDGE SOEFFING: I'll tell you what.
21 Why don't you print out some copies for tomorrow?
22 Because we're kind of reaching the end of the day
23 today.

24 MR. PHELPS: Okay.

25 JUDGE SOEFFING: But I'll need to

1 probably put that in the record.

2 MR. PHELPS: Okay, we can make that
3 happen.

4 JUDGE SOEFFING: So, you can print off
5 some copies that we can all look at tomorrow?

6 MR. PHELPS: Okay.

7 JUDGE SOEFFING: All right? We're
8 getting close to 5:00. I'll let you do that
9 tomorrow. Is there any other question you want
10 to ask on this --

11 (Simultaneous speaking.)

12 MR. PHELPS: I think for now, at this
13 point, if we could -- this was kind of the next
14 route we're going, so I don't think it would make
15 a lot of sense to jump back if we can pick up
16 here tomorrow.

17 JUDGE SOEFFING: Okay, let's go off
18 the record.

19 (Whereupon, the above-entitled matter
20 went off the record at 4:53 p.m. and resumed at
21 4:54 p.m.)

22 JUDGE SOEFFING: Okay, we will end as
23 we are closing in on 5:00. We will end the
24 testimony for today. Dr. Carbonaro, I dismiss
25 you from the witness stand for today. Please do

1 not talk about your testimony with anybody during
2 the break until tomorrow.

3 You're still under oath, and you're
4 still technically on the stand, so you can't
5 discuss your testimony with anybody. And with
6 that, I'll look forward to seeing everybody
7 tomorrow at 9:00 a.m. We're in recess.

8 (Whereupon, the above-entitled matter
9 went off the record at 4:54 p.m.)
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19
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21
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23
24
25

A			
A-C-H-B-A-C-H 31:13	206:24 215:1 216:20	actively 254:12	admissions 105:20
a.m 1:13 4:2 10:20 77:2	218:5,17 219:1,12,12	activities 99:15	admit 39:14,18 82:3
77:3 280:7	228:19,25 236:13	activity 62:4 89:17	84:8 122:11
abbreviation 124:13	262:9 273:18,19	99:14,17 100:25	admitted 13:4 73:5
abbreviations 60:6	274:5 277:2,5	107:3,7 108:9,15	138:1 175:1
ability 27:5 134:20	abused 29:25 106:11	109:3,5,7,23 111:5	adopt 234:14
251:21	112:18 126:19 186:3	132:20 141:4 231:24	adopted 234:12
able 15:12 17:3 19:18	186:21 195:5 218:3	235:4,18	adverse 89:25 135:5,8
20:16 25:18,19 77:12	219:3	acts 46:2 52:5 108:5	135:13 146:6 150:6
77:18 101:21,23	abuser 141:10	199:12	150:10 177:7,13
114:13 155:25 163:17	academia 249:20 255:7	actual 36:25 95:6 102:6	274:15,17 277:6
165:15 170:5 171:7	academic 55:13 61:5	126:22 246:11 257:4	advice 97:25 98:5,12
209:22 211:24 225:17	accepted 29:1 68:24	257:5 266:9 272:21	163:14 178:9
244:13 254:1 264:16	119:1 147:10,11,18	273:2	advisor 71:6
264:24	149:1 150:2,11	acute 268:20 278:3	affiliated 119:2
abnormal 27:14	188:18 199:19 262:1	adaption 266:4	affinities 108:7,8
above-entitled 1:13	accepts 74:5	add 33:22 151:6 237:7	affinity 108:2 109:11
77:1 153:19 223:12	access 77:12,17,19	added 253:14,17	afternoon 154:17 223:7
279:19 280:8	172:16	addiction 61:13 195:11	223:10
above-referred 80:7	accessing 78:4	195:13	age 170:3
82:15 85:4 93:9	accidentally 105:3	Addictions 63:23	agency 6:15 7:22 11:23
122:21 139:8	accuracy 231:4	addictive 195:9	35:13 38:17 40:25
absence 36:5 39:21	accurate 35:19 39:3	addition 33:7 213:5	41:5,6,8,17 42:5 44:6
43:19 58:19 74:3	43:8 58:8 204:13	249:2	47:14 48:9,10,14
76:14 80:5 82:13 85:2	212:1 264:13	additional 11:10 40:25	49:21,24 201:16
93:7 139:6	accurately 168:25	56:18,20 85:17,18,19	203:13
absolutely 51:20 187:4	Achbach 3:5,11 30:13	117:9 172:13 191:2	Agency-viewable 41:14
210:15 228:16 236:16	30:18,19 31:1,4,12,14	213:7	agenda 18:20
abuse 30:5 56:12 58:1	31:24 36:14 37:15	Additionally 5:22 10:4	agent 222:6 228:5
59:8,11 61:24 62:18	40:3 44:1,22 47:12	19:20	agents 88:7 132:24
95:7,11,13,16,18	51:14	additions 57:13 58:7	133:7 220:5
96:13,20 99:10,20,22	achieve 250:3	address 7:2,7,11 8:5,5	aggregate 138:10
99:25 100:2,10 102:1	acknowledge 249:17	8:7,18 14:18 23:23	agitation 277:7
105:12 109:22 112:17	acquire 56:15	54:3,6,7 240:13	agitations 137:3
112:19 113:14 114:9	acquired 55:25 56:17	245:24	ago 27:25 29:16 181:4
125:18 126:4 127:5	acquiring 184:24	addresses 6:23	agonist 107:8 108:11
128:10,19 129:14,16	act 4:21,22 6:5,10 26:24	adequate 29:22 143:3,9	108:13,16,21 109:7,8
134:4 136:21 142:23	45:17 46:1 51:22,25	148:6,10,16,20	111:5 115:20,21
143:1 144:23 145:1	52:4 57:20 67:3,15,17	adequately 63:5,10	117:23 196:14 258:2
145:11,15,19,21	103:6 182:15,16	219:13	agree 16:12 97:9 150:5
146:20 147:2,6	183:1,10 243:7	adjustment 238:25	226:16
151:11,20,24 155:3	251:17	administer 98:1 163:15	agreed 16:8
156:22,24,25 157:1	acting 32:20 34:25,25	193:18,19	agreement 41:8
157:11,18,20,24,25	37:25	administered 111:2	ahead 73:15 136:12
158:2,4 163:4 170:13	action 26:23 27:7 29:10	131:11 185:6 186:1	223:9
174:12 178:3,5	60:1 83:19 91:9 99:24	216:25 262:13 263:11	al 66:13
184:11 186:5,15,17	100:20 106:10 111:20	administration 1:2 2:5	Alaina 2:22 8:13
186:23 187:20 188:5	117:8,19 118:1	5:5 29:18 32:3 38:19	alcohol 72:18 266:12
188:14,15,16,19,23	140:18 187:8,10	54:21 63:16 64:5	Alexander 28:1 104:7
188:25 190:10,13,18	188:12 193:11 200:11	115:17 116:7 141:11	114:24 115:2 179:25
191:5 192:12,19	200:16,20 201:6,20	191:8 231:10,14	Alexis 2:4 7:6
193:2,21,22 194:10	257:24 273:1,5,7	268:21 276:4	alive 176:25
194:12,19,23 195:3,7	actions 61:20 64:18	administrative 1:16	ALJ 3:9 11:25 12:2,5
195:13,15 197:3,12	178:2 201:24	4:19,21 45:18 50:23	39:13
198:7 199:24 202:12	activate 259:13	51:2	alleged 207:17
202:16,21 203:3,9,22	activating 110:25 275:9	Administrator 11:22	allow 252:2 275:5
204:3 205:15 206:1	active 46:23 62:24	13:2,6 33:17 37:4	allowable 154:4
	201:24	38:22	allowed 9:20 16:19,25

25:23
allowing 22:12
allows 100:7
Alright 88:16
alter 231:16,18 234:25
alterations 42:17
amount 159:13,18,22
 159:25 160:6,8,14,25
 161:3,4,10,24,24
 191:7 206:5 230:15
 245:24 257:3,5
amounts 96:7 158:9
 159:9 160:22 161:13
 196:19 199:12
amphetamine 113:8
amphetamines 113:7
 239:13
analogized 197:4
analogizing 197:22
analogues 100:12,14
analogue 46:12,13
 64:17,17 67:3,14,17
 182:15,16 183:1,10
analogues 64:15
 182:10
analysis 68:6,11 74:21
 75:18 79:14 81:16
 83:24 94:21 100:5
 104:11 105:17 130:4
 135:22 155:7,10,19
 155:20 156:15 158:21
 161:17 178:23 181:1
 181:14,22 195:12
 196:4 202:8 203:8
 204:1 205:16,24
 207:8 215:14 228:7
 233:23 236:4 237:18
 237:20 248:2 252:2
 264:20
Analyst 32:17
analytical 173:22
analyze 71:7,11 125:18
 134:12 147:17
analyzed 71:21 133:16
 157:7
analyzing 172:4 253:1
and/or 23:16
Anderson 17:14,17
 22:4
anecdotal 98:25 103:13
 103:13,17,24 104:12
 114:18 116:19,23
 125:22 161:18 169:7
 171:16 172:1 174:22
 204:21,24 205:1
animal 101:15 110:7,10
 112:22 128:8 151:14
 186:6,12 191:1,6,23

194:2 248:20 249:12
 258:4 267:25 268:4
animal's 191:18
animals 61:24 102:6
 112:12,20,25 113:2
 113:19,20 127:22
 151:13 185:14 186:6
 190:14 192:12 195:9
 195:18 262:11 265:8
 266:22 267:7
announcing 4:17
annual 24:23
answer 11:12 191:25
 273:22
answered 46:19 245:11
antagonist 108:19,24
 111:1 115:22,23
 116:4 187:12
anti-addictive 262:4,7
anti-anxiety 262:20
anti-inflammatory
 127:23 258:9 262:24
anticipates 29:9
anxiety 90:6 104:2
 262:16
anybody 41:23 280:1,5
apart 58:6
apologies 54:14 205:1
 272:9
apologize 158:12,19
Appeals 18:14
appear 24:8,17 25:1
 67:17,24 217:14
appearances 2:1 6:22
appeared 14:15 25:4,5
applicable 163:5
application 124:17
 147:15 250:17 251:1
applications 152:20
 247:23 251:7 252:8
 252:10,14
applies 96:24 178:13
apply 10:16 142:17
 181:9 245:15 246:3
 250:9 253:10 255:10
applying 250:7 255:8
appreciate 77:25
approach 278:17
appropriately 33:11
approval 124:5,16
 125:10 245:25 247:10
 248:14,16,22 249:15
 252:25 253:12
approve 247:15
approved 33:18 61:19
 97:1,2 98:9 116:4
 123:18 125:8 126:20
 126:23 132:6 134:5

144:16 147:14 180:25
 199:23 216:22,24
 217:3 218:6,19
 239:18 250:19 259:17
 260:10
approximately 10:21
 18:1 35:9 246:9 247:7
April 57:18
area 59:6
areas 20:12,25 247:1
argue 24:5
argued 67:9
argument 4:14 13:19
arguments 11:14 13:19
 15:10
Arlington 1:12 5:1 6:14
 55:21
Army 1:11
Army-Navy 54:9
arose 23:4
arrangements 24:15
arrived 135:15
arriving 45:10
arthritis 127:24,25
 128:2 173:14
arts 55:15,19 56:1,6,14
asked 9:20 13:14 46:19
 68:2,5 216:14
asking 9:22 37:10
 75:11 125:11 203:12
 205:19,23 206:17
 274:18
asks 79:4
aspects 189:22 190:2
assay 110:11,15,16
 187:11 188:12 189:12
 193:3 259:20
assays 184:18
assess 64:23 87:6
 95:12 107:16 123:11
 170:13 171:14 174:12
 179:5 187:7 188:11
 188:13,15,19 194:12
 239:3
assessed 157:25
 222:14
assessing 100:10
 114:9 127:5 192:19
 261:15
assessment 236:23
assigned 32:12 74:19
 74:24
assignments 32:9
assist 16:18
Assistant 78:22 183:3
associated 105:20
 135:9 139:21 142:1
 150:6 159:17 235:19

assume 60:19 61:1
 100:3 178:6 272:12
attain 61:1
attained 60:20 61:2,3
Attanasio 2:4 7:5,6
attempt 251:17 260:3
attempts 50:12
attend 9:3
attendance 10:11
attended 135:14
attending 6:18
attention 77:9 107:19
 126:10 128:23 146:23
 154:18 181:5
attest 261:1
attesting 35:9
attorney 67:25
Attorneys 183:4
attribute 177:6
attributed 175:4 214:22
auditory 21:2 103:19
 104:1
August 32:7 35:17 50:9
 81:20 82:25 83:1,16
 83:18
AUSA 183:13
author 277:13,15,17
authoritatively 49:11
authorized 10:17
authors 176:17 277:12
availability 202:16,21
 203:22 205:14 206:1
 206:24 207:13,15
 228:25 229:6
available 72:9 87:21
 94:19 99:1 107:2
 118:14 123:18 144:16
 147:25 149:7,11,13
 149:23,25 151:12,23
 155:7 163:1 171:4
 219:16 224:3,19,20
 235:25 240:20,22
 256:9,12 272:24
avenues 255:14
average 247:19,20
 248:24 252:16
aware 28:6 46:23,25
 48:2,18,21 50:14,17
 50:20 97:8 127:9
 128:3 132:7 149:24
 155:14 163:8 164:4,5
 164:18 172:15 183:8
 192:17 194:5 196:9
 196:24 198:9 200:3
 208:20 217:8 237:8
 237:11,22 259:14
 262:3,10,14,22 263:1
 263:8,15,25 264:25

265:3,4 267:11
268:10
awfully 239:7

B

B 2:4 96:17 102:14
162:8,10
bachelor 55:15,19 56:1
56:6
bachelor's 59:2
back 77:4 93:15 95:23
108:7 110:23 111:6
114:18 153:22 154:18
158:24 167:19 173:9
177:16 202:7 223:15
233:7 242:15 247:24
248:3,4 264:18
267:18 270:16 271:25
273:4,17 279:15
back-end 34:3
background 55:11
276:10,22
backup 152:16
backwards 63:13 65:22
bad 116:6,12,16 274:14
ballpark 252:11
ballpoint 120:7
Barrett 66:4
base 123:16 232:1,6,12
233:10,15,18 234:2,9
234:19,22
based 48:23 59:18 62:5
67:24 86:3 87:18
91:13 96:12,14 99:18
100:10 101:16 105:12
105:15 106:6 107:1
114:4,5 117:25
118:21 123:9,22
134:15 140:25 141:16
144:15 146:13 147:4
156:16 161:14,17
164:2 165:9,16,17,18
165:18 167:20 169:9
173:6 181:16 184:2
186:15 189:15,16
191:11 193:6 194:11
195:2 204:19 205:2
205:15 206:17 215:13
218:24 221:14 227:13
229:18 231:12 250:16
256:11 264:20 273:20
basic 107:1 151:8
basically 105:3 115:10
122:2 123:20 131:7
basis 21:13 67:20 97:24
132:17 163:13 169:5
171:7 204:8 222:4
bath 111:10

Beach 133:18
bearing 184:16
began 165:11 260:16
beginning 228:19
begins 260:2,11
behalf 2:2,9,14 7:1 8:4
35:2 37:16 155:21
182:3
behavior 110:23 111:12
134:22 191:18
behavioral 63:25 69:24
73:6 110:21 268:5
behaviors 30:4
Belgium 129:11
believe 16:15,18 17:2
18:1,8 24:19 25:6
42:4 71:14 73:11
85:13,18,20 89:15
90:22 91:2,24 93:22
95:3 105:10 124:12
124:16 127:23 134:4
137:15,19 143:17
146:25 152:12 161:19
166:24 175:15 179:16
179:19 180:3 190:15
195:4,20,25 196:6,12
208:18 210:1,5 213:9
213:20 214:12,15,17
214:19 215:17 218:15
230:25 231:3 237:24
240:9,25 241:18
246:15 254:2,8 256:6
256:8 257:5,6,9,21
258:11 262:18 267:16
275:6,9
believed 89:16 133:3
Benadryl 88:4,7
benefits 264:12 273:25
274:14
benzodiazepine 116:7
benzodiazepines
195:21
best 92:14 236:24
better 28:14
beyond 46:17 70:13
248:8
bias 18:21 19:4
bind 107:2,7 109:2,4
binding 89:16 107:1,16
107:23 259:20
binds 111:13 200:21
biochemistry 56:13
biomedical 55:16 56:20
59:14,16,24
bit 32:23 100:13 121:6
184:18 198:10 245:14
black 120:6 154:13
block 108:20 109:7

blocked 111:3
blocks 109:1 187:13
blood 136:9,25
bloodstream 242:14
blotter 126:16 130:24
131:3,3 133:14,20
164:24
Board 249:9
body 89:6,14,16 102:5
105:15 109:20 139:24
175:9,25 176:6
259:22 263:3 266:3,9
boils 275:23
bona 245:21 246:22
book 114:25 115:5
136:23 169:14 179:14
179:25
books 104:8
border 211:6 222:12
bottle 219:23 220:2
bottles 219:14
bottom 63:9 129:7
177:22
bought 165:10
Boulevard 2:11 8:9
bounced 197:9
bound 49:24,25
Bradstreet 71:3
brain 109:21 200:22
Branch 61:9,15 63:23
63:25
break 10:24 76:9,21
153:13,14,16 223:7
223:11 280:2
breaking 235:6 254:10
breaks 4:17 10:23
breathing 137:13,16
177:12
Brett 2:10 8:4 44:24
93:19 154:24
brett@brettphelpsla...
2:12
briefing 22:19 271:5
briefings 65:15
briefly 40:3 45:10 212:2
briefs 11:17 23:1
bring 30:6 35:23 71:11
77:8 183:13
brings 268:17
Brinks 37:17,18,23
38:22
broadcast 10:15
broader 223:2 229:20
broadly 162:23 179:5
broken 59:17 136:9
138:12 176:8
brought 181:5 259:24
268:16

Buchholz 141:24
building 77:19
bulletin 132:13,14,15
215:10,11,23 216:3
216:10 219:18
bunch 20:2
burden 11:5
Bureau 133:24 134:1
business 47:23 54:3,6
224:15
buy 163:17 164:15
buying 165:8

C

C 163:9,10
C-A-R-B-O-N-A-R-O
53:22
caffeine 136:25 175:3,7
175:8,17
call 26:13 30:10,13 53:5
59:20 106:17 112:10
165:13 261:6
called 31:5 34:4 53:15
63:23 180:17 181:21
181:21
calling 181:19
calls 53:6
camp 275:19
campus 275:12
Canada 91:4
cannabinoids 137:7
cannabis 243:16
244:15
cannula 190:23
capability 106:2 178:9
capable 27:13
capacity 54:22 67:1
92:19
capsule 130:23 134:7
217:12,15,16,17
218:5,6,14,18,23
capsules 126:15
217:10,11
carbon 122:1,2 239:24
Carbonaro 2:21 3:6
7:19 53:7,10,14,22
54:2 58:25 66:2,7,13
66:16 69:3,19 71:3
73:5 74:1,10 77:5
78:18 80:13 91:15
121:9 123:24 151:1
153:24 154:17 159:2
202:6 203:4 223:17
223:24 252:7 279:24
Carbonaro's 17:1
270:13
cardiovascular 90:11
101:3 276:11

care 242:4
career 152:24
carefully 11:18
Carolina 212:18
carried 191:4
carrying 184:21
CAS 119:3 230:22
 231:1 232:4,5,25
 233:25 234:8,18,21
case 5:25 6:1 11:6,7,8,9
 11:25 16:2 17:1 18:8
 18:10,13,25 19:1,3
 20:4,9,15,21 21:6,17
 21:22,25 22:1,1,3,20
 25:22,24 28:16 36:21
 41:10 55:10 61:7
 64:16 67:7 79:20
 99:12 107:3 111:2
 128:3 134:14 147:16
 162:25 175:21 176:17
 182:16 190:25 200:1
 222:24 223:5 242:18
 271:7
case-in-chief 9:25
 25:22
cases 67:14,22 102:22
 135:12 173:19 185:8
 263:9,10 264:23
categories 21:3
cause 13:10 24:11
 25:15 30:3 89:18 90:1
 90:13 107:5 128:15
 136:10 143:17 159:23
 160:9,17 161:16
 192:20 195:13 199:3
 201:7 268:13 269:9
caused 269:12
causes 200:18,19
causing 65:1
caveats 167:21
Cayman 224:6,9,10,23
 225:6,16,22 226:9,22
 256:23
CDC 72:4
ceased 221:8
cell 10:1 102:8 107:8,9
 107:12,14 109:12
cell-based 249:14
cells 61:25 62:11
 107:16 258:3,12
cellular 259:20
Center 55:24 61:13
 63:22
central 109:17,20,23
 110:18 133:25
certain 49:25 108:15
 148:1 180:12 216:4
 217:4 245:19 259:9

 275:1
certainly 22:14 179:3
 202:3 227:6 230:1
 235:5 270:22
certainty 221:6
cetera 4:18 106:9
 129:12
CFR 12:1
challenge 19:25
challenges 19:22
challenging 19:23
 66:10 71:1 90:7
 116:10 277:19,21,22
 278:1
chance 11:20
change 191:17 231:12
 238:21 239:12,17,22
 240:4
changed 48:23 63:24
changes 33:20 95:1
 239:14
changing 239:25
channels 29:21 96:19
 100:4 162:14,18
 178:7
characteristic 163:4
characteristics 170:1
charge 33:1 47:16
chart 129:20,21,22
charts 138:14
chat 105:8
cheaper 256:23,24,25
check 211:21
checked 276:13
checking 211:18,20
chemical 42:15 46:1
 52:5 89:1 104:10
 119:16 142:9 182:22
 209:8 219:15 224:6
 226:9,22 235:3,18,18
 239:18 240:1
Chemical's 256:24
chemically 99:13
chemicals 46:8 115:12
 164:9 219:5 224:10
 224:23 225:2,8 240:4
chemist 61:22 104:8
 115:9 211:12 232:13
 233:4 238:15
chemistry 56:13 115:11
 118:16,18,19,22
 123:11 136:24 144:8
 147:20,24 148:2
 173:22 238:24
chemists 232:14,21
 233:12 234:10,20
 238:15
chemists' 234:12

Chief 2:5 32:21 34:25
 37:19
chloroamphetamine
 1:7
choose 49:22 193:23
 194:3
chooses 257:10
choosing 185:14
chose 237:17
chronic 267:25 268:21
Circuit 18:13,14
circumstances 217:4
citation 141:23
citations 116:21 179:22
cite 18:16 104:5,21
cited 22:2 118:25
 169:14 192:17 232:4
 233:14 236:6 277:9
 278:6,19
cites 278:13
claim 29:11
claimed 24:13,20
claiming 216:3
clarification 37:8
 131:23 135:24
clarify 49:2 224:1
clarity 39:16 101:6
clarity's 108:10
class 99:11 100:9 193:7
 203:6 268:13
classes 56:11,13,18,21
 59:10 66:21 70:5,10
 193:9 195:16
classic 103:25
classified 271:22
clauses 208:2
cleaner 82:2
clear 78:6 101:5 114:21
 198:3 226:24 230:22
 270:11
cleared 37:3
Clearnet 164:14
clerk 2:22 119:13
clinical 62:15 63:24
 98:13 110:8 124:4,8
 125:20 128:4 148:13
 148:23 149:3,21,24
 170:12 248:18 249:12
 250:23 261:6,9,13,16
 262:5,15 272:22
 275:17
clinically 29:3
close 10:24 36:12 279:8
closed 29:19,24 30:6
 42:13 255:4
closely 237:3
closer 156:8
closing 9:21 11:14

 13:18 279:23
cluster 263:13
CND 91:24
co-counsel 202:1
Cocaine 217:3,6
Cognitive 62:19
colleagues 157:11
 216:14
collected 71:18,19 87:2
 165:13,19
collects 86:19 240:19
colloquy 13:16
Colorado 8:19 212:16
combination 88:5
 105:19 111:3
combine 240:21
come 22:13,14 33:5
 34:6 64:5 95:21 119:4
 128:25 134:6,23
 152:20 169:6,11
 183:1,3,5 202:6
 216:22 219:7,10
 226:10 232:24 247:23
 251:2 276:9
comes 23:25 49:19
 67:23 124:21 182:17
 182:17 205:2
comfortable 227:23
coming 17:17 108:10
 245:25 248:17 266:13
commence 10:19
comment 34:7 35:15
 40:10,15,16 42:4,9,13
 50:25 174:1 201:23
 244:16
commenters 44:2,4
comments 3:12 33:11
 34:5,20 35:3,10,12
 40:5,7,12,13,18,22,24
 41:10,12,12,15,18,22
 42:1,6,8,12,14 43:1,3
 43:5 44:4,6,8,10
 47:14,17,19 48:2,8,15
 48:20,24 49:13,18
Commission 92:9
common 112:16 116:9
commonly 90:4
communication 155:13
 155:15
communications
 156:17 196:17 256:11
community 96:10 106:4
 106:13 158:11 159:11
 178:11 183:14
companies 224:5,16,17
 224:20 225:11,21
 227:18,19,24 265:4
company 224:11 225:6

257:9	concurrence 78:25	consumption 221:16	47:15 48:11,12 56:6
company's 257:14	155:14	221:25	60:14,17 64:8 68:9
comparable 241:17	condition 123:22	contact 30:15 65:5	73:23 79:9 81:6,22
compare 100:7 108:7	144:18	152:17	87:11,12 88:11,15
117:17 134:13 168:10	conditions 276:11	contain 85:25	89:23 92:20 93:23
194:21	conduct 10:9 44:16	contained 220:21	94:7,24 95:16,20 96:4
compared 67:5 71:10	45:17 52:1 71:24	containing 147:15	96:10 97:10,15
99:10 100:8 192:7	154:4	content 47:24	104:21 105:21 107:12
198:1 204:6 257:7,22	conducted 4:20,23	CONTENTS 3:1	108:22 113:5 114:19
comparing 100:18	184:19 263:20	context 220:9,12 223:3	116:12,20 121:10
151:20,22 186:4	conducting 191:20	contexts 274:24 275:8	124:22 125:25 130:17
238:17 257:25	confer 202:1 265:11,15	continually 194:3	130:24 133:4 142:18
compelling 50:2,3	273:4	continue 10:20 139:25	142:20 147:2 148:18
competition 109:6	conference 15:24 16:8	223:21 252:2 253:16	154:24 161:6 162:18
compiling 47:13 155:18	confidential 47:22	254:1 264:24	177:4 182:10 184:11
207:20	confirm 209:9 211:8,24	continued 52:3 266:4	197:14,18 198:20
complete 35:19 39:3	211:25	269:7	200:25 201:17 202:12
43:8 247:25 248:3	confirmed 86:22 130:4	contraction 111:7	202:13 203:4 204:23
250:16,20 251:1	167:19 208:2,12	contractions 110:24	212:10 213:23 214:12
completed 250:19	210:3,7 211:3	contractor 210:8	214:15,17 215:24
completely 19:6	conflict 237:25	contractors 211:21	216:16 221:9 225:13
completeness 39:16	conflicts 237:22	contracts 188:13,14	225:15 229:3 230:24
completing 45:11	conformable 227:19	contrary 178:8	231:2 235:13 237:14
compliance 45:16	conforming 51:23	contrast 227:9	238:23 239:10,13
51:25 52:4	conformity 18:23	control 81:18 83:14,19	240:5 241:4,24 245:6
comply 10:8	Congress 33:5	97:18 99:9 225:21	247:5 248:9 255:24
component 20:14	conjunction 57:22	240:18 243:6 268:25	258:19 265:22 266:16
196:4 230:4	consequences 150:7	controlled 1:5 4:5,21	266:20 21,24 272:6,7
compound 216:24	278:4,5	6:4,9 26:23 27:20,21	275:24
231:7,13,16 238:25	consider 11:18 68:23	45:16,24 46:1 51:22	correcting 165:20
compounded 126:20	207:3 235:15	51:25 52:4 57:20 60:5	correction 213:11
computer 9:10	consideration 78:2	60:14,16 64:2,15,24	corrections 11:16
concentrate 59:5	199:15	90:20,22 91:2,4,12	correctly 96:10
concentration 59:23	considerations 201:24	92:1 97:21 142:7	correlating 188:20
107:24 108:3	considered 64:16	144:9 148:16,20	correspondence
concern 65:19 179:8	113:14 135:5 146:24	151:25 152:5 168:3,5	112:18
201:3,5,16	155:3 160:7 181:16	168:17,18,20 178:21	cost 246:9,17
concerned 21:7	193:13 201:2 203:21	199:19,22,25 204:16	costs 246:11 256:20
concerns 41:7 183:14	228:9 236:3 251:15	204:17 209:11 215:14	cough 62:25 199:2
conclude 103:16	256:15 274:17	222:19 226:7 240:7	Council 5:12,14
109:18 112:21 114:13	considering 94:13	243:3 247:5 253:24	counsel 2:5,9 4:14,14
114:16 118:22 123:15	198:17	controlling 74:12	4:16 6:15,16,17 7:14
126:6	consist 28:17	convenience 10:23	7:18 8:2,12 10:10
concluded 9:25 25:22	consistent 19:7 98:24	convention 29:5 91:7	16:8,18 31:5,17,21
109:25	104:3 132:25 133:8	92:10,17	44:25 53:15,23 77:14
concludes 73:4	175:13	conversations 71:5	202:19 265:15
conclusion 12:24 52:23	constitutes 94:11 181:6	converted 32:17	countries 90:24 129:5
74:18 96:12,22 106:1	273:13,19	Coordinator 32:16	129:10 240:20 241:4
106:5 111:24 114:2	consult 86:6 105:5	copied 37:1	241:6,9,22
117:20 118:4 141:19	152:18	copies 11:25 84:10,11	country 123:20
144:7,14,19 145:5	consulted 133:1,9	278:21 279:5	counts 204:2
169:6 175:19 194:18	145:4	copy 9:4,9,15 35:8,20	couple 13:24 15:1
272:17	consulting 116:19	38:1,3,4 39:4 43:5,9	57:15,17,24,24 69:14
conclusions 74:15 86:1	141:19	84:13 120:16 121:1	224:2 235:21 241:6
92:2 114:5 150:4	consume 185:22	122:16,18	252:24
concur 25:17 110:2	consumed 161:5	cord 109:21	course 29:8 32:25
concurrent 155:22	176:22 221:7,9,10	core 99:16	33:15 41:11 116:11
156:13 172:5	consuming 161:9 175:2	correct 17:15,16 45:5	courses 70:4,13

court 4:11 10:6,17,17
15:13 17:6 18:14,19
18:24 22:17 26:22
30:24 34:19 65:19
66:25 67:12,21 69:14
74:17 77:11,14 84:10
89:10 91:21 101:9
106:23 108:12 119:20
129:21 132:13 156:2
156:10 163:2 182:20
251:13,19
Court's 15:11 20:4 78:2
154:3
courtroom 16:20
covered 240:13
COVID 213:24 214:4,13
214:22
crashing 28:4
create 82:2 96:8 106:11
115:2 158:10 159:9
created 81:22 83:9 84:2
94:6 115:5 138:14
187:19
creates 94:2
creating 178:10 271:23
creation 187:21,23
credence 171:17 172:8
crime 133:18,25
criminal 163:7
criminology 73:1
criteria 56:14 269:2,14
271:18 275:4 276:1
critical 20:14 117:8
128:21 270:12
cross 3:3 113:3,24
131:25 132:2 153:13
223:21
cross-examination
44:17,20 154:1,21
CSA 27:2 95:19,24
97:18 99:8 180:14
181:21,23 225:10
245:18 250:13
cues 187:13
current 32:19 37:9 45:3
45:3 50:8 58:9 85:22
118:8 125:17 126:3
128:10 129:16 144:5
144:6 173:2 178:20
230:21 235:10,15,23
235:23 236:1,10,14
236:18,24 252:18
currently 28:25 29:14
32:1,2,20 37:25 54:18
68:24 97:10,12,15
124:20 147:9,11,18
150:11 199:18 201:3
222:18,20 246:15

247:14 251:7 252:8
264:17
curriculum 57:12
cut 131:14
cutters 87:22 88:2
CV 58:9 63:2 70:23
246:1

D

D 177:18,21 181:12
DAD 72:18
daily 15:9 21:13
danger 217:24
dangerous 26:25 30:3
134:22 200:16,22
201:22 216:19
dangers 141:2 216:16
Darknet 164:14
data 71:4,6,8,16,17,20
71:21 72:2,12 86:8,20
87:6 88:9 94:11,13,14
94:16,18 96:15 98:24
107:1,17 114:4,16,18
123:23 125:20 126:2
137:22 138:10 151:9
151:12,17,21,23
160:12,20,21 165:10
165:13,14,19 168:12
168:24 169:5 172:2
183:19 188:18 189:8
191:16 193:6 195:1
202:15 204:10 205:3
205:7,8,15,24 207:20
207:21 209:1,17,19
210:4 211:19,20,24
212:9,20 214:8,10,24
219:16 227:25 229:18
229:21 240:21,22
242:10,11 266:18
271:24 272:1
database 85:15 86:17
126:9 165:15 167:18
241:15
databases 65:1 70:15
70:18 149:15
date 4:9 40:19 81:19
82:22 83:5 236:10,16
237:14 250:20 253:15
253:17 257:16
dated 83:16,17,18
dates 11:15 169:19
179:11,13
David 9:2 134:25 135:2
day 10:19,21,22 28:7
53:1,2 101:17 250:20
265:24 268:1 270:15
278:22
de 115:5

DEA 4:25 6:13 32:6,7
32:10 33:3,9 35:3
40:19 41:10,11 44:1,9
45:19 46:9 48:23
49:16 50:20 52:7,9
55:1,4 57:25 64:11
65:16 75:10 79:4,17
86:19 91:18 93:25
94:2,8 132:16,20,23
133:7 147:16 149:10
151:10 152:21 153:2
153:3 157:10 164:16
167:19 174:4 179:4
180:8 182:14 198:17
200:16,23 201:3,14
201:20 202:17 205:3
208:8,17 210:10
215:21 224:24 225:1
225:20 226:11,25
227:2,4 234:17
235:14 236:15,17
244:13,24 245:20
246:11 247:10,15
248:8,24 249:23
250:10 251:17 252:25
253:4 254:21 255:16
255:19,23 256:3
263:20
DEA's 37:16 49:12 65:9
75:20 81:24 83:19
84:4 138:18 156:23
157:1 162:17 181:19
211:17 215:13 226:8
236:24 249:2,3
266:18,25
dead 136:21 175:18,22
deadline 35:4
deal 46:12 88:10 225:10
254:15
dealing 46:13 65:24
deals 64:14 65:23
dealt 157:23
death 105:21 176:14
209:13 242:5
deaths 150:7 173:17
decades 27:21,25
29:16 180:2,6,19
187:25
December 3:12 5:3
35:1 36:16 37:11 38:2
38:15,15,25 40:19
56:4 83:23 214:5
decide 23:14 204:14
decided 59:9 92:9
128:1
decision 11:19,21 50:4
250:11
decisionmaker 11:23

declaration 3:11 34:18
35:16,20 39:15,18
decomposed 136:22
175:25 176:1,7
deceased 215:6
dedicated 77:24
deduce 111:1
deemed 24:9 25:7,9
199:23 218:8 251:1
deep 20:10
defer 25:21 26:8 171:23
233:12 234:10,20
deferred 232:21 237:19
defers 94:15
define 112:9 159:12
179:4 202:17 203:13
266:1 269:3
defined 27:12 95:19
157:11
defining 110:9
definition 156:23,24
157:1,18,20 158:3,5
178:15 180:11 181:17
203:18 204:12 205:21
205:22 235:15 236:24
271:16 273:9
definitions 101:6 157:2
definitively 176:5 188:5
degree 56:9 59:13,16
59:24 62:3 103:21
106:22 157:12 170:14
degrees 55:14
delirium 201:8
delivery 131:20
demonstrate 13:10
demonstration 226:19
demonstrative 119:8
denotes 110:17
Denver 2:17 8:19 45:11
deny 22:12
department 1:1 50:1
79:4,8 105:20 135:15
depend 184:22 223:4
231:20,23 242:10
253:23
dependence 61:24
72:18 139:15,17,24
140:1,1,6,9,11,19,22
141:5,7,9,18 142:2
146:18 189:3,5,10,12
189:15,18 265:21
266:2,7,19 267:7,20
268:13,20,23,25
269:1,4,15 270:13
271:11,18,19,23
272:3,6,10,12,14,21
273:3,9,13,15,16
dependent 139:22

140:17 266:12
depending 115:16
 211:16 245:18 247:18
 247:22 254:13 258:23
depends 110:9 185:7
 193:25 246:7 273:14
 276:16
depressing 28:3
depression 90:6,15
 277:7
deprived 27:3
describe 34:22 88:17
 133:13 173:21 211:10
 240:15 257:19
described 36:20 50:22
 50:24 225:3 233:22
describes 234:8
describing 179:9
designation 69:15
designed 29:20
desire 269:24
desired 20:15 237:23
detail 34:23
detailing 34:24
details 220:25
detection 215:14
determination 162:24
 200:3 214:25
determine 28:20 68:12
 94:8 95:16 98:7 105:6
 127:4,6 128:9,18
 140:4 186:2 203:20
 231:8 268:19
determined 150:14
 255:25
determining 74:13 81:3
 126:3 146:24 198:18
develop 27:5
developed 27:25 188:5
development 142:3
 259:19
devices 10:2
dextromethorphan
 62:14,18,24 66:8
 71:15 198:23 199:9
 199:11,17 201:1
diagram 121:9,12,15,20
 122:6
diagrams 123:6 238:4
died 176:22
difference 110:14
 121:22 233:17 234:5
 261:9
differences 85:11,13
different 21:4 62:17
 65:1 66:21 83:16
 87:17,18 89:15
 102:18 104:11,16,16

109:12 112:6 123:8
 129:15 157:15 158:3
 167:20 169:11 192:9
 193:10,22 196:15
 200:10,11 210:25
 211:22 222:10,12,13
 222:13 225:2 231:24
 232:25 234:24 239:8
 245:21 256:13 259:21
differing 19:8
difficult 64:12 101:8
digging 271:3
diisopropyltryptamine
 60:8
dilated 135:17 137:4
dimethyltryptamine
 60:7
DiPT 60:8,12,13
dire 69:13,21 73:4
direct 3:3 31:22 46:17
 52:22 53:25 77:7 95:5
 107:19 112:3 126:10
 128:22 146:22 191:15
 226:15 227:3 228:12
 251:10 269:16
directed 31:17
direction 10:8 38:25
 62:13
directly 42:5 185:11
disadvantage 77:18
disconnected 28:9
discovery 227:25
discrete 21:1
discretion 18:18,24
 20:5 254:2,5,7,14
 255:19,23 257:14
discriminate 101:21,24
 102:20 112:23 113:20
 113:21 198:5
discrimination 101:7,9
 102:11,16 112:6
 114:4,11 128:9,12
 145:4 184:10,19
 187:5,8,16,19,22
 188:2,15,18,22 189:4
 189:11,16,23 190:9
 192:3,10,22 196:21
 197:8,13,23 272:1,5,8
 272:9
discriminative 66:17
 102:23 112:5,8,11,16
 112:19 113:1
discuss 52:22 64:22
 118:16 280:5
discussed 15:25
 112:22
discussing 216:10
discussions 4:15

diseases 258:22
dismiss 279:24
disorder 262:9
disposal 28:14
dissertation 56:22,23
 66:14
dissolved 131:6
distinctly 28:6
distortions 134:21
distress 104:2
distributed 29:25 97:16
distribution 29:19
 97:19 255:4
diversion 29:20 32:5,11
 33:3,4 45:4,8,15 46:7
 46:11,24 51:17,20
 52:11 96:18 97:2
 100:4 162:13,18
 178:7 228:5 254:8
Diversions 32:21
diverted 97:6 126:21
division 32:13 46:11
DMT 60:7,9,13 66:9
 102:21 103:11 106:9
 112:23 113:2,23
 114:8 141:4 144:3
 145:7,10 196:1
DOA 230:23
DOB 27:17 89:2,21 99:7
 99:13,19 106:9 113:2
 113:16,22 114:7
 117:18 133:3 256:23
 257:2
DOC 1:7 4:7 6:8 27:10
 27:22,25 28:8,19,21
 28:23 29:4,12,23 46:4
 46:24 47:3,6 50:12
 58:4 68:1,3,6,13,24
 74:15 75:2,12 78:25
 81:3,18 83:14,20
 85:16,17 86:11,12
 88:14,18 90:19 91:1,4
 91:10 92:5,8,9,19
 97:4,9 99:1,5 100:8
 100:13,23 103:9,10
 103:14,24 105:7,19
 106:2,21 107:2,9
 109:9 110:1 112:21
 113:9 114:6,12,22
 116:24 117:7,9,19
 118:4,22 119:4,17
 123:14,19 125:2,12
 126:4,25 128:20,21
 129:2,4,9,24 130:19
 132:12 133:20 134:12
 135:9,23 136:18,25
 137:1,7 138:11,22
 140:5,23 142:15

144:8,14,15,15 145:1
 145:5,20 146:3,4,7,9
 146:16,19 147:16
 148:2,7,10,14,23,24
 149:1 150:6,8,9,20,23
 151:2,9,18 155:4
 159:20 160:6 163:21
 164:3,9,17 170:20
 173:18 175:2,3,3,5,17
 175:20 177:2,4,5,8,14
 180:6 182:10 183:9
 183:22 192:7,25
 196:21 197:11 198:5
 202:17,23 203:3
 208:12 209:25 219:6
 229:2,11,13,15,20
 230:6 231:1 237:9,12
 238:18,21 240:17
 242:21 243:9,25
 259:10 266:20 267:7
 268:7,19 269:18
 272:13,23 273:19
DOC's 142:25 143:10
 143:13,16,21
docket 1:5 4:8 34:4
 41:13,16 42:3
Doctor 53:9 136:12
 165:4 228:20 235:6
 273:8 276:20
doctorate 60:20
document 23:11 33:16
 33:19,23 34:2,11,15
 34:22 36:8,12 37:2
 38:10,14,23 39:24
 42:19,23 43:22 57:9
 57:14 58:22 75:9,16
 76:17 80:8 82:16 84:2
 85:5,23 86:6 91:22
 92:4 93:10 94:3,5
 122:22 139:9 141:20
 192:18,23 194:11
 232:15 234:15,15
documents 12:4,10,18
 31:16 33:9 39:17
 74:24,25 75:20 80:13
 83:16
DOE 43:6
dog 110:23 111:7,10,10
 111:16
DOI 1:6 4:6 6:3 27:9,22
 27:25 28:2,19,21,24
 29:12,23 46:4,23 47:3
 47:6 50:12 58:4 68:1
 68:3,6,13,24 74:15
 75:2,12 78:25 81:3,18
 83:14,20 85:16,19
 86:11,12 88:14,17
 90:19 91:3 97:4,9

98:25 99:5 100:8,13
 100:22 102:17,18
 103:3,14,24 105:6
 106:2,21 107:2,9,18
 107:20 108:4 109:25
 110:20 111:3,18,21
 111:23 112:21,23,25
 113:3,5,6,16,17,18,20
 113:21 114:6,12,22
 115:14,14 116:24
 117:11,12,16,18,21
 118:22 119:3,17
 121:9,22,24 123:14
 123:19 124:25 125:14
 126:4,25 127:16
 128:6 129:24 130:12
 132:11,23 133:4,7,15
 134:3,12 135:22
 138:11,22 140:5,23
 142:11,22 143:13,16
 143:20 144:8,20,23
 145:5,15,18,24
 146:16,19 147:15
 148:2,7,10,14,21,23
 149:1 150:7,9,18,23
 151:2,9,18 152:10
 153:1 155:4 159:20
 160:6 163:21 164:2,9
 164:17 165:7,10,21
 170:20 172:22,23,24
 173:2,5,7,12,18,20
 175:2,4 177:2,8
 179:10 180:5 181:23
 182:10 183:9,22,23
 186:13,16 192:6,24
 194:1,6 196:21
 197:11 198:5 202:17
 202:23 203:3 205:15
 206:3 207:17 208:12
 209:24 212:8,11,24
 213:3 218:13 219:6
 220:1,2,11 224:3
 226:10 227:11,12
 229:1,11,12,15,19
 230:5,23 232:5,20
 233:14,22 234:2,8
 236:20 237:9,12,12
 238:17,21 239:12
 240:24 241:2 242:21
 243:9 245:3 256:23
 257:9,11,16,18,20,21
 257:22,25 258:8
 259:10 262:4,11,15
 262:22 263:2,4,6,12
 264:16,21 265:6
 266:19 267:7 268:7
 268:19 269:18 272:13
 272:23 273:19

DOI's 142:23 143:4
DOI/DOC 46:5
doing 15:9 32:14
 102:11 127:20 147:13
 158:2 187:1 222:23
 245:21 248:7 265:1
DOM 27:17 88:25 89:2
 89:20 100:14,17,22
 102:20 103:3,10
 106:9 110:1 111:16
 112:10,11,23 113:2
 113:16,19,20,21
 114:7 117:18 119:21
 121:21,23 122:6
 141:4 143:22 145:6
 145:10 147:7 182:10
 182:12 186:12,14
 189:17 196:5 198:10
 238:18,21 256:23
 264:18 271:14
DOM's 186:15
dosage 159:25 162:1,2
dose 101:22 115:16
 131:17 276:3,3
doses 62:25 101:24,25
 104:16 160:16 199:2
downloaded 34:8 35:10
 42:14 43:1
downregulated 267:15
DPW 34:25 50:8,9
Dr 2:14 3:6 5:18,23 6:16
 7:19 8:13,18,20,24
 11:7 12:14 15:7 16:9
 16:12,14,19,22 17:1,7
 17:14,15 22:3,4,5,6
 53:6,10,14 54:2 58:25
 69:3,18 73:5 74:1,10
 77:5 78:18 80:13
 91:15 121:8 123:24
 151:1 153:24 154:17
 157:19 159:2 202:6
 203:4 223:17,24
 252:7 279:24
drafted 81:17 172:7
 237:1
drafting 32:21 33:1,2
 37:20 118:15
draw 111:18 119:21
 120:1 238:16
drawing 120:2 122:11
 238:3,18
drawings 119:17
drew 141:18
drive 1:11 2:6 7:2,3,7
 7:11 54:4,9 277:2
drop 214:20
dropped 50:21
drug 1:2 2:5,9 5:5,13,15

27:18 28:25 29:2,17
 29:18 32:2 38:18
 42:15 45:1,25 54:21
 61:18,20,23 63:15
 64:5 70:19 72:18
 86:16,23 87:6,16,20
 88:3,10,13 91:2 96:7
 96:18,19,24 98:16,18
 98:20 99:23,23,24
 100:1 101:7,9,15,22
 102:1,11,13,14,16
 105:15 108:14 109:22
 111:13 112:6,9,17
 114:4,10 118:16,17
 123:18,25 124:4,6,8
 124:15,16 125:6
 126:9,17 127:6 128:8
 128:12 129:18,23
 130:6,7,23 131:2,6,10
 131:20 132:5,6,19
 139:18 141:10 142:8
 144:16 145:3 146:25
 147:15 150:3 156:24
 157:11,24 158:9
 159:8,16,19,22
 161:25 162:14,14
 164:2,13 168:13,13
 169:7 170:10,17
 174:3 178:1,1,2,4,15
 178:19,21,25 179:4,6
 179:8 180:9,17 181:7
 181:10,13,13,19
 182:4,18,19,22,22
 184:9,18 185:5,15,19
 186:7,8,20 187:5,8,13
 187:14,15,18,19,22
 188:2,5,14,16,17,22
 189:4,11,16,23 190:8
 191:2,10,23 192:2,10
 192:22 193:7,25
 194:4,21 195:12
 196:21 197:5,8,12,22
 197:25 198:23 199:15
 201:3,4 203:24
 204:13,16 209:9
 210:24 211:3,9,16,25
 216:18 217:6,9,22
 220:16 239:4 245:24
 245:25 253:13 254:17
 256:18 257:22 259:18
 260:9 266:5 269:11
 269:12 271:8,22
 272:1,4,7,9 273:24
drug's 268:2
drug-to-drug 203:16
 207:12
drugs 27:13 29:13,20
 29:24 30:1 45:21,22

45:23 46:8 56:12 59:8
 59:11 62:21 64:16,18
 64:23,25 65:6 67:4
 86:20 87:21,23 88:5
 90:10 91:25 100:2
 101:17,25 104:17,24
 105:1,19 112:15,19
 115:3,10,11 118:1,3
 128:13,15 134:5,18
 143:17 145:6 147:1
 150:13 151:19,24
 164:6 167:18 168:2
 168:15 176:11 177:5
 178:6,13,23 180:18
 181:15 182:25 183:6
 184:13,15 185:18,22
 186:1,4 187:9,9
 188:25 191:22 192:13
 192:14,24 193:9
 194:20 195:17 196:20
 198:4 200:8 204:2,7
 205:10 207:24 208:3
 208:9 210:18 215:14
 216:12 218:3 219:4
 219:10,17 220:6,8
 221:19 222:1,9,14,17
 236:12 257:24,25
 259:17 260:7 262:12
 271:14 272:2,11
 273:6
due 50:21 137:5 142:2
 142:3 198:18,19
duly 31:6 53:16
duplicate 39:14
duration 117:14 129:14
 140:18 145:14 162:5
 202:11
durations 117:19
duties 51:23 62:20 63:4
 63:9 65:4 152:14
DXM 201:7,21

E

E 1:16 4:10
e-portal 35:11
earlier 67:7 100:13
 125:25 173:10 180:23
 187:24 189:7 198:22
 200:7 216:9 245:2
early 259:18
easier 154:6,9
easily 231:22
Eastern 10:20,21
ecstasy 113:10
education 55:12 56:8
 59:1
effect 89:6 92:7 101:18
 105:15 110:18,19

113:13 115:14 116:3
 118:3 127:7,8,10,11
 127:17 128:6 159:15
 159:21 160:18 186:8
 186:25 187:15 196:11
 274:15,17 275:7,10
 275:11,13
effective 174:16 218:9
 253:15,17
effects 27:14 30:4
 61:17 62:19,19 63:1
 67:5 89:19,25 90:5,8
 90:9 99:6 100:8,22
 101:2,3,17 102:1,12
 102:13,24 103:19,25
 104:12,15,24 105:14
 106:16,19,20,24
 107:6,8 109:10,17
 111:3 112:5,8,11,16
 112:19,20 113:25
 114:12 117:14,21,24
 127:23 128:14 134:13
 134:20 135:6,8,13
 143:5,10,16,21 145:6
 146:6 150:8,10
 161:16 165:2 170:10
 174:15 175:8,10,13
 175:19 177:7,13
 189:3,19 191:11
 196:23 199:3 200:17
 200:19 235:1 239:2,9
 268:5 271:10,15
 273:23,25 276:12,25
 277:1,6
efficacy 148:17,21
 149:6 218:7
eight 24:21 68:5 74:20
 75:17 79:13 81:4,16
 83:24 86:2 94:21
 105:7,17 151:10
 155:10,20 156:14,20
 158:21 166:7 178:23
 181:1,22 195:12
 196:4 237:20 251:11
 252:1
eight-factor 28:20
eight-part 74:11
eighteen 167:2
either 24:17 25:6 40:7
 62:11 123:19 125:3,6
 163:7 255:14 268:15
 270:25
Elder 16:9,12,14,19
 17:7 22:4
electronic 3:12 10:2,16
 35:10 41:12 43:2
 47:16
electronically 10:14

33:24 35:4 40:8 42:3
element 238:25 239:25
eleven 166:13
email 9:6
emailed 35:17
emergency 105:20
 135:15 174:23 175:12
 242:4,8
emerging 57:25
emphasis 69:5 73:18
 74:2,6
employed 32:1,2 54:18
 54:20,22 55:3 157:10
employee 24:22 25:4
employees 24:18,21
en 44:6
encapsulated 217:12
encapsulation 218:2
encounter 46:4 87:10
 94:16 129:25 130:1
 219:25 220:15,25
encountered 126:8,14
 130:15 161:1,7 169:3
 206:11 213:3,7,14,17
 216:12 221:15,18,19
encountering 46:5
encounters 85:17 86:9
 86:21 129:23 133:12
 138:12,22 164:2
 165:16,21 168:9
 206:14 211:2 212:12
 212:15,24 213:8,22
 215:6
ended 71:22
ends 261:3
enduring 278:3
enforce 51:22
enforcement 1:2 2:5
 5:5 29:17 32:3 38:18
 52:2 54:21 64:5 86:20
 87:19 88:11 94:16,18
 96:15 98:24 125:19
 130:3,8 133:12
 138:21 160:12,20,21
 161:7 168:9 183:2
 211:2 221:22 222:5,6
 222:11
enjoy 270:2
ensure 26:24 33:19
 47:21 51:24 52:3,7
 236:9
ensures 27:2
ensuring 29:21 33:9
 34:6 45:16
entail 45:14
entailed 62:9 65:7
entering 136:9
entities 150:24 246:14

entitled 16:15 17:3
 134:25 136:23
entry 222:12
epidemiological 71:8
 72:23 73:1
epidemiology 16:23
 70:3,5,10,14,16 71:4
 71:6 72:14,17,20,21
 73:9,12
ER 174:25 176:25
Erowid 116:19,22,22
 161:21 169:13,17
 170:6,9 172:14,17
 269:23,25
Erowid.org 104:22
error 50:23 51:2
Eshleman 66:13
especially 168:1 263:5
 275:14
ESQ 2:3,4,4,10,15
essential 19:11
essentially 14:14
 108:13,18,20 109:21
 114:8 116:19 124:5
 130:3 131:5 136:8
 139:17,24 146:3
 152:24 175:4 181:18
 185:17 275:24
EST 1:13
establish 47:5 171:7
 272:4
established 73:8 95:12
 211:8 252:24
estimate 176:4 207:10
 224:18
et 4:18 66:13 106:9
 129:12
ethical 124:7
ethics 248:18 249:9
euphoria 269:12
Europe 241:4,5
evaluate 106:18 109:22
 117:12 147:11 162:24
 199:25
evaluated 70:17 116:25
 178:22
evaluation 42:16 74:23
 75:12,19 78:24 79:15
 80:17 86:4 94:9 96:14
 104:4 123:17 141:22
 147:5 161:12 162:22
 169:9 171:13,18
 172:1,8 180:18 182:6
 182:8 214:25 227:13
 232:25 233:8 236:21
 237:5
evaluations 124:7
eventually 260:10

262:1
everybody 22:15 280:6
evidence 11:3,10,12,19
 13:11,14 23:16 26:9
 35:24 36:10 40:1
 43:24 58:24 76:19
 80:8 82:16 85:5 93:10
 94:11 96:6,15 97:6
 98:10,15 105:13
 106:11,15 122:22
 125:22 126:7 127:19
 129:4 134:4 139:9
 140:11,24,25 142:22
 142:25 143:4,10,13
 143:15,20 144:22,25
 145:10,18,21 146:17
 148:19 149:5,6,11,18
 149:22,23 150:15,22
 153:7 158:8 159:7,14
 159:16 160:13 162:3
 162:17,19,20 164:17
 164:25 168:8 169:2
 171:4,16 173:2,19
 203:24 204:1,2,20,21
 205:9 206:19,20,25
 207:2 216:16 217:1
 219:3 221:20 256:8
 266:18 268:23,24
 273:21
exact 190:10
exactly 20:9 45:13
 174:2 224:10
examination 31:5,22
 51:11 53:15,25 69:21
 77:7 131:25 151:3
 153:13 223:21
examined 31:7 53:17
examiner 175:18
example 266:11
exception 22:11 42:4
exceptions 11:21
 260:15
excerpt 278:14
excluded 276:15
exclusion 275:4,25
 276:7,8
excuse 72:16 195:15
 230:23
excused 52:21 53:3
exercise 18:24
exhibit 3:8 12:5,11,19
 13:8 23:7,7,8,11,13
 23:16 34:13 35:7,24
 36:3,6,9 38:8 39:7,12
 39:13,19,22,25 42:21
 43:12,12,18,20,23
 57:5 58:12,17,20,23
 75:5,8,15,24 76:5,12

76:15,18 78:17,21
 79:23 80:3,6,9 81:9
 81:12,15 82:12,14,17
 82:22 83:2 84:1,9
 85:1,3,6,11,12,22,25
 86:7 91:15,16 93:1,5
 93:8,11,16,18 94:21
 112:4 119:6 120:3
 122:11,20,23,25
 123:2 128:23 137:23
 137:25 138:2,5,25
 139:5,7,10 154:19
 158:18,22 165:4,6
 177:17 184:8 202:10
 212:3,3,8,21 228:18
 230:20 265:19 276:19
exhibits 11:25 12:2,8
 12:14,25 13:3 14:1
 23:25 31:16 39:14
 130:22 212:6
exist 134:14 238:7
exists 241:13
expect 168:21 197:18
 268:22
expectations 10:10
expected 268:14
experience 28:3 46:3,6
 55:12 62:5,16 63:14
 69:24 90:7 116:6,10
 116:15 150:17 153:3
 189:22 190:3 250:7
 255:6,14
experienced 137:3
experiences 66:11 71:1
 179:10 277:19,23
 278:2
experiment 110:13
expert 2:21,22 7:20
 16:14,22,23 17:2 18:2
 19:5 21:2 22:11 28:19
 28:22 55:10 66:23
 67:1,2 68:2,8,18 69:4
 73:6,8,11,16,17 74:1
 74:5 274:19
expertise 17:4 19:23
 20:9,25 275:18
experts 18:7 19:22,24
 20:11,23,24 149:2
expire 211:14
explain 33:13 40:3 41:9
 83:15 89:10 101:9
 106:23 108:11 129:20
 132:10,13 136:2
 182:14 184:17 190:21
 191:4 210:23 213:6
 243:1
explained 125:24
exploratory 246:6

explore 19:9
explored 151:3
extend 21:11
extent 20:22 21:10
 47:20
external 210:5
extremely 27:22 207:22
 271:9

F

F.3d 18:16
face 136:23
facility 5:1 6:14 246:21
 249:19
fact 16:17 123:5 134:2
 141:8 148:6 171:1
 194:18 200:23 216:15
 217:22 219:9 221:14
 222:21,25 234:9
 254:10 256:22 260:21
 274:12,20
factor 68:6 74:20 75:18
 79:13 81:4,16 83:24
 94:21 95:4 96:1,17
 100:6 105:17 106:14
 106:17,25 114:3
 118:8,12,13 125:17
 125:18 129:13 134:10
 139:14 142:5,17,21
 143:6,12,15 144:5,13
 145:13,22 146:14
 148:15 149:9,10,12
 150:1 155:20 156:14
 156:22 158:7,21
 161:11 162:13 163:3
 171:24 175:16 178:13
 178:23 181:1,9,12,14
 181:22 184:8 195:12
 202:8,11 203:10
 205:2 228:19 230:20
 230:20 235:10 236:5
 237:20 240:10,12
 252:1 264:10 265:19
 267:2 273:17
factors 68:9 69:14 86:2
 95:13,16,22 140:19
 146:23 151:11 155:10
 156:20 157:7 196:4
 198:16 202:7 251:11
 251:12,12 273:18,20
 276:7
facts 15:10 47:5
fail 260:7
failed 113:11
fails 24:8
failure 24:11 136:11
fair 50:6 58:8 90:12
 122:5 202:24 264:4

fall 27:1 275:19
fallen 46:2
false 192:4,5 209:24
 210:6,16
familiar 91:6,9 131:1
 148:17 152:19 244:23
 263:18
family 276:9
fancy 110:12
fantasies 28:11
far 29:23 163:6 183:8
 236:1 252:23 267:16
fashion 134:18 151:22
fashioned 121:8
fast-beating 177:11
fastest 247:17
fatigue 104:1
FD 155:9
FDA 63:16 79:1 98:9
 124:5 134:6 147:14
 155:2,6,12,16 180:19
 188:14 199:23 216:22
 216:23 217:3 218:6
 218:19 248:2
FDA- 239:17
FDMS 34:21
fear 90:6
features 201:12
federal 5:3 18:12 33:8
 33:14,15,21,22,25
 34:1,4 35:2,11 36:14
 36:18 37:21 38:4,13
 38:16,21,24 41:13
 42:3 43:3 49:15,17,20
 80:15 83:12 86:22
 221:23 222:11
fee 246:12,16
feel 77:17 157:17 197:9
 198:9 227:18,23
 237:6
feeling 190:7
felt 103:3 272:18
Fentanyl 215:6
fide 245:21 246:22
field 32:13 65:15 69:24
 70:3 72:13 73:8,12
 254:9 274:19 275:12
field's 254:5
fields 254:9
fifteen 166:21
fifty-one 42:7
figure 171:21 255:16
file 11:17 37:9 42:14
filed 5:4,7,11,18,20,23
 9:9
files 24:7
filing 9:1,5,15,20 19:24
 24:23

final 44:5 49:19 137:1
 253:14
find 71:1 75:1 100:21
 110:21 118:11 147:14
 162:19,21 169:22
 217:12 259:1 260:15
 277:24
finding 216:25 218:20
findings 100:11 162:17
 234:13
finds 168:18
fine 76:22 122:16
 132:22
finish 198:4
finished 158:20
firm 204:11
first 5:6 11:6 13:25
 14:23 17:25 26:14
 30:10 31:6,9,12 53:16
 53:19 55:13 56:5 57:8
 59:1 66:6 75:7,7 79:5
 81:9,15 82:3,21 94:23
 95:7 96:1 98:1 106:16
 120:14 124:21 129:15
 137:21 147:14 149:9
 154:18 155:2 165:6
 177:18,23,24 180:5
 181:5 184:20 188:7
 197:5,21 199:18
 206:10 213:10 241:10
 276:22 277:15,17
fit 74:15 81:3 105:7
 142:11,15
five 85:17 132:11
 147:17 166:6 183:21
 236:20,25 237:14
 251:12
Florida 90:23 133:17
 212:16
fluctuates 252:17
focus 224:9
focused 56:10,22 107:6
 241:1
focusing 59:7
follow 18:11 209:2,5
 224:1 225:10 230:18
 244:8
followed 36:21 208:24
following 28:17 220:4
 268:20
follows 31:7 53:17
food 63:15 101:16
 185:3
forced 185:18 262:18
Forensic 85:14 86:15
 132:16 215:13 216:6
form 25:5 80:14 83:12
 126:17 130:24 131:3

131:20 133:7 134:3
 216:12,15,23,25
 217:1,10,22 231:7,9
 231:10,12,15,21,25
 232:6,11,12
formal 4:19 70:2,14
 72:25
format 4:25
formed 145:13,22
 146:15
former 37:19
forms 126:15 127:1
 226:9 234:24
formula 118:24
formulation 134:8
 218:8 276:3
Forster 66:16
Fort 55:24
forth 247:24 248:3
Forty 212:13 213:1
forum 105:4 127:19
forums 160:15 161:14
forward 180:13 183:17
 225:9 245:17 280:6
forwarded 13:1
found 87:1 126:17,25
 130:7 133:14,20,23
 136:21,21,22 164:23
 175:17 218:14 219:19
 220:20 251:19
four 17:12 28:5 66:6
 71:2 95:13,15,16,21
 157:6 166:2 273:18
 273:20
fourteen 166:19
fourth 99:22
frame 250:11
France 129:11
Frank 2:3 6:25
free 231:25 232:6,12
 233:10,15,18 234:2,9
 234:19,22
friends 104:15
front 34:14
full 28:4 98:23 113:2
 202:25 255:23
full-time 24:21
fully 102:23 103:10
 112:24 113:6
function 259:21
functional 107:17
functioning 139:25
functions 241:14
further 16:7 26:1 44:13
 51:5 52:15 237:7
 242:11

G

Galveston 61:9
Garcia-Romeu 65:24
gastrointestinal 104:2
Gatch 65:25 66:17
gathering 172:24 173:1
 173:9,24
gender 170:3
general 28:2 49:3,4
 58:5 91:11 215:3
 221:1 222:25 229:16
 229:18 236:7 257:19
 258:1 259:5 260:15
 260:18 266:15 273:8
 274:10
generalizing 278:7
generally 41:19 46:8
 56:8 79:6 96:24
 101:13 110:6 118:15
 124:21 132:21 139:20
 140:21 149:20 151:10
 151:11 190:23,24
 192:20 199:1 218:20
 219:15 224:12 233:16
 235:21 238:15 259:18
 265:8 269:5 276:8
gentle 28:10,11
Georgia 133:24
getting 77:24 101:22
 190:15 219:6,10
 225:6 250:2 254:3
 279:8
Giroir 93:19 154:24
give 11:15 15:1 81:11
 84:18 111:10 115:25
 119:12 128:1 158:23
 170:12,19 172:8
 174:14 186:13 187:12
 191:24 195:10 228:17
 229:7 241:7 267:24
given 22:8 29:15 65:15
 101:18 102:25 103:5
 109:6 111:13,16
 173:8 194:1 195:18
 204:11 234:9 262:11
gives 105:13 108:6
 126:18 183:25
giving 78:23 184:25
 227:23
glad 268:16
glass 107:13
GLEASON 2:22
go 15:16 51:17 59:1,9
 61:4 63:13,13 65:21
 73:14 93:15 94:20
 118:8 136:12 153:17
 157:6 159:1 172:17
 173:9 178:23 180:18
 184:7 202:7 204:10

204:18 205:8 207:25
 212:5 214:1 215:17
 220:5 223:9 230:7,19
 233:7 238:1 242:15
 249:1 250:2 252:22
 259:16 260:16 270:16
 271:3 272:23 279:17
go-to 65:9
goal 26:24 258:20
 259:6
goes 93:25 95:23 155:4
 225:5 248:19 256:19
going 8:8 15:6 16:23
 18:3 20:2,3 21:22
 22:6,12,25 25:20 28:7
 59:9 64:21 65:3 76:7
 77:13,24 95:5 120:9
 124:8,15 140:19
 152:8 154:13 158:20
 159:18 167:16 179:1
 186:8 201:4 202:6,9
 219:19 221:10 226:14
 226:23 228:13 248:20
 251:25 257:16 258:6
 260:12 261:4 263:24
 267:1 271:17 273:17
 274:2,23 279:14
gold 114:8 190:9
 192:11 195:8 197:3
good 7:5,9 8:3,15,23
 9:13 13:10 17:11 18:8
 23:21 24:11 25:15
 26:16 30:16 31:24,25
 44:22,23 53:1,2,8,10
 54:2 69:16,18,20
 76:21 154:17 157:16
 188:1 189:24 209:15
 223:7
gotten 240:14
government 2:2 3:2,4
 3:10 6:15,24 7:1,6,10
 9:4,24 11:5,7,9 12:8
 12:11 14:1 17:21,24
 18:2,6 20:21 23:5,7,8
 23:9,10,13,15 24:5
 29:9 30:12 31:6 35:7
 35:23,24 36:3,6,9
 39:12,19,22,25 43:17
 43:20,23 49:15 51:9
 53:6,16 57:5 58:11,17
 58:20,23 69:3 74:1
 75:4,8,15,23 76:4,12
 76:15,18 77:18 78:17
 78:21 79:22,23 80:3,6
 80:8 81:9,11,14 82:3
 82:11,14,16,22 83:2,5
 84:1,7,8,25 85:3,5,11
 85:12,21,25 86:6

91:15 92:25 93:1,5,8
 93:10,16,18 94:21
 119:6 122:19,22,25
 128:23 137:22,24
 138:2,24 139:4,7,9
 152:25 158:18 230:19
 251:21
Government's 2:21
 9:23 16:25 18:7 19:3
 21:6,21 25:21 28:16
 28:18 34:13 38:8 39:7
 42:21 43:12 55:10
 154:19 158:22 202:9
 228:18 265:19
governors 24:25
graces 28:10
grade 50:5
graduate 59:15 70:11
grams 232:10
grant 77:14
grave 201:16
great 34:10 153:15
greater 108:2 115:15
Griffith's 157:20
Griffiths 62:13 66:7
gross 238:10,14
grounds 18:8
group 89:24 104:14
 105:8 112:25 121:25
 140:10 172:24
groups 102:19
guardrails 275:2,22
guess 86:9 102:10
 169:16 209:3 235:9
 241:10 246:18 273:12
 273:22
guidance 105:12 274:7
guidelines 22:8
guise 98:4
guy 208:22
guys 226:10

H

H-E-A-T-H-E-R 31:12
habituate 184:25
half 56:24
hallucinate 200:24
 201:2
hallucinations 27:15
 100:25 104:1 137:3
 143:18
hallucinogen 62:6,22
 65:23,25 66:3,10,11
 66:18 99:14 100:14
 147:8 199:12 200:4
 229:20 270:3 274:16
hallucinogenic 27:10
 63:1 69:5 73:19 74:3

74:6 88:19 89:19
 100:25 103:18,25
 107:6 114:9 127:7,11
 128:6,14 134:20
 160:10,18 161:16
 193:16 198:19 199:3
 199:14 200:7 273:23
 273:24 274:6,9,12,20
 275:7,10,12,13
hallucinogens 57:19
 58:5 60:1 62:2,16
 65:9,16,20 66:1,15,21
 88:23 89:7,24 102:24
 104:9,10,11,13 108:5
 108:8 109:14 114:11
 116:2 117:15 118:2
 124:10,19 135:1
 140:7 142:1 146:5
 177:15 184:12,15
 190:12 192:8,20
 193:4 194:13,15
 196:10 197:13,16
 202:22 203:7 229:1
 229:12 268:12 269:14
 272:15 274:24 277:2
 278:7
halt 29:11 245:8
halted 253:20
hand 31:2 53:12 136:24
handle 152:15 227:4
handled 45:24
hands 27:1
handwritten 123:2
hang 33:20
happen 87:15 90:10
 104:15 139:23 141:2
 162:21 275:2,5 279:3
happened 41:9 184:5
 268:9
happening 92:8 111:17
 140:17 168:25
happens 120:19 140:9
 140:13 253:11 259:2
harm 30:4,5 65:1
 103:20 159:23 218:21
 251:14,25 269:9
harmful 26:25
harms 139:20 140:3
 159:17 169:7 251:18
 275:16
Harrison 16:9
Harvard 57:18
hazard 96:8 106:3,11
 158:10 159:10
hazards 178:10
HCI 233:19 234:6
head 151:21,21 169:21
 179:17 196:25 215:8

224:22 263:16
head-twitch 258:4
headache 104:1
headaches 263:14
headnote 18:17
headquarters 32:16
 54:9 254:5,16
health 55:23 78:23 79:4
 79:8 89:25 96:8 106:3
 106:12 117:4 128:17
 134:11,17 135:6,8
 145:24 146:9,12
 158:10 159:10 177:7
 177:13 178:10 259:8
 276:12 277:6
healthcare 150:16
healthy 114:15
hear 22:21 29:4 30:18
 30:20,22 62:1
heard 27:16,17 116:11
hearing 1:13 4:23,25
 5:4,6,11,17,20,23,25
 6:14,19 9:3 10:5,9
 11:1,13 13:17,22 14:6
 18:9 24:6,8,10,17
 25:8,9 34:19 52:24
 121:3
heart 177:11
heartbeat 135:25
Heather 3:5,11 30:13
 31:4,11
held 15:24
Heldreth 9:3 24:12,13
 24:20,25 25:1,2,5
Heldreth's 25:10
help 20:8 40:24 75:18
 112:8 278:14
helped 255:16
Hennessey 17:14,17
 22:4
hepatic 136:10
heroin 108:21
hey 226:10
HHS 74:21,25 75:11,18
 79:8 80:18 81:6 94:15
 97:1 103:15 105:10
 105:18 106:7 110:22
 152:22 155:21 171:24
 172:3 181:2 182:7
 192:17 204:23 214:24
 233:8 237:2,9,19,23
 265:11 266:18 267:6
 269:5 272:17,18
 274:15
HHS' 86:3 114:5
HHS's 74:24 78:23
 93:23 94:9 96:14
 104:4 105:16,23

123:16 141:20 144:15
 147:5 150:5 161:11
 161:17 169:9,13
 171:12 182:5,6
 194:11 232:24
high 62:25 109:11
 146:20 147:1,1,6
 199:2 252:16
higher 168:16,22
 229:23
hinder 29:11
historically 183:12
 252:15
history 125:17 126:3
 128:9,18 129:16
 136:20 144:23,25
 145:11 157:4,6
 187:22
hit 214:4
hold 55:13 56:25
 121:16,16 155:24
 175:16
holidays 41:20
home 136:21
Honor 6:25 7:6,10,16
 8:4,6 9:7,16,18 14:14
 15:20 16:13 17:24
 19:16 23:18 24:4
 25:14 26:4,7,15,21
 30:24 35:22 36:2 39:6
 39:10 43:11,16 44:18
 47:8 51:6,10 52:18
 58:11,16 69:2,10,12
 73:4,24 76:3,25 78:12
 82:1 84:24 93:4 139:3
 153:10,15 154:2,11
 158:20 201:25 202:5
 202:19 223:8,24
 226:13 227:7 228:16
 244:17 251:9,13
 252:5 265:15 270:10
 278:18
HONORABLE 1:16
Hopkins 61:10 62:7,9
 62:11,12,20 63:11
 70:18 157:23 196:18
Hot 2:11 8:9
hotspot 77:15,24
hour 10:22
hours 28:5,14 41:20
 115:15 116:15 135:19
house 149:15
household 70:19
housekeeping 4:16
human 79:5,8 110:7
 114:15 132:6 144:16
 171:22 174:14 175:9
 182:23 189:22 190:3

258:22 259:7
humans 29:3,15 57:23
 66:3 101:13 103:23
 112:20 114:13 151:16
 170:12 186:2 258:14
 258:18,22 259:25
 260:8,22 261:3 265:8
 266:23 267:8
hundred 42:7 172:25
 173:8 174:5,6 241:6
hundreds 191:9
Hurwitz 66:7
hybrid 4:24
hydrogens 122:1
hypertension 135:17
 137:6

I

IACUC 248:21
idea 229:14 246:17
identical 39:13 123:6
identically 244:9
identifiable 47:22
identification 12:6,9,12
 12:17,23 34:13 36:4
 36:10 38:7 39:20 40:1
 42:21 43:18,24 57:4,5
 58:13,18,23 75:4,24
 76:5,13,18 78:17
 79:23 80:4 82:12 84:9
 85:1 93:6 137:25
 138:3 139:5
identified 20:23 133:15
identify 57:9 75:8 81:15
identifying 169:25
 208:8
Il 45:23 67:6 199:21
 244:10,11
ill 24:13
illegal 220:17 222:2,9
 222:23
illicit 99:1 217:2 218:1
 227:19
illicitly 217:7
illness 25:10,16
illustrative 119:20
images 28:11
immediate 142:6 176:2
impact 259:7
impacts 239:1
impaired 134:21
implement 33:4
implications 124:4
important 35:12 48:9
 127:3,5 151:10 231:5
 232:1 264:10 275:7
 275:10
impregnated 131:8

in-house 254:23
in-person 4:24 16:9
inception 188:2,8
incidents 136:17
inclined 237:6
include 92:9 118:13
 125:21 132:18 175:1
 208:25 237:17 240:23
 271:4
included 23:10 56:12
 105:16 123:19 130:22
 153:6 236:20
includes 4:13 68:8
 243:13 266:22
including 12:2 57:18
 100:15 117:15 150:7
 202:23 229:1 237:10
inclusion 105:16 275:4
 275:25 276:6
incomplete 214:9
 247:24 251:2
increase 168:4 204:16
 230:11,12
increased 191:7 256:12
 256:14 263:9
increases 256:21
IND 123:24 124:21,24
 125:2 265:12
independent 243:24
 249:11
Indiana 85:18 212:16
indicate 161:14 170:7
 170:16 218:25 222:22
 269:24
indicated 23:9 173:4
 209:15 241:10
indicates 114:5 167:15
indicating 98:25
indication 110:8 170:19
 172:23 173:15 261:13
 261:16
indicative 186:23 194:9
 219:11 230:2,15
indicator 184:10,14
individual 10:7 14:12
 49:18 135:21 159:25
 161:4 170:4 173:10
 175:22 222:22
individually 44:3 49:14
 49:22 50:2
individuals 17:12 96:6
 96:9 97:23 158:8,11
 159:8,11 161:13
 163:12 196:17
INDs 124:9
induce 134:20
induced 110:24
induces 159:16

industry 105:12 192:23
 261:19,22,23
infer 260:20
inference 186:19
 188:20
inferences 191:14,22
inferred 186:16
inferring 87:9
information 35:14
 40:25 41:24 47:22,23
 47:25 48:6,10,19,21
 72:9 85:14 86:16,25
 87:2,3,5 88:10 94:17
 94:19 95:9 105:11
 106:6 107:24,25
 108:6 117:10 118:14
 123:21 125:21 126:22
 126:24 128:25 132:18
 134:23 147:24 149:17
 155:8 169:15 170:4
 171:2,14 172:13
 182:19 184:1,3
 219:14 220:21 235:3
 235:24 240:19 241:3
 242:18 245:19 255:17
 256:9 272:24
informed 48:14
informing 35:13 48:9
infusions 191:2
ingested 135:21 218:12
ingesting 278:2
ingredient 62:25
inherent 217:24
inherently 171:3 216:19
 218:16 274:21
inhibit 245:3
initial 120:2
initialing 122:6
initially 23:19 80:19
 188:3
initials 122:3
initiates 108:17
initiation 95:23
initiative 97:24 163:13
injected 185:11
injection 267:25
injections 185:9
input 242:23
inquire 31:21 53:24
inserted 190:24
insomnia 104:2
inspections 45:19 52:2
install 246:24
instance 108:21 131:2
instances 87:23 222:13
instantaneously 40:14
institution 248:17
 249:17

institutional 245:25
 248:14,14,15,22
 249:15
institutional's 248:21
institutions 246:13
instructed 4:11
intend 11:4
intended 134:9 182:23
 185:23 218:1,12
 274:16,17
intense 90:7
intentionally 273:23
interagency 65:2
interested 15:8 237:10
 275:20
internal 215:17
international 240:18
 241:18
internationally 65:3
 92:1 227:17 240:22
internet 77:17,19 78:4
 172:16
interpret 194:8
interpretation 182:2
 195:1
interpretations 187:5
interpretative 28:12
interrupt 23:17
intoxication 242:2
intoxications 128:24
 241:24 242:13
intraperitoneal 185:9
introduce 13:7
introduction 109:19
 229:16
intubated 137:5
investigate 45:21 51:21
 52:12
investigated 59:25
 150:13 151:8 263:6
 267:17
investigation 46:11
 275:14
Investigational 123:25
investigations 45:18
 46:23,25 52:2,6
 133:24 134:1
investigator 32:12 45:4
 45:8 51:17,21 52:11
 228:6 247:25 248:4
investigators 45:15
 46:7 254:8
invited 57:19
involve 62:2
involved 36:25 50:11
 50:15 135:13 182:18
 208:1
involvement 36:23

182:21
involving 67:14 136:18
iodine 121:24
iodoamphetamine 1:6
Iowa 212:16
IRB 248:19
Ireland 129:12
issue 6:1 11:19 15:23
 16:6 17:13 20:19 21:5
 21:20 23:4,14 24:2
 183:15
issued 10:5 38:17,18
issues 13:24 35:13
 48:10,14 157:23
 171:15 175:11 177:12
 201:15
issuing 225:21 244:23
 251:16
italics 177:21
Italy 129:11
item 220:24
items 235:21
IV 67:11 244:2

J

Jackson 18:15
January 5:7,13,18
 32:13 35:5 40:20,21
 63:19
Jaster 2:22 8:14 15:7
 17:14 22:5
job 54:24
Johns 61:10 62:7,9,11
 62:12 63:11 157:23
Johnson 66:7
joined 63:24 183:12
joining 62:10 152:25
 153:2
joint 5:24
jointly 5:25 11:8
Joseph 17:14
journal 72:11,13
journalism 21:12
journalist 15:8
journalistic 15:7
journals 72:21 236:12
judge 1:16 4:3,10,15,16
 7:13,17,21,25 8:7,11
 8:15,20,23 9:8,12,17
 9:19 12:7,24 14:3,9
 14:11,16,20,22,25
 15:14,18,21 17:7,10
 17:20 19:13 20:17
 21:9,14,18 22:21,24
 23:2,3,21 25:11,20
 26:5,10,13,16,19 30:9
 30:16,21,25 31:8,14
 31:20 35:25 36:3

37:13 39:8,11 43:14
 43:17 44:15 46:18
 47:9 51:7 52:16,20
 53:1,4,8,11,18,23
 54:11,15 58:14,17
 68:16,20,22 69:7,16
 73:10,14,20,25 76:1,4
 76:10,12,20,23 77:4
 77:21 78:1,3,8,10,13
 79:25 80:3,10 82:5,8
 82:11,18 84:11,22,25
 85:7 93:2,5,12 119:12
 120:3,5,11,14,18,20
 120:25 121:3,16
 122:13,17 123:1
 127:13 131:24 136:12
 137:24 139:1,4,11
 153:11,16,22 154:6
 154:10,14,15 155:24
 156:7 158:14,17
 171:8 202:3 223:6,9
 223:15,20 226:16,23
 228:13 244:19 245:10
 251:20 270:8,18,23
 278:20,25 279:4,7,17
 279:22

judgment 134:21

jump 279:15

Justice 1:1 50:1

K

Kansas 166:2 212:17
Kansas's 133:25
Kayla 2:4 7:10
Kd 107:20
keep 50:1 193:23 195:9
 277:3
keeping 18:9
Kentucky 133:18
kept 75:20 79:17 84:4
 138:18
Ki 107:25
kidney 136:10,11
kind 15:10 21:12 67:12
 88:17 89:24 131:19
 152:18 156:3 162:25
 173:21,22 184:20
 191:4 198:2 243:7
 249:12 257:20 261:19
 266:13 267:18 271:4
 278:22 279:13
kinds 90:8
kinetics 268:2
Kingdom 91:5 129:11
knew 173:4
know 15:12 18:11 20:1
 20:25 23:18 24:18
 41:6 50:18,19 62:21

64:11 86:14 89:24
 90:25 91:4,18 97:3
 101:7 111:6 114:23
 115:6 120:23 128:11
 128:13 139:19 149:16
 151:7 156:11 158:1,5
 159:20 161:8 163:6
 163:25 169:19,23
 170:23 171:21 174:2
 175:21 176:10 179:14
 180:10 183:12 184:25
 188:1,7 189:17,19
 190:6 193:18 194:22
 195:4 196:16 200:2
 204:24 207:9,16,23
 213:23 215:5,8,25
 216:4 220:8,12 222:7
 222:8,10 224:3
 225:12,24 226:14
 229:19,22 232:5
 233:2,9,13,17,20
 234:1,4,6,17 236:17
 241:8,11,13,14 242:1
 242:12 243:5,5 246:9
 247:7,20 250:10,15
 251:6,24,25 252:7,15
 252:18 256:15 258:6
 258:14 262:17 263:4
 264:6,15 267:9 269:8
 269:22 270:1 272:25

know-how 16:18 17:4

knowing 28:13 127:25
 128:2 140:3 141:1
 174:15

knowledge 42:10 44:11
 48:13,22 86:11 88:14
 90:19 92:14 97:5
 98:19,21 115:13
 118:9 124:9 125:3
 144:6 148:23 150:19
 150:25 155:15 183:11
 216:23 220:22 230:21
 235:11,16,18 236:10
 251:16 263:19

known 27:8,10,11
 87:22 88:7 89:25
 99:13 100:8 102:1
 106:21 110:1 112:17
 115:1 117:2,23
 118:19,23 119:1
 122:8 147:20 148:3
 186:5,15 188:24
 192:14 194:14 236:14
 258:1 268:12 271:25
 272:3,11 275:24
 276:3,3

Kreinheder 2:4 7:9,10
 30:12 31:23 35:22

36:11 37:10,14 39:6
 40:2 43:11,25 44:13
 46:16 47:4 51:10,12
 52:15

L

L 2:4

lab 87:15 130:2,2

168:18 179:12 183:25
 210:4 225:7

lab-to-lab 207:19

labeled 38:7 96:3

219:13,23 220:2

laboratories 86:24

133:19 263:20

laboratory 85:14 86:15

133:18,25 134:1

208:16 209:8 220:1

labs 86:22 87:16 88:6

88:10,13 153:7

167:21 168:3 192:9

204:17 208:5 209:4

209:12 210:19 211:1

211:7 216:2,5 219:6

219:11 221:24 224:13

264:2,21

lack 35:14 48:11 123:22

150:2

lacked 48:19

laid 86:2

language 180:13,21

182:7

large 107:15 172:24

173:24 198:16 199:12

233:19

largely 64:14 94:17

141:20 204:8 235:19

241:1 276:11

Las 2:12 8:9

lasted 28:5 170:17

lasts 115:14,18 116:14

late 13:10

latest 257:16

law 1:16 2:11,16,22

16:15 17:3 86:20

87:18 88:10 94:15,18

96:14 97:25 98:24

119:13 125:19 130:3

130:7 133:12 138:21

160:11,19,21 161:7

163:15 168:9 183:2

211:2 221:22 222:4,6

222:11 254:11

laws 33:5 49:25

laying 136:22

lead 7:14 32:16 90:8

134:3 143:16 230:10

240:7 277:5,13

leap 186:20

learn 101:15,19 102:19

learned 186:6 262:12

leave 20:4 118:16

lectern 154:5

left 37:24 57:21 64:1

121:15,20 213:10

235:17

legal 222:5,18

legally 254:1

legislative 157:3,6

legitimate 29:22 96:19

97:6 100:4 131:20,23

132:5 162:14,18

let's 61:12 81:14 95:25

96:17 112:10 118:8

121:5 123:13 125:16

139:14 147:9 153:17

175:6 186:12 220:7,7

223:9 224:9 279:17

letter 74:21 75:10 79:7

80:17,23 91:23 93:19

123:7 154:23 155:2

156:17 249:16,25

250:2,3

letting 156:11

level 49:20 220:24

259:23

lever 101:16,19 185:2

186:7,9,10,13,14,22

191:1,6,9

levers 112:13

liability 62:18 95:13

114:9 139:15 140:6

140:23 141:18 146:16

146:18 157:25 158:4

170:13 174:12 188:14

188:15,19 193:2,21

194:12 195:7 265:21

266:2,19 267:7

liaison 33:14,16,23

36:15 37:5 38:21

51:24

liaisoning 33:8

Liaisons 36:19 37:22

license 224:24 225:1,6

225:13,16 226:4

245:16 246:6,10

247:8 248:9,11,14,15

249:5 252:19 253:25

255:8 265:2

licensed 97:25 163:14

licenses 57:1 225:2,21

227:1 244:23 245:5

250:8,12 251:8,16

252:9 263:21

licensing 248:8

licensure 255:6

life 28:4 102:3
light 14:13 135:18
likewise 5:24
liking 269:12
limit 206:6,9
limited 46:6 49:16
 163:1,3 235:21
 258:16
line 252:3 276:24
lines 177:19,23
linked 197:6
linking 189:14
liquid 126:15 130:23
 133:7
list 107:11 135:3 213:10
listed 6:4,9 16:14 99:25
 177:21 178:3 232:10
 233:21 234:1
Listen 27:24
listening 19:5,11 21:6,7
lists 24:25 137:9
literature 75:1 95:12
 267:9
little 32:23 34:23
 100:12 121:6 131:16
 156:7 184:17 198:10
 230:18 245:14
live 259:21
local 86:21 130:11
 221:23 222:10
lodged 19:22
logged 30:15
logistical 77:10
long 28:6 32:6 50:7
 55:3 105:15 115:14
 115:19 116:16 117:13
 117:19 122:15 140:18
 170:17 175:22 176:4
 191:9 247:8 258:14
 259:2 265:24
long-acting 270:3
 271:13,14
long-lasting 170:23
 271:9
longer 61:7 132:17
 181:15 215:22 248:5
look 22:1 31:15,17 63:3
 63:8 65:17 75:3 81:8
 81:14 82:21 83:1
 91:14 93:15 95:25
 96:17 103:13 105:7
 105:11 107:25 125:19
 125:22 126:2 128:8
 128:16 132:9 137:22
 151:17 165:4 175:15
 202:8 206:10 212:2
 233:7 239:6,7 256:9
 266:25 268:4 276:18

279:5 280:6
looked 71:15 72:8
 129:17 204:25
looking 18:17 21:12
 24:23 41:23 61:17,19
 62:17 92:3 103:22
 129:13,19 157:17
 158:14,15 170:10
 203:23 206:12 212:8
 220:5 253:5 257:23
 262:4,15,22 263:1,12
 265:5,19 267:12
 270:14 271:19,20,24
 274:11
looks 105:8 133:17
 238:11 264:20
loop 255:4
lorcaserin 61:18 62:4
lot 19:4 64:12 114:10
 167:15 187:16 240:3
 246:19 249:20 250:1
 252:25 257:21 260:7
 275:3 279:15
Lots 191:17
Loved 115:1
low 196:19 252:16
 256:14
lower 108:3 168:2
lozenges 132:8
LSD 27:17 99:6,13,19
 100:22 102:20 103:3
 103:11 106:9 112:23
 113:2,23 114:7
 124:11 141:4 143:25
 145:7,10 151:25
 168:21 170:18 189:17
 194:22 195:5
lunch 10:23,24 153:13
 153:14,17

M

M 2:21,22 53:14
M-A-N-N 7:1
M-O-R-R-I-S-S-E-T-T-E
 7:3
ma'am 176:18 243:11
 247:12 277:17
Madison 133:8
mailed 42:5
mailing 54:7
main 62:20
Maine 212:17
maintain 19:17 39:15
 266:5
major 199:15
making 19:6 61:21,22
 100:2 178:6 186:20
 256:16

MAKR 3:8
man 27:25 135:13
 136:20 137:2
managed 33:12
management 34:4
 41:13 42:3 263:2
managing 34:5
manifesting 27:12
manifests 111:16
Mann 2:3 6:25,25 7:13
 7:16,19,24 8:1 9:6,10
 13:23,24 14:5,10,13
 14:18,21,24 15:23
 17:21,24 19:14 20:19
 20:22 21:10,16,19
 22:2 23:25 24:2,4
 26:3,4,19,21 30:9,10
 53:4,6 54:1,17 58:11
 58:25 59:4 68:16,19
 68:21,23 69:2 73:10
 73:13,17 74:8,9 75:23
 76:20,22 77:6 78:14
 78:15 79:22 80:12
 81:11,13 82:1,7,20
 84:7,12,15,18 85:9
 92:25 93:14 119:11
 119:15 120:4,8,13,21
 121:2,4,19 122:10,24
 123:4 127:14 131:25
 132:4 136:16 138:2,4
 138:24 139:13 153:9
 153:12 171:6 202:19
 226:13 228:11 244:17
 245:7 251:9
manufactured 29:25
 97:13
March 91:25 214:6
marginal 196:2
marked 12:4,10,18
 34:12 36:4,9 39:19,25
 42:20 43:18,23 57:4,5
 58:12,18,23 75:4,24
 76:5,13,18 78:17
 79:23 80:4 81:9 82:12
 84:9 85:1 93:6 139:5
markers 139:22 262:19
 269:12
marketing 147:15
Maryland 54:5
masse 44:6
match 208:8
matches 209:18
material 77:18
materials 31:16 86:5
matter 1:4,13 4:4 15:5
 77:1 153:19 223:12
 256:22 279:19 280:8
mattered 263:11

matters 4:17
maximum 247:21
MDL 111:2
MDMA 113:9,13 124:11
 125:8 135:21,23
 152:5,8 168:15,18,21
 177:4,13 196:2,13,14
mean 15:14 21:1 60:24
 67:13 70:15 71:19
 89:11 92:11 95:8 97:7
 99:2 100:5 110:5
 111:7 115:8 117:16
 123:24 124:2,14
 131:3 132:5 134:5
 140:15 141:9 147:22
 151:7 155:9 157:12
 162:20,25 164:8
 167:24 186:24 193:21
 195:6 203:23 204:4
 214:21,23 217:11
 218:3 220:15 221:8
 228:14 230:9 234:14
 236:17 238:13 239:8
 244:1 260:6,25 262:6
 270:18 273:20 274:13
 277:22
meaning 207:5
means 27:12 33:17
 95:9 98:2 102:2
 107:21 108:1,12
 125:24 147:23 167:25
 179:7 221:7 236:24
 242:3
meant 94:14 105:2
 142:6 221:24
measure 189:21 190:2
 190:13,18
measured 158:4
measuring 190:9
mechanism 100:19
 106:10 111:19 117:25
 187:10 188:11 193:10
 196:16 200:10,15,20
 273:1,5,7
mechanisms 59:25
 61:19 187:7 257:24
 258:21
mediated 112:1
medical 15:8 29:1 61:8
 61:14 68:25 74:22
 75:11 78:24 79:14
 80:17 94:9 96:25 97:1
 97:24 98:5,12,14
 118:17 123:14,15,17
 123:18,21 141:22
 144:14,20 147:10,11
 147:17,18 149:2
 150:3,12,14,17

163:14 172:7 175:18
 178:8 180:20 199:19
 235:19 237:5,8 244:3
 260:21,25 261:3,5,9
 261:11 264:12 267:9
 273:25 274:8
medications 27:4,6
 276:14
medicinal 104:7 115:9
 127:8,9,17
medicine 61:10 62:25
 150:24 261:25
meet 44:24 92:16
 242:25 249:3 269:1
 269:14 271:15
melting 233:24
member 92:15
members 10:11 91:3
mental 276:10
mention 98:22 147:6
 241:1
mentioned 13:25 58:7
 62:21 72:10 74:11,16
 86:13 99:12 117:7
 160:17 163:16 169:4
 169:11 174:22 182:9
 189:1 216:2,9,11
 224:2 230:1 262:21
 263:18
mentioning 257:2
mentions 117:7
mescaline 27:16
messed 89:1
met 91:24 92:22
metabolites 176:8
methamphetamine
 103:5 113:8,12
 136:20
method 208:21
methods 211:8,11
methy 121:25
metric 261:12
metrics 95:11 107:22
 158:5
Mexico 8:10
mic 156:7
mice 101:12
Michigan 132:24,24
microgram 132:12,14
 132:15,25 133:9
 205:4 215:10,11,23
 216:3,10 219:18
middle 98:23
milligrams 159:21
 160:7 257:7,7
mind 27:12 89:7 246:5
 261:12
mine 72:15

Minnesota 212:17
minor 15:5 238:20,25
 239:12,15
minute 215:10 223:10
mirror 157:18,19
 243:21
mirrored 237:3
mischaracterizing
 202:20
misinterpreted 191:17
 192:2,3
missed 230:13
Missouri 212:17
misspoke 195:15
mistaken 24:19
mistakenly 23:10
mixed 89:1
mixup 158:12
models 262:7,18,19
 264:14
modification 123:10
modified 122:23 123:2
mole 232:10
molecular 88:22 118:24
 232:9,11,20 257:23
molecule 238:11,13
 239:12
molecules 61:23
mom 127:25 128:1
moment 14:4,7 30:14
 77:7 153:9,18 202:1
monitor 64:23,24 65:2
month 172:22
months 247:15,17
 248:24 250:21 251:3
 252:22
morning 7:5,9 8:3,25
 31:24,25 44:22,23
 53:8,10 54:2 69:18,20
morphine 67:10
Morrisette 2:6 7:2,7
 7:11 54:4
mother 173:12,13
motion 9:9,24 14:1
 22:10 23:6 25:18,19
mouth 131:10 156:4
move 35:23 47:7 75:23
 79:22 82:3,6,8 84:8
 85:10 92:25 106:14
 118:7 137:20 138:24
 139:14 177:17 227:5
 230:17 240:11 244:20
 259:21 265:18
moved 45:11 230:6
moving 201:14 240:12
 245:3
multiple 192:9 268:1
muscle 110:23 111:6

muscles 136:8
mushrooms 277:20
 278:2

N

N-I-D-A 155:3
N,N-diisopropyltrypt...
 60:4 66:18
N,N-dimethyltryptam...
 60:2 102:21
naloxone 108:25 116:1
name 31:9,9,11,12,13
 44:24 53:19,19 89:1
 245:23
names 71:2 227:24
naming 227:19
Narcan 115:25
nation-wide 208:7
National 70:19 85:14
 86:15
Nations 91:11 240:20
natural 88:20
nature 28:3 70:16 90:5
 219:15
Navy 1:11
NDA 124:13 125:5,7
 180:25
NDAs 124:18 125:5,11
 180:22,24
necessarily 141:12
 151:15 160:23 165:14
 165:16 177:10 189:11
 193:5 205:17 217:23
 218:25 220:5 221:11
 222:3,22 230:12
 236:15 239:7 240:7
 243:21 256:22 258:25
 259:10 260:6 261:5
 261:15 268:14 274:13
necessary 16:1 89:18
 107:5
need 13:9 33:10 40:14
 57:14 76:21 95:1
 111:20 124:4 199:8
 199:25 245:16,20
 253:20 268:15 270:15
 271:3 273:21 278:25
needed 10:23 33:6
 40:20 47:23 249:12
needs 84:10 139:24
 266:4
negative 278:3,5
negatives 192:5 278:8
 278:9
neither 28:25 29:2
 148:25
nervous 109:17,20,24
 110:18

neuroscience 21:2
 55:17 56:19
neurotransmitters
 89:14
Nevada 85:20 213:5,11
never 156:9 250:3
 260:8
new 8:9 23:6 33:5 48:19
 61:22 99:9,23 123:25
 124:16 150:13 172:21
 178:1,4,13,15,19
 179:2,3,4,7,8 180:9
 180:11,12,15 181:7
 181:10,13,16,19
 182:4 188:16 205:21
 213:13,16,21 252:10
 252:14 257:24
NFLIS 86:14 87:11,23
 87:25 88:9 125:24
 126:2,8 129:18,23
 137:21 160:12 167:17
 167:25 202:15 203:24
 204:15,19 205:7,15
 205:24 210:17 213:25
 215:2 219:25 221:3
 221:20 229:25 241:17
NFLIS-Drug 85:15 86:9
 86:25 87:3 160:23
 167:17 184:6 204:7
 208:1 228:23
Nice 44:24
Nichols 134:25 135:2
nicotine 64:3
NIDA 79:1 155:3,6,13
 155:16,19,22 156:13
 188:12
night 9:7
nine 166:9
nineteen 167:4 179:18
ninety-one 179:18
NM 2:12
non-clinical 250:24
non-controlled 52:12
 87:13,23,25 88:1
 168:2,20 215:15
 226:5
non-drug 101:18
non-fatal 241:23 242:2
 242:12
non-hallucinogens
 259:12
non-human 258:13
 273:3
non-psychoactive
 240:1
non-responsive 135:17
non-scheduling 33:2
 49:5,10

non-scientist 239:5
noncontrolled 168:23
nonfatal 128:24
nonhuman 101:12
 190:25
North 55:23 212:17
Norway 129:11
Nos 12:5,11,19
nose 191:1
note 19:20 39:12
 105:10 107:3 117:1
 126:18 141:25 144:15
 192:19,22 194:13
noted 10:4 20:11 85:19
 97:1,3 101:2 110:22
 111:1 163:3 173:10
 195:11 213:16
notes 16:3 105:18
 117:13 250:13 270:11
notice 1:13 3:11 5:2
 10:4,9 13:10 35:1,15
 36:16,21 37:11,15
 38:1,14,17,20 39:4
 40:4,6,11,17 41:3
 50:25 64:20 83:13,21
noticed 13:8 14:5
notified 41:5
notion 266:6
notwithstanding 25:10
November 1:10 4:9
 10:5
novo 115:5
NPRM 5:2 35:8 80:18
 81:17 83:19,22,25
NPRMs 155:11
number 13:25 40:10
 64:20 80:4 82:12 85:1
 90:9 93:6,18 107:15
 108:1 115:10 116:23
 119:3 130:14,20
 138:12 139:5 165:17
 176:11 188:25 192:7
 202:22 215:5 224:20
 228:25 229:17,23
 230:2,6,23 231:1
 232:4,5 233:3,20,25
 234:8,18,21 241:8
 250:17,25
numbered 35:7
numbers 119:2 167:14
 167:17,22 168:1,4,7
 168:10 204:15,18,20
 206:17 207:8 228:1
 229:7 230:14 232:20
 233:1
numerous 208:13

O

oath 77:6 153:25
 223:18 280:3
object 73:5
objection 17:25 18:6
 23:19 35:25 36:2,5
 39:9,10,21 43:15,16
 43:19 46:16 47:4,10
 58:15,16,19 69:8
 73:21 74:4 76:2,3,14
 80:1,2,5 82:9,10,13
 84:23,24 85:2 93:3,4
 93:7 122:14,15
 127:12 131:22 139:2
 139:3,6 171:6 226:13
 226:17,24 228:11,15
 244:17 245:7 251:9
 252:4
objections 4:14 13:12
 13:13
obligated 92:19
obligations 29:7 92:22
 242:25 243:2,4,10
 244:14
observe 16:25
observing 105:14
obtain 56:9
obtaining 246:10
obvious 29:2
Obviously 184:24
occur 212:15 275:16
occurred 83:20 213:19
October 15:24 83:3,7
 83:17
offer 11:16 13:13 23:15
 39:7 43:12 58:12
 68:17 69:3 122:11
offered 13:1,3,15 20:13
 36:4 39:20 43:19 47:5
 55:9 58:18 73:13,17
 74:1 76:13 80:5 82:13
 85:2 93:7 139:6
offering 18:4 73:15,22
office 2:5,11,16 6:22
 8:5,7,18 33:4 45:24
 46:22,24 63:22
 132:16 203:13 215:13
 216:6 278:13
offices 254:9
official 10:16
oftentimes 248:16
 260:3 276:13
oh 8:8 76:7 117:17
 154:6 158:4,11,13,13
 158:13 203:15 205:1
 247:19 263:8
Ohio 212:18
okay 7:13,17,21,25 8:11
 8:15,20,23,25 9:8,12

9:17 14:16,21,24
 15:17,18,21 17:7,10
 17:20,21 19:13 21:9
 21:14 22:15,23 23:2,3
 23:21 24:2 25:11,20
 26:5,10,19 30:25
 31:20 34:15 36:13
 37:12,13 39:11 43:17
 44:12 46:3,10,15 47:2
 47:9,18 48:1,7,13,18
 48:22 49:7,12,21
 50:11,16,20 51:1
 52:14,16,20 53:8 54:8
 54:10,15 55:25 57:3,7
 59:22 63:2 64:4 65:17
 68:8,11,22 70:2,9,13
 70:22 71:13,24 72:2
 72:10,22,25 73:3,14
 73:25 75:3,6,7 76:4
 76:11,23 77:4,21 78:1
 78:8,20 79:11 80:24
 81:14 82:5,9,11 83:1
 83:4,15 84:12,16,25
 85:21 86:13 88:16
 89:23 93:15,21,22
 94:20,22 101:4
 102:10 103:9,22
 104:21 106:14 109:9
 111:24 112:3 116:14
 118:7,18 119:5,7,24
 120:5,11,12 121:5,8
 122:5,17 125:16
 126:10 128:22 135:20
 135:24 136:7,17
 137:20 139:4 146:22
 147:9 148:15 149:22
 153:11,16 154:10,13
 154:20 155:1,17,23
 156:5,12,19,19 157:5
 157:9,14 158:1,7,16
 159:1,3,4,7,24 160:5
 160:5,11,19 161:8,20
 161:23 162:6,6,11
 162:23 163:6,9,11
 164:4,11,16,19,22
 165:5,18 166:5
 167:14 169:4,10,15
 169:19,22,25 170:5
 171:20,25 172:3,10
 172:16,20 173:21
 174:8,17,25 175:6,11
 175:21,24 176:13,24
 177:6,11,16 178:12
 178:16 179:7,9,21
 180:4 181:3,9 182:1,9
 182:25 183:5,9,13,19
 184:7,17 185:5,10,14
 185:17,21,25 186:18

187:18 188:4,9
 189:13 190:5,8,21
 191:13,19 192:24
 193:8,12 194:7
 195:22 196:14 197:1
 198:2,12,22 199:7,22
 200:6,21 201:1,7
 202:4 203:8,12
 204:24 205:5,11
 206:8 208:19,21
 209:16,21 210:14,22
 211:17 212:5,7,20
 213:18 214:7,10,20
 215:5,9,19 217:8,14
 217:18,21 218:10,16
 218:23 219:9 220:7
 220:11,19 221:1,5,12
 221:14 222:8,15,21
 222:25 223:9,15,19
 224:14,18,23 225:12
 227:15 228:23 229:4
 230:5,14,17 231:1,4,7
 231:15 232:4,9,16,19
 232:23 233:6,9,21,22
 233:25,25 234:4,7,12
 234:17,24 235:5,8,22
 236:1,9,14,19 237:8
 237:13,17,21 238:1
 239:5,11,16,20,25
 240:6,10,12,23 241:3
 241:6,9,14,17,21
 242:1,11,17 243:1,8
 243:13,16,25 244:4,7
 244:13 246:17,23
 247:1,3,7,20 248:6,23
 249:10 250:6,10
 251:3,6 252:18 253:8
 254:17,22 255:2,5,13
 255:23 256:3,15,18
 257:1,8 259:4,11,14
 260:2,9,14,19,24
 261:8,17,24,24 262:3
 262:14,21 263:1,7,12
 263:17,23 264:3,7,15
 264:25 265:4,18
 266:8,17 267:13,23
 268:6,11,16 269:3,10
 270:4,7,22 271:2
 272:20 273:12,17
 274:10,18 275:1,18
 275:22 276:6,19,22
 277:25 278:10,24
 279:2,6,17,22
old 121:8 212:9 236:25
 237:14
once 34:1 42:13 76:8
 101:23 121:2 140:16
 140:20 168:5 185:1

247:9 251:1 254:17
 255:18 256:18 269:19
 269:21 270:5
one-year 61:16
ones 67:18 72:4,6,16
 133:14 168:2 172:7
 197:6 211:1 216:7
 230:18
online 33:25 99:3 105:4
 105:8,8 114:17
 127:19 149:16 163:1
 163:22,25 164:6,10
 164:11,17 165:1
 169:24 174:7 224:7
 225:19
open 34:11 38:6,9
 42:19,22 235:20
opening 3:2 9:21 11:3
 15:22 26:2,8,11,20
operating 208:24 209:7
 259:15
operational 178:15
opinion 67:4 68:2 99:18
 142:19,22 143:3,12
 143:15,20 144:7,11
 144:22 145:3,9,14,17
 145:23 146:1,8,11,15
 146:19 148:9 150:15
 150:22 182:7 261:18
 261:21 274:19 275:19
opinions 18:3,23 19:8
 67:20,24 68:9 151:1
opioid 193:20
opioids 115:25 137:8
opportunity 11:2,14
 15:2 24:9 41:4 44:5
 69:13 194:2 195:19
oppose 25:18
opposed 23:19 29:10
 48:3 127:7
options 255:9
orally 22:22,25 218:12
order 10:13 21:11,22
 65:22 82:2 118:11
 259:15
ordered 219:5
orders 6:21 15:13
organization 117:1,4
 128:18 182:3
original 50:12
Orlando 133:17
other's 18:23
out-of-time 23:5
outbursts 90:17 201:10
 277:8
outcome 237:23 276:17
outline 11:3
outlined 95:24

outset 11:1
outside 29:23 46:22
 47:1 48:16 225:24
 226:15 228:4 234:16
 244:18 248:23 251:10
 251:23 254:15 255:25
 256:1,17 264:8 273:9
overall 49:16
overdosing 116:2
overlapped 56:21
overrule 252:3
overruled 46:20 171:8
 245:12
overseeing 33:7
overt 110:21

P

P-R-O-C-E-E-D-I-N-G-S
 4:1
p.m 10:21 40:21 153:20
 153:21 223:13,14
 279:20,21 280:9
package 248:1,2
packaging 219:14
page 63:3,3,8,14 66:4,6
 71:2 78:20 79:11 92:3
 95:5 96:1 103:22
 107:20 112:3 114:22
 116:25 119:5 122:24
 123:1 128:23 129:19
 132:9 138:11,11
 159:1,3 162:7,7 165:6
 177:17,22 184:8
 202:9 212:5 228:18
 230:19 238:1 265:20
 267:1,3 276:18,20
pages 75:7,14 80:24
pain 263:2,3,10,10
pair 131:14
pairs 266:7
Palamar 16:22 22:6
Palm 133:17
Panacea 5:7,8,9 9:1,20
 14:14 15:2 24:3,4,5
 24:14,16,18 25:2,8,15
 25:23
Panacea's 9:5,15,24
paper 35:4 40:8 57:21
 71:4,20,22 72:11
 119:22 126:16 127:22
 130:24 131:3,5,8,9,12
 131:21 132:7,8
 133:15,21 164:24
 173:11 175:23 236:5
 246:20 258:7 277:11
 277:15,18 278:6,11
 278:19
papers 71:15 72:13

86:10 176:17 236:6
 236:11 246:1
paradigm 187:3,6
 188:18
paragraph 98:23
 103:23 107:19 129:8
 155:1 163:10 177:18
 177:20 276:23 278:11
parallel 189:24
parameters 170:14
paranoia 90:13 277:7
part 19:1 29:5,18 46:10
 46:11 51:23 65:4 70:4
 70:7 79:19 80:18
 91:18 99:8 100:15
 105:7 116:5 122:11
 122:19 147:17,19
 148:5 152:14 163:9
 200:6 203:24 207:7
 225:12 227:3 228:8,9
 229:13 232:15 236:3
 237:18 240:10,18
 252:1 254:15
partial 113:13,15
partially 113:12 136:22
 176:1
participants 62:17
 114:15
participate 20:16 22:8
 24:6,10
participating 6:13 14:6
participation 25:8,9
particular 20:11,12,25
 59:5,22 79:20 86:16
 96:13 100:6 114:3
 118:12 253:1
particularly 16:22
 90:10
parties 5:20 6:12 10:10
 11:13,15,20 13:17
 15:25 65:15
partners 65:2
parts 197:10 222:12
party 8:14 11:2 13:7,9
 13:21 16:10 17:13
 19:18 20:6 24:14,14
 25:16 104:13 135:14
pass 153:10
pathway 61:5
patients 27:3
pattern 125:17 126:3
 127:5 128:10,18
 129:16 144:23 145:1
 145:11 193:22
Paul 1:16 4:10
Pause 30:17 69:11
 223:22 235:7 265:16
pay 50:4 246:14

PCP 65:23
PCP-like 65:24
peaks 211:22
peer 72:13 215:16,18
pellet 186:11
pellets 185:4
pen 119:9 120:7
pencil 119:9
pending 251:7 252:8
Pennsylvania 212:18
people 20:3,6 96:16
 98:3,6,10,10 99:4
 105:13 116:9 118:25
 127:4,6,10 128:5
 140:15,25 160:14
 161:8,15 162:3
 163:17,21 164:1,5,24
 164:25 165:8,9
 170:15 171:11 172:25
 173:4,8,9,16,20 174:5
 174:7,12 175:1,11
 176:24 187:1 193:18
 225:25 227:11 234:16
 241:19 255:16 269:21
 269:22,23 270:2,5
 271:8,13 275:6
period 34:8 40:16 42:9
 42:13 56:21 63:18
 180:12 186:11 191:10
 205:18 268:1
permanent 225:13
permission 13:9 77:14
 154:3
permit 13:12 22:6
permitted 6:19 11:11
 22:18
person 6:13,19 10:13
 17:8,19 22:13,14 24:7
 24:8,10,18 25:2,6
 34:19 65:9 117:25,25
 160:24 170:11 175:4
 271:21
personal 47:22,25
 156:17 196:16 250:6
 255:5,13 256:10
 261:18,21 274:19
 275:18
personally 71:7 72:23
 169:16 207:4 237:22
 265:3
personnel 10:18
PET 57:23
Petitioner's 2:22
Petitioners 3:17 5:21
 11:9,11 18:1,10 19:18
 74:4 77:12 135:3
Petitioners' 12:19
pharmaceutical 265:5

pharmacokinetic 231:19 232:2 234:25	phenethylamines 114:25 126:11,13,14 202:22 203:7 271:13	69:2 70:22 84:8 91:3 95:2 110:4 120:16 152:17 154:18 217:21 217:23 229:5 233:24 254:11 261:14 279:13	potent 27:23 117:22 159:20
pharmacological 67:5 106:16,18,20,24 109:10 110:15 117:21 118:3 134:15 141:4 143:4,10,14,16,21 231:8,11,24 235:4 239:2	phone 77:15 78:9 120:24	pointed 156:3	potential 19:4 30:3 35:13 48:10,14 95:7 95:11 99:10,20,25 100:2,10 101:1 105:13 109:23 113:15 142:23 143:1 146:20 147:1,2,6 151:11,20 151:24 155:4 156:22 163:4 169:7 177:12 178:3,5 184:11 186:5 186:16,17 188:17,23 190:10,14,18 191:5,5 192:4,12,19 194:9,19 194:23 195:3,14,16 197:3,11 198:7 199:24 214:23 219:12 240:17 256:13 259:24 263:13 264:12 272:14 273:6
pharmacologist 54:23 55:7 59:20 63:15,21	physiological 90:9 139:15,20,23 140:5,8 141:9 146:16 265:21 266:1,2,7,19 267:6,20 268:20,23,25 271:18 273:10,15	policy 2:9,9 5:12,13,14 5:15 16:16 32:17,22 33:1 37:20 45:1 192:18	potentially 20:13 22:19 26:25 186:21 209:24 216:17 258:23
pharmacology 55:18 56:11,19 59:10,13,24 63:25 69:4,25 73:6,18 74:2,5 123:9,11 182:23 219:16	physiologically 266:12	population 271:19	powder 126:15 130:23 132:23 134:3,6,8 216:12,15,19,25 217:1,6,9,13,15,17,19 217:22 218:2,4,11,24 219:2,20,20 220:2,20 220:21,23
pharmacology-based 72:16	pick 155:25 197:25 279:15	portal 33:25 41:15 241:12	powders 219:7,10
phase 259:25 260:8,10 260:16 275:15	picture 120:21 121:2	portion 109:16 234:11	PPS 5:10
PhD 55:16,22 56:3,15 56:18 59:9,12 60:20 61:1	piece 131:8,12,16	Pose 13:13	practice 150:24
Phelps 2:10,11 8:3,4,8 8:13 9:14,16 15:4,5 15:17 16:11,13 17:9 17:16 19:15,16 20:18 22:16,23 23:2,17 24:1 25:11,14 26:6,7,12,15 26:17,18 36:1,2 37:7 37:12 39:8,10 43:14 43:16 44:16,18,21,25 46:21 47:7,11 51:5 52:16,18 58:14,16 69:7,9,12,18,22 73:3 73:21,23 76:1,3,7,11 76:25 77:8,10,23 78:2 78:5,9,11,12 79:25 80:2 82:9,10 84:13,16 84:20,22,24 93:2,4 120:15,20,23 122:13 122:15 127:12 131:22 132:3 139:1,3 153:12 153:14,25 154:2,8,11 154:16,22 155:23 156:1,5,9,18 158:7,16 158:19,25 171:9,19 201:25 202:4,14,24 203:1 223:6,8,20,23 223:25 226:18,20 227:6,8 228:16,22 244:20,21 245:13 251:13 252:5,6 265:14,17 270:8,10 270:22 271:2,6 278:17,24 279:2,6,12	piecemeal 13:12	posed 145:24 146:9	practitioner 97:25 98:5 98:12 163:14 274:8
	PiHKAL 114:25 160:16 161:22 170:22	position 9:23,23 15:12 17:22 19:17 25:15 34:24 45:3,13 46:4 48:23 61:6 226:8 266:25	practitioners 98:16
	PiHKAL's 169:14	positive 86:22 130:5,5 130:12 136:25 168:17 210:3,9,16 211:3,6 242:7 278:3,5	pre-clinical 110:5
	pill 216:20,22	positives 192:5 209:24 210:6	pre-registration 52:6
	Pls 250:4 255:11	possess 222:18	precedent 49:25
	place 78:24 79:1 124:7 243:22 244:5 275:2,5	possession 12:7,13 221:6	precipitate 268:3
	placed 28:24 29:16 30:2 68:13 74:14 199:20,21	possibility 18:21,21 19:9 210:15	preclinical 258:11,17 259:17 260:2,8,11,17 260:20 261:25 262:5 262:14 264:14 265:13
	Placement 1:5 4:5	possible 10:25 176:14 176:21 183:24 192:2 209:21,23 213:9 260:7 267:5 268:18	precursor 115:12 142:7
	places 169:11 227:10 227:15 228:2 229:8	possibly 234:7	predate 215:20
	placing 64:18 152:10	post 104:23 127:18,19 172:17,21 173:3,21 174:9	predecessor 37:4
	plainly 29:1	post-hearing 11:17 271:5	prefer 211:12
	plan 10:24	post-market 105:11 171:14	prehearing 15:24 16:7 18:4
	planning 41:6	postdoc 61:16 71:5	prepared 52:8
	Plant 5:7,8 9:1 14:14 24:14,16 25:3	postdoctoral 60:24,25 61:6,13 62:8	preparing 86:6
	play 41:21	posted 21:13 34:6 41:17 169:20 226:9	prescribed 199:1,4 217:9
	plea 67:23	posting 40:12 41:18	Prescribing 98:20
	please 6:23 26:22 31:1 31:8 34:11,22 38:6 42:19 49:2,2 53:11,18 57:3,6 58:13 73:16 78:16 79:24 83:2 91:14,15 93:1,16 136:13 137:22 138:25 159:1 176:19 177:17 177:18,25 190:1 212:3 277:4 279:25	postings 15:7	prescription 199:5,9
	Plenty 29:13	posts 169:17,23 170:6 170:9,10 171:10 172:6 173:6	presence 19:11
	plugged 154:12		
	plus 175:3		
phenethylamine 104:9 229:1,12 270:3	point 19:23 21:23 25:13 41:16 50:21 65:5,18		

present 2:20 5:25 6:13 9:20 11:2,4,8,9 17:19 19:19 22:25 25:23 251:24	process 13:22 15:3,19 36:20 49:17 72:3 79:3 124:3,16 152:20,23 179:2 180:19 215:18 247:10 252:14 253:21 259:19 276:13	253:1,5	publication 36:24 37:1 37:3 50:19 215:16
presentation 21:22 22:20 26:9	processes 65:6	prove 148:16	publications 65:18,19 70:23 149:13
presentations 57:17,25 58:2	processing 248:25	proved 148:20	publicly 72:9 155:7
presented 13:19 176:24	produce 63:1 100:24 103:18,25 104:25 117:23 145:5 146:6 150:10 192:15 193:15 196:7 215:22 268:19	provide 16:5 17:4 278:18	publish 33:18 72:19,21 120:10 132:17,18 240:21
presenting 20:21 175:12	products 113:2 191:12 196:18 255:20	provided 11:24 13:9 67:7 72:3 104:10 106:7 120:6,17 121:13 156:14 158:22 160:13,22 191:23 204:23 205:25 206:18 228:1 237:2	published 5:2 33:10,11 34:2 35:2 36:17 38:2 38:13 40:20 41:2 57:22 70:15 71:20 72:12,22 80:14,16,18 80:19,20,21 81:17 83:11,13,22,25 86:10 127:22 134:14 135:12 148:14 172:22 174:7 179:10,15,25 192:16 193:6,14 197:25 216:8 236:12,18 237:16 253:15,16 258:7
press 101:16,19 185:2 186:7 191:6	produces 150:8 159:14 186:13	providers 150:16	pull 165:15
presses 186:10,14	producing 27:14 193:2	provides 10:9	pulled 34:20 71:9,21 278:19
pressing 186:9,22 191:8	product 126:23 216:22 218:6,20	providing 47:13	pupils 135:17 137:4
Presumably 176:23	products 63:22 123:18 126:20 144:17 199:6	provision 64:17 67:3	purchase 163:21,24 164:5,9,11 199:9 224:4 227:12 256:21
presume 222:16	professional 56:25	psilocybin 27:16 57:22 62:14,18,22 65:25 66:2,5,8,11 124:11 168:22 189:18 194:22 195:25 274:22 275:15 277:20 278:2	purchased 99:3 224:8 254:19,20
presumptive 130:5	profile 142:13,15	psychedelic 29:13 62:22 117:24 136:23 258:2	purchases 224:6 225:18
pretty 192:14 204:6 238:10 257:15 264:11	profound 90:5	psychedelics 27:11,19 69:6 257:23 259:9	purchasing 164:1
prevent 29:20	program 152:16 153:5	psychic 27:14 139:15 139:25 140:11,22 141:5,6,16 146:15,17 265:21 269:1,4,14 270:13 271:10,18,23 272:3,5,10,11,14 273:9,15	purely 4:16 164:20
previous 6:21 22:10 32:9 35:6 37:9 74:25 156:21 157:9 163:20	project 56:22,23 74:20 246:5 253:2	psychoactive 159:15 160:18 240:8	purpose 34:18 35:15 40:22 48:8 67:15 85:21
previously 32:11 35:7 36:8 39:24 43:22 58:22 76:17 157:3 184:9 188:21 230:13	promulgated 182:6	psychological 90:4 101:1 103:20 110:19 140:1 159:15 189:3,5 189:10,12,15,18,21 190:2	purposes 29:22 38:7 77:16 78:3,4 119:8,20 164:12 183:7 226:19 257:4,6
primarily 28:25 45:22 134:19	prong 96:13,20 97:22 99:22 100:6	psychology 55:16 56:6 56:11 59:2,6,11	pursuant 1:13 4:20 5:1 5:4 6:5,10 68:12
primary 152:17	prongs 171:13	psychopharmacolog... 110:11,15 175:8	purview 46:2 47:1 48:16 256:2
primate 190:25	pronounce 137:14	Psychopharmacology 72:11 110:17	push 121:7
primates 101:13 258:13	pronounced 136:3	psychosis 276:9,10	pushing 112:13
print 278:21 279:4	proof 11:6 13:13 174:9 174:18	psychotic 27:15 201:12	put 11:6,10 21:25 22:3 23:24 26:10 77:15 86:24 87:3,4,5,23,24 114:10 117:6 120:8 126:8 131:2,9,9 156:7 170:2,3 180:13 200:8 215:12 225:9 232:25 237:6,19 243:22,23 244:5 245:17 279:1
prior 22:19 26:9 45:10 48:19 86:11 157:9 232:16	properties 114:6 160:10 198:20 199:15 231:8,12,19 232:2 258:2 262:5,23 263:2 274:6,13	Psychotropic 29:5 91:7	putting 18:10 207:21
priorities 87:17 167:21	propose 73:7	public 10:11 15:15 33:10 34:7 40:11 41:5 41:17,18 47:14,14 48:8,15,23 104:23 134:11,17 145:23 146:9,12 155:15 160:15 161:14 169:1	
private 149:17 246:13	proposed 3:11 5:2 12:8 12:14,25 13:3 23:6,7 23:8,10,12,16 35:1 36:16 38:14 40:4,6 41:3 64:20 83:14	public's 181:5	
probably 121:6 279:1	proposing 73:11		
problem 19:2 156:5,10 226:11 271:2	prosecuted 183:1,10		
problematic 274:21	prosecutes 182:15		
problems 28:12	prosecutions 163:2,7		
procedure 4:22 14:23 49:13,16 79:20 209:7 259:15	prospective 45:19		
procedures 13:22 15:4 15:19 208:25	protocol 211:17 245:24 246:8 247:13,13,18 247:25 249:1 250:17 250:24,24 253:6 268:2		
proceed 26:2 46:20 69:17 74:8 77:6 78:13	protocols 216:5 225:20		
proceeding 7:23 66:22 203:4			
proceedings 4:20 5:9 5:16,19,24 6:3,8 7:15 10:3,12,15,19 12:25 13:5,20 15:15 22:10			

Q	
qualifications 249:3	103:11 184:23,24,24
qualified 20:24 149:2	259:2
qualifier 207:5	Raul 2:14 5:18 8:18
qualifies 180:8	rave 135:14
qualify 59:19 248:22	raw 71:21
271:10	reach 106:4 144:7,13
qualities 200:7 201:22	247:24
262:24	reaching 74:14,18
Quantico 32:14 45:12	278:22
quantity 257:4	reaction 142:10
quarters 57:16	read 47:24 48:5,17
query 85:16	127:21 170:22 173:11
question 13:14 22:16	177:18 228:17 236:11
37:8 51:13 68:21	257:18 267:5 276:23
77:11 83:4,5 101:8	reading 277:3
146:7 157:16 174:18	ready 154:14,15
176:19 177:9 189:25	real 51:19 174:10,19
190:1 191:20 199:8	really 28:5,13 107:24
209:2,3 220:13 229:4	114:15 116:6 140:9
235:9 245:8,12	189:24 205:2 227:2
247:11 252:21 270:9	267:16 270:25 271:21
279:9	reason 50:2,3 100:15
questioning 252:3	198:16 244:7
questions 13:21 14:22	reasonable 100:3 178:6
15:3,19 26:1 44:14	194:17 260:19 272:12
51:5 52:15 55:11	reasons 16:16 140:16
252:24	167:20 208:14
quick 22:16 37:7 51:13	rebuttal 11:10 13:11
76:9 120:15	recall 46:5,13 55:25
quickly 51:19	129:6 175:23 179:13
quite 60:16	179:16 189:6 219:21
quota 255:22 256:4	219:24 257:2 258:13
quotas 255:24 256:12	269:25 270:4,19
256:16	278:10,12
quote 28:2 276:19	recaps 15:9
278:19	RECD 3:8
quoted 189:8	receive 9:4,15 11:16
quotes 114:22,23	33:16 37:2 38:1 40:10
R	
R-H-A-B-D-O-M-Y-O-...	40:25 42:1 101:15
136:15	180:25 191:2,7
radar 211:4,5	250:18
radioligand 107:23	received 9:1,6 36:5,10
radiotracer 57:23	38:3,4 39:21 40:1,21
raise 31:1 53:11	41:10,11,15 42:2,8
Ramos 2:14 5:18,23	43:3,20,24 44:7 48:24
6:17 8:18,21,24 11:7	58:19,24 70:2 74:20
16:8 17:15 22:5	76:14,19 80:6,8 82:14
Ramos' 12:14	82:16 85:3,5 93:8,10
range 56:10 264:11	122:22 139:7,9 186:7
ranging 107:20	242:4
rapid 135:25 137:13,16	receiving 48:20
142:3	receptor 89:17 99:15
rat 103:2,6 186:22	99:16 107:4,7 108:2
ratio 265:1	108:15 109:4 110:25
rats 101:12 102:19	111:5,14 112:2
	117:23 140:8 177:15
	192:15 194:16 200:13
	259:13 263:5 267:15
	receptors 62:5 89:9,12
	89:15 107:15 109:12
	259:7
	recess 10:22 76:24
	223:10 280:7
	recognize 34:15 38:10
	42:23 78:20 79:12
	91:16 138:7
	recognized 19:24
	150:23 227:17
	recollection 278:15
	recommend 244:2
	recommendation 74:22
	75:13 78:24 79:5 86:4
	93:23 94:10 105:24
	141:21 181:2 237:4
	recommendations
	128:17
	recommended 11:19
	11:21
	Recommending 98:18
	record 4:4,12,12 10:14
	12:2 13:5 31:10 36:6
	39:16,22 43:20 53:20
	58:13,20 75:25 76:15
	77:2,5 79:24 80:6
	82:2,4,14 85:3 93:1,8
	101:5 120:5 122:10
	122:18 136:13 138:25
	139:7 153:18,20,23
	223:13,16 270:16
	279:1,18,20 280:9
	recorded 86:10 167:25
	242:13
	recordings 10:16
	recordkeeping 52:8
	records 75:21 79:17
	81:24 84:5 91:19
	138:19
	recreational 163:22
	164:6,13 183:15
	200:4
	recreationally 99:4
	183:6 226:1 227:11
	recross 3:3 52:17
	redacted 41:25 47:23
	Reddit 127:18 170:10
	172:21 174:1 226:9
	redirect 3:3 51:9,11
	reduce 140:18
	reduced 263:10
	reduction 213:24
	refer 5:8,14,20 6:3,8
	181:23
	reference 207:16
	209:17 210:20 211:14
	211:23 216:21 229:17
	257:10,12,22 258:5
	referenced 39:15,17
	207:13
	referencing 212:1
	referred 19:21 27:18
	141:20 180:23
	referring 37:8 159:24
	180:5 248:10 262:13
	266:14 273:11 274:22
	275:23 278:9
	refers 219:19
	reflect 120:6 122:19
	138:21 168:25 245:11
	271:1
	reflex 111:9
	refresh 278:14
	regard 146:2 221:20
	244:14
	regarding 15:6 17:22
	21:20 24:3 68:3,6
	95:4 96:22 114:22
	117:20 118:4,9
	128:24 134:10 137:1
	138:22 142:21 144:5
	144:13,14,19,23
	145:1,13,14,15,22,23
	146:8,14,15 148:21
	151:2 172:13 194:25
	201:20 225:3 230:21
	235:9,11 246:18
	270:16
	regards 20:1 207:22
	232:1 270:12
	regime 208:16
	region 87:18 134:1
	Regional 133:25
	Register 5:3 33:9,14,15
	33:21,22,25 34:1 35:2
	35:11 36:15,18 37:22
	38:4,13,16,21,24 43:4
	80:15 83:12
	registrant 254:25
	registrants 45:19,20
	46:9 51:24 52:3,9
	registration 52:7
	246:12,16 247:16
	249:3 251:22 252:12
	253:18 254:4,13,21
	254:24 255:11
	registrations 153:8
	225:11 226:25 227:2
	227:4 244:25 245:1
	250:5
	regulate 92:16 150:24
	243:7
	regulations 33:6 51:23
	124:6 225:9 245:17
	246:3
	regulations.gov 41:14

regulatory 32:21,25 37:20 45:18 52:1	rephrase 199:8 220:12 228:15	requested 25:19 35:3 41:24	responds 191:1
reinforcer 101:16 185:3 185:3,20	replaced 37:23	requesting 4:17	response 19:15 44:4 49:18,19 94:2 108:17 108:20
reiterated 272:18	replacement 37:25	requests 5:4,21,23 40:7	responses 110:21
relate 132:20 251:11	report 24:24 94:23 95:2 95:6 100:16 101:4 117:6,10 121:13 129:1 132:10,25 133:6,9 136:19 159:2 174:6 205:2,4 208:11 209:13 210:13 212:25 213:12 219:25 240:15 240:16,21,23 241:25 242:16	require 10:1 49:17 191:14,21 200:8 248:8	responsibilities 33:14 51:16 52:9 63:5,10
related 16:17 47:5 59:11,11 61:20 66:4,8 66:14,21 75:1 86:8 90:11 94:18 99:23 117:15 127:22,24 132:19 141:7 147:24 148:14 149:20 151:24 175:19 178:1 218:8 218:21 225:11 228:5 236:12 240:21 242:19 257:24 258:22 261:16 262:23 267:15 274:24 277:22	reported 87:14 111:4 132:12 167:19 184:6 194:15 204:9 205:7 207:9,11 220:14 229:25 267:8 269:6 269:13	required 49:23 56:9,14 56:16,17 60:25 61:4 87:10,24 221:2 222:4 247:3 250:10 254:19	responsibility 33:18 51:2
relates 129:2 134:19 228:7	reportedly 135:21	requirements 247:2	responsible 33:8 34:3,5 34:9 41:18 47:13
relating 27:13 57:25 67:8 86:25 92:4 118:17 143:6,12 235:2 259:24 271:25	reporter 4:11 10:17 30:22,24 155:25 156:2	rescheduling 244:15	rest 176:8
relation 174:3	reporting 165:1 215:2 268:9	research 29:11 61:14 72:3 97:4,7 100:21 104:3 127:16,20 149:14 151:8,8 152:8 152:11 153:2,4 164:12 183:7 219:4,4 224:6,12 225:3 226:21 236:2,2,16,18 236:19 237:9,11,13 237:15,21 244:23 245:4,9,21,22 246:5,6 246:22 248:7 251:14 251:18,24 253:11,13 253:16 255:20 257:3 257:4,6,16,17,20 258:16,20 259:5,6 260:3,20,21 261:3,6,7 261:9,10,11,13,25 264:1,16 265:6 269:17	restate 73:15
relative 95:6,10 99:10 102:1 142:23 143:1 159:18 179:2,3 273:6	reports 64:25 88:1 98:25 103:14,17,20 103:24 104:12 114:17 116:20,23 127:15,21 128:5 130:17,20 134:14 146:4,13 155:18 161:18 167:23 169:8,10 174:22,23 174:25 192:6 204:5 204:22,25 206:2,16 207:25 210:4 212:11 212:24 213:25 214:1 214:2 215:12 229:23 230:13,15 241:19 269:23 270:1,1 271:12	researched 29:14 152:3	restating 15:10
released 135:20	representation 58:9	researcher 102:12 152:15,20 153:1,3,5,8 185:7 244:25 245:1 245:16 247:15 250:5 251:22 253:18 254:4 254:24 255:11 275:20	restrictions 15:6
relevant 94:10,13,14 207:22 251:18	representative 6:15 7:22 9:2 16:10 24:16 25:17 42:16	researchers 27:4 219:6 245:4 248:6 256:21 259:16 265:1	restroom 76:9
reliability 171:7	representatives 6:12 6:16 17:13	researching 62:14	rests 11:7
reliable 170:8 171:3 172:4	represented 23:12	reserve 10:6	result 242:4
relied 161:11 171:12 193:16 237:2,4	representing 8:12,17	reserving 22:17	results 71:11
rely 87:15 151:11 170:14 171:16	reproduced 147:25	residence 132:23	resume 202:2
relying 171:16 192:8 211:21	reproduced 147:20 148:3	residual 28:6	resumed 77:2 153:20 223:13 279:20
remain 16:20	republican 116:22	respect 68:1 86:1 91:10 107:18 109:9 110:20 112:21 134:12 140:5 140:23 150:4	retained 13:4
remember 21:3 176:3 242:16 256:25 258:8 270:24 277:18	request 5:6,11,17 16:21 16:24 17:5 20:15 30:14 69:13 77:11 120:15 249:16	respond 44:1,3,6 49:13 49:22 262:12	retract 263:8
remembering 270:25		responded 44:9	return 153:17
remind 77:5 153:24 214:3 215:11 223:17		Respondent's 21:25	review 13:5 33:19 47:18 47:20 66:9 72:13 117:8 128:21 134:24 152:21 155:18 169:16 170:9 171:17 172:9 209:22 210:5,13 211:18 215:18 232:16 232:19 270:16
remove 10:7 111:11		Respondents 22:3	reviewed 34:20 35:6 74:24 75:1 81:3 155:20 156:13 172:6 208:4 215:16 232:14 232:18 234:15 264:5
removing 239:24		responding 50:1 248:4	reviewing 41:22 71:17 106:19 170:6 179:6 248:17
renal 136:10			reviews 249:9
render 68:2 240:1 250:11			revisit 22:2
repeat 149:8 176:19 190:1			reward 185:19
repeated 141:13			rhabdomyolysis 135:18 136:6 137:6
repeatedly 139:18 140:3			rheumatoid 127:24,25 128:2 173:13

94:6 95:4,25 97:22	276:4 279:14	174:13 181:18 184:2	14:14 24:15,16 25:3
98:22 103:12 110:4	routine 132:17	184:4 186:20,24	55:16 56:20 59:14,17
115:13 118:7 119:19	routinely 170:9 236:11	189:9 193:1,4 197:11	132:16 215:13 216:7
121:9 123:13 124:24	rrush@rrushlaw.com	234:21 270:24,25	scientific 17:4 74:22
127:3 129:19 132:9	2:18	272:7 274:4,5	75:11 78:23 79:14
132:22 133:6,11	rule 10:15 25:24 38:22	says 18:17 24:7 40:4,13	80:17 86:10 94:9
134:10 137:18 139:14	41:2,16 44:5 49:19	63:4,14 94:8 99:5	95:12 97:7 106:15
142:5 148:19 153:22	67:3 251:23 253:14	103:23 107:20 112:15	118:9,14 123:16
154:7 157:24 161:1	ruled 251:14	117:13 130:22 155:2	127:21 141:22 143:4
161:18 163:18 164:12	rulemaking 3:11,13 5:2	156:17 158:7 161:3	143:9 144:6 149:6,11
165:19 169:8 170:13	33:2 34:9 35:1 36:16	162:12 181:12 202:14	149:18 172:7 173:11
170:24 172:14,18	38:14 40:4,6 41:1,4	202:20 220:19 228:23	193:3,6 205:23 209:4
174:23 175:14,25	43:2 49:4,5,17,20	249:17 267:4 268:18	230:21 231:5 235:11
177:3,13 178:18,19	79:19 83:14 85:23	270:19,24	235:16 236:10,12
179:18,20 180:2	Rulemakings 64:21	schedule 1:8 4:8 6:4,9	237:5,11 253:2
181:24 184:4 190:11	rules 18:12 67:4 78:7	27:19,20 28:24 29:16	257:17 259:5 267:8
193:9,24 200:22	120:24	30:2 46:6 50:12 57:20	scientifically 170:8
201:8,16 203:25	ruling 21:24 22:17	60:2 64:19 67:6,11	171:3
204:22 205:8 210:20	25:21 69:15	68:13 74:13 78:25	scientist 185:18
212:9,21 214:11,14	rulings 4:15	79:2 92:10,19 99:6,12	scissors 131:14
214:18 216:12 217:4	run 259:2	100:14,17 106:8	scope 46:17 129:13
217:15 219:7 221:5	Rush 2:15,16 8:16,17	109:13 118:2 134:16	145:14 202:11 225:24
222:2,18 226:21	8:17,22 9:14,18 15:18	144:9 146:25 147:8	226:15 228:4 244:18
227:12 228:10,17	15:20 16:11	151:25 152:5,10,15	251:10,23 254:15
230:3,7 233:23		152:19,23 153:4,7	256:17
234:13 235:1,12	S	174:4 182:12 195:24	Scott 37:17,18,19,23
238:5,8,12,18,22	sad 28:4	198:18,19 199:17,20	38:21
242:21 243:9,17	safe 27:3,5 30:7 60:19	199:21 201:14 204:14	screen 14:7,12 120:9
244:24 245:5 246:20	65:8 151:16 174:15	229:23,24 230:6	screen's 154:13
246:24 247:4 249:14	180:4 218:9 220:3	239:23 243:19,25	se 165:12
249:23 250:2 253:2	247:2	244:2,6,10,11,25	sealed 219:23
254:1,11 255:21	safes 220:5 246:24	245:1,2,3,15 246:6,10	search 119:3
256:5 258:16,17	safety 96:9 106:3,12	247:8,15 248:7	searchable 149:16
259:8 260:11 262:24	124:7 148:6,10 150:2	249:18 250:4 251:8	Seattle 32:12 45:9,10
265:24 266:15 267:2	150:13 151:13,14	252:8 253:18 254:3	second 5:11 15:23 16:7
267:19 268:23 269:19	158:10 159:10 178:11	254:24 255:10,19	18:12,14 23:4 37:21
270:23 271:3 272:21	218:7 259:24	256:4 257:13 264:1	50:25 69:9 96:20
274:1,6,10,11,14	sake 108:10	264:22 265:2 272:25	103:23 121:17 148:5
276:2 277:14 278:8	sale 97:10	scheduled 28:21 29:7	155:24 175:7,16
279:7	sales 164:17 167:15	34:1 45:25 94:12	228:17 265:14
risk 134:11 145:23	saline 101:18 102:20,21	108:5 199:16 217:9	Secretary 24:24 78:23
146:8,12	102:22 113:21 131:7	249:4 253:10 254:18	91:11
risks 134:17	231:22	256:19,20 264:18	section 12:1 32:5,20,22
Robert 2:15,16 8:17	salt 231:15,21,25 232:6	schedules 1:5 4:4	32:24 33:1,3,7 34:25
25:1	232:7,11 233:10,15	29:18 45:23 243:14	37:19,21 38:25 49:9
rodent 103:2,6 111:16	233:16,18,23 234:1,8	243:16,20,21,23	49:10 50:8 64:14,19
185:11 190:7,24	234:18,22	scheduling 27:7 29:10	75:17 114:3 138:15
195:23	sample 210:9,12	48:3,4 49:6 50:21	138:16 152:15 177:21
rodents 62:11 101:12	257:12	64:18 75:12 94:10	232:22 233:4 235:17
101:14 111:13 173:11	samples 130:23 208:13	141:21 200:9 201:6	237:1,2 241:20 256:1
189:22 190:3 258:9	satisfy 118:11,12	201:21,24 207:22	Section's 42:16
258:11 259:22	saturate 131:12	230:9 242:20	Sections 6:5,10
Roland 62:13 70:20	saturated 131:6	school 59:16 61:10	secure 246:24
71:5 157:19	save 131:24 132:1	70:12	security 10:6 52:8
role 35:12 48:9 65:13	saw 220:2	science 2:9 5:12,14	see 14:20 19:4,4,10
room 174:23 175:13	saying 140:13 151:17	20:10 55:24 56:13	61:23 64:25 78:16
242:8	160:23 161:12 168:24	59:24 63:22	87:21 91:25 101:25
route 115:16 231:9,14	170:15 171:11 173:7	sciences 5:7,8 9:1	107:1,2 111:10,15,15

111:17 112:15 116:18 119:16 120:14 121:5 127:18,21 128:5 129:4 130:14 138:5 141:23 149:4,25 157:15 159:4 168:11 170:15 172:21 174:12 187:12 200:1 209:17 211:6 221:18 254:16 seeing 280:6 seek 13:9 270:2 seeking 23:6 52:6 59:23 173:16,20 271:13 seeks 13:7 23:15 seemingly 103:19 104:14,18 181:16 seen 111:12 127:15 131:1,19 204:2 208:15 268:7,8 274:15 seize 220:6 222:5,11 seized 126:8 129:5 132:23 133:7 161:1 182:19 208:23 220:8 220:9 222:1,9,21 223:1,3 seizure 96:15 130:3 182:18 183:17 206:22 223:4 229:18,20 seizures 47:2 86:21 87:1 98:25 129:10 132:19 137:4 169:3 183:2 205:3 206:13 218:13 220:11 221:23 230:2,7 self 277:8 self-administered 191:11 195:18,21 196:1 self-administering 192:13 196:11 self-administration 190:16,19,22 191:13 191:16,18,21 192:1 192:16,21 193:1,5,15 194:2,6,14,25 195:2,6 196:3,7,13,19,23 197:2,8,17 198:8,11 262:10 267:19 self-selecting 185:21 self-selection 192:25 sell 224:5 225:8,17,22 225:25 227:18,19 selling 225:1 sells 224:11 send 11:22 210:10 sending 232:17	sends 155:12 sense 279:15 Sensible 2:9 5:13,15 45:1 sensory 134:21 sent 34:12 38:6 42:20 43:6 75:18 84:15 219:11 sentence 155:2 177:25 202:25 268:17 276:23 277:3 sentenced 67:10 sentencing 67:8 separate 80:21 131:16 September 55:5 63:19 64:8 sequester 16:9,12 18:25 sequestration 16:1,5 16:16 17:22 18:18 20:20 21:11,21,23,24 22:18 series 239:22 serious 146:6 150:6,10 serotonin 89:8,11,13 89:14,17 99:15,16 107:4,7 109:12 110:25 112:2 116:3 117:22 140:8 192:15 194:16 200:13 259:6 259:13 263:5 serve 35:12 40:23,24 67:1 served 50:7 66:23 67:2 serves 41:4 48:8 Services 79:5,8 serving 7:14,22 67:15 session 41:1 sessions 101:20 set 250:11 256:4 275:24 276:2,4 sets 71:8 setting 194:3 255:24 256:16 275:3,24 276:2,5 Seven 82:23 165:24,25 seventeen 166:25 shake 111:8,11,17 shakes 110:23 shaking 137:4 shape 25:5 shared 117:14 200:20 Shaw 65:23 shorter 10:23 shortly 122:18 shoulder 156:3 show 28:23 99:9 108:14 120:9 128:15 159:16	182:21 187:19 188:23 189:2,5 191:4,10 195:2 197:11,16 219:2 221:18 267:20 270:20 272:5,8,9,10 showed 137:6 278:13 showing 113:3,25 121:5 161:6 196:10 272:1,21 shown 25:15 57:4 160:9,14 196:22 198:7 shows 24:11 129:21,22 162:3 168:8 169:2 188:24 197:2 205:25 206:23,25 217:1 273:21 Shulgin 28:1,8 104:5,6 104:6,7 115:2 160:16 179:9,25 Shulgin's 114:24 shut 152:10 side 41:14 136:23 175:13 sidebar 13:16 sides 11:24 sign 33:24 signatories 8:14 signed 33:17 35:17 37:3,5,15 38:20,22 93:19 154:24 significance 123:5 126:16 129:14 145:15 145:18 202:12 203:3 203:9,19 204:12 215:1 228:10,19 significant 96:18 100:4 147:24 159:23 162:13 178:7,8 184:10,16 196:8 198:12,16 202:16,18,21 203:14 203:22 204:3,6,13 205:14,23,25 206:4,5 206:14,19,24 207:3,6 213:24 219:11 228:8 228:12,24 229:6,19 239:1 242:24 significantly 234:25 256:21 Silver 54:4,12 similar 27:22 67:10 88:23,24 89:3,5,20 99:6,13 100:9,19,22 101:25 102:13 106:10 108:5 109:13 110:1 111:9,19 114:1,7 117:19 118:3 128:11 134:18 141:3 143:22	143:24 144:2,8 145:6 146:4 147:7 150:8,9 151:22 170:19,20 186:24 187:10 188:24 189:9,19 194:22 224:15,16,17 239:7 256:24 272:2,11,25 273:5 similarities 99:19 similarity 106:7 118:1 134:16 182:22,23 simplification 238:11 simplify 102:10 simply 5:9 Simultaneous 279:11 single 70:25 87:10 162:1 197:1,15 198:6 209:22 sinus 135:16,25 sir 52:25 78:5,5 sit 22:7,11,12 situations 80:22 sixteen 166:23 sketch 123:2 slightly 83:24 small 104:13,14 109:16 123:9 131:8 159:22 238:13 239:22 240:4 smaller 108:1 smoked 218:11 snorted 218:11 snuff 208:17 so-called 18:7 19:21 Soeffing 1:16 4:3,10 7:13,17,21,25 8:7,11 8:15,20,23 9:8,12,17 9:19 12:7,24 14:3,9 14:11,16,20,22,25 15:14,18,21 17:7,10 17:20 19:13 20:17 21:9,14,18 22:21,24 23:3,21 25:11,20 26:5 26:10,13,16,19 30:9 30:16,21,25 31:8,14 31:20 35:25 36:3 37:13 39:8,11 43:14 43:17 44:15 46:18 47:9 51:7 52:16,20 53:1,4,8,11,18,23 54:11,15 58:14,17 68:16,20,22 69:7,16 73:10,14,20,25 76:1,4 76:10,12,20,23 77:4 77:21 78:1,3,8,10,13 79:25 80:3,10 82:5,8 82:11,18 84:11,22,25 85:7 93:2,5,12 119:12 120:3,5,11,14,18,25
---	---	---	--

121:16 122:13,17
 123:1 127:13 131:24
 136:12 137:24 139:1
 139:4,11 153:11,16
 153:22 154:6,10,15
 155:24 156:7 158:14
 158:17 171:8 202:3
 223:6,9,15,20 226:16
 226:23 228:13 244:19
 245:10 251:20 270:8
 270:18,23 278:20,25
 279:4,7,17,22
sold 29:25 88:6 226:21
 228:2
solubility 231:16,18
solubilize 231:22
solvent 131:7 231:23
 231:23
solvents 231:20
somebody 116:8
 140:16 161:25 174:10
 249:16 266:11
somebody's 242:14
somewhat 258:7
SOP 208:23
SOPs 208:1,4
sorry 23:17 37:7 54:16
 67:19 76:5 81:10
 115:23 142:3 143:14
 149:8 154:12 162:9
 235:18 272:8
sort 105:9 134:7 172:24
 259:20 261:11
sought 173:12
sound 148:17 179:18
sounds 73:20 179:20
source 225:19
South 2:17 8:19
spades 28:9
span 241:22
speak 29:14 49:6,8,11
 217:23
speaking 79:6 118:15
 132:21 170:8 171:3
 182:3 218:20 249:8
 259:18 265:9 279:11
special 69:4 73:18 74:2
 74:6 245:19
specialization 55:17
specializations 59:18
specialty 59:23
species 184:23 185:12
specific 22:7 34:9
 56:19 64:3 73:21
 86:20 89:17 111:5
 116:24 117:9 128:20
 129:9 151:18 157:13
 162:1,2,4 165:17

179:13 194:12,13
 200:13 203:6 205:18
 205:18 218:8 222:24
 229:11 242:16,18
 243:9 246:4,24
 253:13,19 254:19
 263:4 267:11
specifically 17:1 59:7
 60:1 62:15 72:17 73:6
 89:9 91:3 95:19
 110:22 111:21 129:6
 151:18 157:5 159:24
 164:1 165:7 173:7
 175:5 178:13 181:12
 181:24 182:9 190:4,6
 192:19,22 194:1,24
 194:24 195:11 203:2
 205:4,19 216:11
 220:25 221:17 224:3
 225:5 232:19 233:24
 246:23 249:8 251:14
 263:6 265:7 270:1
 278:12
specifics 243:5
Speculation 127:12
speculative 164:20
spell 31:9 53:19 136:13
spinal 109:21
spoke 187:24
spoken 251:16
Spring 54:5,12
Springfield 2:6 7:3,8,11
 54:12,13,15
Springs 2:11 8:9
SSDP 5:16,23 6:16 8:2
 8:4,12 11:7 12:13
 16:8
SSDP's 8:5
SSDP/Ramos' 9:23
staff 10:6 32:16
stage 49:19
stand 279:25 280:4
standard 87:16,17
 114:8 178:17 190:9
 192:11 195:8 197:3
 203:21 208:8,24
 209:7,16 211:14,23
 257:3,10 258:5
 259:15 261:20,23
standards 10:9 207:13
 207:16 208:7 209:4,6
 210:20
standing 154:5
standpoint 153:1
stands 86:14 124:17
start 55:6 106:25
 153:12 168:3 197:22
 225:7 259:19

started 59:7,10 62:12
 152:16 197:5 214:5
starting 32:13 202:9
 276:24
starts 217:18 276:23
state 24:24 31:8 53:18
 59:15 85:18,19 86:21
 87:18 90:20 100:13
 118:8 133:18 138:12
 144:6 208:15 213:7
 213:16 221:23 222:11
 230:20 235:10 246:2
 247:6,6 249:7,8
state-level 248:11
 249:5
state-to-state 207:18
stated 40:16 45:2 96:10
statement 9:21,22 11:3
 26:8,11,20 33:23
 117:18 126:11 150:5
 203:6 229:10,17
 272:19
statements 3:2 15:22
 18:5 26:2
states 1:1 18:13,14
 27:15 68:25 90:21
 92:12,18 123:20
 129:24 130:15,20
 147:10,12 205:12
 207:17,23 212:14
 213:2,4,14 242:21
 244:8,12 264:9
stating 9:2 229:5
statistic 70:10
statistics 70:5,11
stay 18:22
step 152:24 237:7
stepping 262:2
steps 74:17 184:20
 246:20 249:2 250:1
 260:4
stick 151:23 184:24
stimulant 175:10
stimulants 102:25
 103:1 175:14
stimulus 66:17 102:23
 112:5,8,11,16 113:1
 114:6
stipulated 67:23
stool 262:2
stop 68:17 116:3,9
 140:14 141:10 168:19
story 29:9 174:9,18
STP 27:18 110:1 122:8
straight 255:8 266:1
strange 30:3 134:22
stream 136:9
street 2:16 8:19 88:6

99:1 163:17 164:23
stretch 87:24
strictly 177:8 182:1
stringent 276:1
strong 112:18 117:24
 160:17
strongly 272:18
structurally 117:15
structure 88:22 119:3
 119:16 123:10 146:4
structured 150:8
structures 238:16
Students 2:9 5:12,14
 44:25
studies 72:20,21,23
 101:7,10,11,14 102:8
 102:12,17 107:8,9,11
 107:12,12,14 110:5,7
 110:7,10 112:6
 114:14 127:16 128:9
 145:4 148:6,10,16,20
 149:14 151:13 153:5
 153:6 158:2 184:19
 185:4 187:19 188:23
 189:2 191:13 192:3,9
 192:11 193:1 194:18
 195:23 196:2,10,22
 197:13,24 198:8
 218:7 233:13 236:6
 257:18,21 258:4,6
 259:17 260:1,11,15
 260:17 262:3,11,15
 262:22 263:1,12,17
 264:1 267:14,19
 268:6 269:17 272:5,8
 272:9,20 274:23,23
 275:2,5,16 276:1
study 111:1 124:3,6
 151:14 165:11,12,14
 165:20 184:21 185:24
 187:2 191:21 192:9
 193:6 194:5 196:6
 245:19,22 248:19,20
 249:13,14 258:23
 267:11,25 268:15
 276:15,16 278:1
studying 102:6 259:1
 264:21,22
stuff 28:7 170:3
subdue 116:8
subject 216:20 218:17
 218:25
subjective 62:19 189:3
 276:25 277:1
subjects 273:3
submission 124:5
submissions 47:2
 132:11,12 155:11

submit 11:20 22:19
25:19 33:24 37:6
40:15 67:21 172:11
248:1
submitted 23:5 35:3
38:24 40:7,18 47:15
47:19 67:3 87:10
125:8,9 155:11,21
210:5 245:20 247:10
265:12
subparagraph 159:5
162:10
subsection 162:8,9
subsequent 5:22
substance 45:25 60:3,5
66:20 67:11 74:12
87:25 94:12 96:7,18
97:23 98:1 99:24
100:1,17 118:9
123:12 134:2 140:2
142:6,7,9 148:25
152:1,6 162:14
163:12,15 168:17,19
170:23 178:2,4
182:12 197:21 200:17
209:11,14 217:2,3
221:7 222:5 226:5
230:22 235:11,25
239:2 242:7 247:4
249:18 253:9,19,24
255:18,20 256:4,5
262:9 274:20
substance's 95:6,10
106:15
substances 1:5 4:5,21
6:5,10 26:24,25 27:11
27:20,21 29:6 45:17
46:1,12,14 51:22,25
52:4,12 57:20 64:2
65:24 67:6 69:5 73:19
74:3,7,23 87:14 88:1
88:17,19,20 91:7 98:9
99:2,6,9,11,12 100:9
104:16 106:8,19
112:24 113:4 114:10
134:16 140:10 141:7
144:9 152:23 158:9
159:9 161:9 164:15
168:11,20,21,23
169:1 170:18 176:6
176:15,21 180:1
191:14 193:17 195:24
201:15 203:9 204:5,9
207:17 210:16 216:4
218:3 220:16 222:2
224:11 227:20 230:10
238:7 239:23,23
240:7,8 243:13

256:13 257:1,13
264:19,22 269:8
273:1 274:11 277:5
substances' 64:15
substantial 94:11 106:2
142:22,25 145:10
178:9
substantially 114:7
substitutable 197:12
substitute 14:2 23:6
65:12 102:25 113:6,9
113:11,16 186:6
187:9 196:21 198:6
substituted 66:1
102:23 103:10 112:24
113:12,20,22 186:15
substitutes 197:16
substitution 23:20
113:3,4,13,15,25
123:9
subtle 28:10
suffering 177:7
sufficient 89:18 96:8
107:5 151:15 158:9
159:9,12,18 160:8
161:9,13,23
sugar 185:4 186:11
suggest 98:13 103:24
128:13 134:8 144:17
218:21
suggesting 111:4
suggests 217:25
Suite 2:17 8:19
summarize 61:15 62:8
63:5,10 64:10 66:25
74:17
summary 63:4,9 129:23
138:10 203:5 229:10
supervision 150:3,14
supervisor 65:14
suppliers 254:19
supply 29:22
support 32:22 33:1
37:20 48:3 64:16
145:5
suppose 171:23 220:18
259:3
supposed 118:11 243:8
suppressant 199:2
sure 19:6 61:16 83:18
120:18 132:3 157:21
176:11 178:14 187:21
191:24 201:23 203:18
215:20 220:4 224:22
225:23 227:16 228:14
230:16 232:8,13
233:1,5 236:8 238:13
248:10 250:4,22

252:20 253:6 259:3
260:14 261:22 262:6
265:25 273:11 274:2
274:25 278:16
surrebuttal 11:12
surveillance 105:11
171:14
survey 70:19,25 71:16
71:19 278:1
surveys 71:25 72:1,4,8
suspected 215:14
sustain 47:9 226:16,24
228:13,15
Sustained 127:13
244:19
Sweden 129:10
swim 262:18
sworn 31:6 53:16
symptom 137:9
synthesized 115:4,7,10
118:25 180:5 181:4
254:23
synthetic 88:21
system 29:19,20,24
30:6 34:3,4,21 41:13
42:3 43:4 75:21 77:13
77:19 79:17 81:24
84:5 86:16,19,23
90:11 91:18 97:18
102:5 109:17,20,21
109:24 110:18 200:12
208:10
System-Drug 85:15
systems 138:18 259:22
266:9

T

T 2:15,16
T-A-C-H-Y-P-N-E-A
137:10
T-H-E-R-E-S-A 53:21
T.J 2:22
table 7:18 8:12 154:4
tablet 126:15 130:23
134:7
tablets 126:21
tachycardia 135:16,25
137:5
Tachypnea 137:15
take 23:1 65:17 70:6
76:9,21,24 81:14
84:20 104:17 105:2
120:21 131:14 137:22
139:18 140:16 162:7
165:3 177:16 182:20
183:17 185:15 194:3
202:8 212:2 218:4
223:7,10 237:6 241:7

247:21 265:20 269:21
269:22,24 270:5
271:8,21
taken 70:4 91:10 109:5
134:24 135:14 137:7
140:20 199:11 225:14
246:20
takes 88:9 161:25 247:8
269:18,18
talk 15:2 24:3 57:19
60:23 61:12 116:5
123:13 125:16 147:9
175:6 207:15 215:9
280:1
talked 15:16 74:10
100:12 115:24 132:11
137:21
talking 72:5,6 101:6
112:4,12 149:19
179:11 197:7 200:11
200:12 209:17 226:25
227:1,1 235:23,23
251:6 273:15 278:8
talks 94:12
Tanner 17:14
tapentadol 67:8
tasked 45:15 118:10
TC 122:3
team 270:11
technical 16:17 20:8
technically 59:14 280:4
techniques 210:25
technology 4:25
televise 10:14
tell 32:23 64:13 67:12
67:13 91:21 94:14
102:12,17 107:21
143:21,24 144:2
165:9 212:23 213:2
221:15 223:1,2
227:22 228:2 229:9
245:14 278:20
telling 108:4
temporal 180:11,15
181:17
ten 166:11 186:10
ten-year 241:22
tend 168:2
Tennessee 212:18
term 86:13 88:2 102:2
110:6 113:6 116:11
136:2,5,13 228:11
terms 19:11 22:3 58:2
63:2 65:8 88:22 89:6
110:21 115:14 118:18
140:5 169:1 261:25
test 28:20,23 74:12
81:4 87:20 88:6,14

96:13,20 99:23 105:7 111:20 147:17,19 148:5 189:12 194:8 204:18 208:13 209:14 209:15,22 210:12,23 210:23 211:4,5 267:10	theory 123:8 225:18 226:2 235:24 therapeutic 261:12 274:24 275:8,11 therapy 116:5 Theresa 2:21 3:6 7:19 53:7,14,21 69:3 thing 15:11 111:17 136:24 140:9 173:16 266:14 267:6 274:14 things 15:1 132:8 149:15 187:11,16 189:15 191:17 207:14 208:22 235:20 240:3 240:14 245:23 246:1 259:5 269:11,13 275:4 276:12 think 18:23 20:1,2,7,14 20:22 21:1,5 72:15,19 105:1,2 107:10 111:6 136:3 150:1 153:14 154:8,8 155:9 159:14 159:21 165:3 175:16 176:16 180:16 196:2 203:15 206:19 207:4 207:7,21 211:4 213:11 219:2 227:3 235:8 245:8 247:14 251:20,22 252:13,22 253:3 258:12 267:1 269:21 270:12 271:15 275:1,11 279:12,14 thinks 200:16 third 5:17 71:2 97:22 148:15 150:1 155:1 276:24 thirteen 166:17 thoroughly 150:12 thought 173:17 thousand 166:7,9,11,13 166:15,17,19,21,23 166:25 167:2,4 three 5:4 28:5 61:7,11 63:3,3 75:14 102:22 102:24 122:1 133:11 135:12 146:23 166:2 166:14,16 172:25 173:8 174:6 239:14 239:16 247:14,17 248:24 251:3,12 252:22 259:25 260:10 260:16 three-dimensional 238:8 three-part 28:23 74:12 tied 186:9 205:21 ties 267:18 time 10:20,22 23:15,25	25:23,25 28:6 30:5 36:15 41:2 45:12 50:15 59:8 60:17 61:19 63:18,25 67:23 67:25 76:21 80:20 101:23 118:15 134:24 152:17 162:5 170:17 176:3,14,22 180:12 181:2 184:25 186:11 187:15,15 191:7,10 200:2 205:22 211:15 213:10 215:7,21 223:7 227:13 247:21 250:11 252:19 255:7 258:15 260:12,13 264:18 268:1 timeline 248:5 timelines 250:15 timely 23:8 times 161:25 191:9 192:17 193:14 205:6 219:8 221:13,24 268:1 title 32:19 54:24 203:10 277:18,23 TM 66:2 Tobacco 63:22 today 14:15 17:6,18 26:9 64:22 77:25 120:16 168:15 169:12 188:6 198:23 200:1 278:23 279:24,25 today's 4:9 203:3 token 27:2 told 121:3 250:17 tolerance 142:4 266:6 267:14 tomorrow 278:21 279:5 279:9,16 280:2,7 tongue 131:9 top 63:4 92:6 169:21 179:17 196:25 215:8 224:22 248:24 263:15 top-down 65:21 total 206:12 212:11,23 213:8 214:2 229:13 totality 155:9 204:4 205:17 206:10,15 207:8 229:12,15 250:18,25 264:6 271:24 toxicity 136:11 toxicological 135:22 toxicologist 176:12 toxicology 241:12 track 33:20 tracking 40:10 traditional 61:4	trafficked 229:8 trafficking 202:16,21 203:22 205:14 206:1 206:24 228:8,10,12 228:14,25 229:7 train 185:2 trained 102:19 103:11 112:9,23,25 113:19 113:21 186:12 187:14 training 32:14 60:24 61:6,13 62:8 70:3,14 70:20 73:1 tramadol 67:10 transcribed 4:13 transcript 11:16,17 245:10 270:20 271:1 transfected 107:15 transferred 32:15 34:8 254:25 transferring 255:7 translates 107:13 transmittals 37:2 transmitted 42:15 traveled 185:1 treat 128:1 173:13 treating 262:8,16 263:13 treatment 61:21,24 116:1 123:22 262:1 treaty 29:6 65:6 91:1,13 92:15,23 242:25 243:2,4,10 244:14 tremors 266:13 trends 57:25 87:7 129:17 trial 62:17 125:21 149:25 170:12 trials 98:13 124:8 148:13,23 149:3,21 272:23 275:17 tribunal 8:25 10:6,8 15:25 16:3 23:14 74:4 tribunal's 6:20 tried 267:10 trip 116:12,16 true 29:12 35:8,19 39:3 43:8 149:4 172:19 178:12 194:25 210:1 238:24 250:22 256:18 try 116:9 151:23 268:3 trying 99:7 171:21 174:4 229:5 254:12 268:8,10 tryptamine 104:10 196:18 tryptamines 66:1 Tuesday 1:10 turn 15:1 119:5 162:7
---	--	---	---

239:22
turned 10:2 133:4
 173:18
turning 14:3 15:22
twelve 166:10,15
twenty 167:6,6,8,10,12
twenty-one 167:8
twenty-three 167:12
twenty-two 167:10
two 24:25 36:18 37:21
 56:18 60:1 61:8 62:21
 63:8,14 75:7 80:21
 83:15 100:18 104:8
 115:3 116:21 132:11
 136:17 147:13 166:7
 166:8,9,11,13,15,17
 166:19,21,22,23,25
 167:2,4 172:25 173:8
 174:6 176:15 177:19
 177:23 184:8 197:10
 203:9 204:5 205:9
 206:14 234:24 259:25
 265:25 267:1,3
 275:11 276:18,20
two-dimensional 238:4
two-page 138:5
type 56:8,9 110:13
 168:11 185:24 224:10
 224:15 245:18 248:7
 248:13 255:6 263:21
 276:16
types 109:12 219:5
 225:2 263:25
typically 39:11,13 217:6

U

U.N 241:5,22 243:4,14
 243:16 244:1,11
U.N.'s 241:11 242:23
 243:20
U.S 150:16 183:3
 202:15 228:24
Uh-hum 51:15
ultimate 11:22
ultimately 260:21,23
UN 29:6 65:5 91:1,2,13
unable 9:3
unclear 18:3
uncontrolled 168:6
 257:12
under-reported 168:7
undergoing 253:21
 275:15
undergrad 70:8,9
understand 20:8 24:12
 31:18 171:15 205:6
 250:1 252:20 258:21
 274:3

understanding 20:12
 79:3 88:9 98:2 127:10
 130:1 149:10,12
 152:22,25 155:12
 156:12 179:24 181:7
 201:19 210:17 218:1
 254:6 256:10 259:4
 259:23 263:3
unethical 170:11
 174:14
unfair 238:14
United 1:1 18:13,14
 68:25 90:20 91:5,11
 92:12,18 123:19
 129:11,24 147:10,12
 240:19 242:21 244:8
 244:12 264:9
universities 246:13
university 55:21,23
 59:18 61:8,10,14 63:6
 220:1
university's 248:19
unlawful 29:21
UNODC 91:24
unpleasant 116:15
unresponsive 135:16
unscheduled 247:4
 253:9 256:19
update 33:5
updated 23:12 57:15
 83:23 85:16 212:20
 213:12 238:2
updates 57:14
usage 230:2,11,15
USC 6:5,10 28:18 68:12
 86:2 146:23
use 29:1 36:7 39:23
 43:21 58:21 61:20
 68:25 70:18,19,19,21
 76:16 78:9 80:10
 82:18 85:7 87:6 88:2
 88:4 93:12 96:25 97:1
 99:4 101:14,14
 105:18 107:23 110:10
 112:7 118:17 123:14
 123:15 125:23 128:4
 128:12 132:6 134:9
 139:11 140:2 144:14
 144:20 147:10,11,18
 150:3,6,12,13,17,23
 151:16,21 162:1,5
 163:22 164:6 172:23
 178:8,22 179:5
 180:20,21 182:24
 183:15 189:4 199:19
 200:3 211:1,5 218:1
 218:22 225:25 227:11
 235:19 238:2 241:16

241:20 244:3 258:4
 262:15 263:13 266:4
 269:5,7 270:21
 273:19 274:4,8,9
useful 27:3,5 126:22
 275:14
user 105:4 106:3,12
 178:10
users 165:17 169:24
uses 28:14 105:10
 123:21 149:10 188:12
usual 87:13
usually 44:1 91:24
 94:15,16 95:9 126:19
 134:6 140:20 142:1
 151:8 182:17 187:8
 191:6 209:14 216:21
 217:25 235:17 246:13
 248:12,13 261:11
 266:3,5 267:24
utility 98:14

V

v 18:15 45:23 199:21
 244:2,12
VA 2:6
valid 193:2,5,8,13 194:8
validate 209:18
validated 37:5
validity 189:24
value 260:21 261:1,24
values 108:1
varies 168:13 203:15
 207:12,18 247:13
 250:23
variety 45:17 277:6
various 67:4 74:16
 126:15 211:7
vary 117:24 130:2
 167:20 185:8 231:10
 247:22 249:7
varying 101:25
vastly 239:8
Vegas 2:12 8:9
veracity 171:10 172:13
verify 171:10 173:23
version 23:11 233:16
versus 67:8 102:20,20
 233:18 239:16 250:24
video-conference
 4:24
view 28:4 33:10 34:7
 41:17,19 118:10
viewable 40:14
violating 15:13
violation 226:3,6
violent 90:17 201:10
 277:7

Virginia 1:12 5:1 6:14
 7:4,8,12
virtually 14:8 24:17
 25:6
visual 103:19,25
visuals 28:11
vitae 57:12
vitro 107:11,11 259:20
vivo 102:2
voir 69:13,21 73:4
volition 98:6 185:15
volume 38:15
voluntary 86:23 87:4,5
 87:9 167:18 183:25
 204:8 208:10 221:4
vote 91:25 92:2 243:6
voted 91:12
VTC 4:25 6:20 14:12
 16:4,4,24 20:3 22:7,9
 22:13 30:15

W

W 2:3
wait 252:19
waiting 253:11
waive 25:9
waived 24:6,9 25:7
 246:12
walk 28:19,22 156:20
walked 220:1
want 14:18 22:1,24
 23:24 55:10 68:17
 77:8 82:5 84:19
 104:25 120:22 126:10
 137:20 146:22 154:12
 172:17 182:20 198:3
 225:7 227:11 240:13
 265:25 271:8,21
 279:9
wanted 14:2 15:11
 23:18 24:3 183:17
 224:1 230:18,22
 245:15
wants 22:13 131:25
 185:8
Washington 24:24 45:9
wasn't 219:22 237:9
watch 18:22 20:16
watching 18:7 19:3
 20:3
water 111:11
way 25:4 92:16 103:7
 108:13 110:12 121:7
 121:8 131:4,11 148:1
 161:15 163:23 171:9
 188:9 190:18 193:19
 214:21 220:17 221:13
 226:14 227:9 244:17

267:20,21 269:5
270:19
ways 116:9 147:13
164:24 190:13 211:25
255:3 267:22
we'll 20:4 23:23 84:20
120:18,25 121:8
122:17 202:2 240:11
244:20 252:22
we're 20:2 41:23 64:21
78:6 86:17 112:4
153:22 158:14,20,20
162:25 165:14 179:6
200:12 202:6 203:23
209:16 247:14 266:14
270:10,14,15 274:11
278:22 279:7,14
280:7
we've 74:10,11,16
86:13 101:2 137:21
198:2 226:10,25
240:12
website 40:9 71:9
225:19 256:24
websites 164:8,14
224:7 227:17,18
week 17:18,19 23:5
252:12
weekends 41:20
weighs 184:15
weight 114:10 232:9,11
232:20 233:10,11,15
233:18,19 234:6,9,9
234:19,22 251:25
weight-loss 61:18
weights 234:5
welcome 8:24 22:14
154:17
well-controlled 275:3
well-established 187:2
well-known 141:5
went 74:25 77:2 153:20
223:13 249:23 264:12
279:20 280:9
weren't 176:6,9 213:13
213:21
West 134:1
Western 133:19
wet 110:23 111:7,16
white 132:22 134:3
Wi-Fi 77:12,15
wide 264:11
widely 149:6,11,23,25
181:6
widespread 150:17
willing 140:2
willingly 141:1
willingness 139:18

Wisconsin 133:8 166:3
212:19
withdrawal 139:21,23
140:13,14,21 266:6
268:3,4
withdrawn 83:21
witness 3:3 7:20 16:9
19:5 20:13 30:11,23
31:11,19 37:11 51:6
52:25 53:2,3,5,21
54:13,16 57:3 59:3
68:18 69:1,13,20
73:16 74:5 78:16
91:14 119:14 120:12
121:18 123:3 135:2
136:14 153:10 154:20
156:16 158:17,23
171:6,12 202:13
223:19 228:21 279:25
witnesses 6:18 10:10
14:12 16:1,3,6,17,22
17:23 18:2,19,22
19:12 20:20 22:9
26:14 251:24
word 27:11 33:23,24
62:1 108:11 112:7
words 27:24 109:1
190:10 230:10
work 49:9 62:6 63:6,11
63:14,16 64:2 65:2
70:23 77:24 89:8,11
140:7 152:21 157:9
158:21 177:15 190:22
192:15 194:15 195:6
196:14 243:2 249:20
255:3 258:21 259:5
worked 45:3 49:7 65:4
67:25 255:11
working 61:22 62:12
65:6,12,22 70:17,20
152:23 157:22 180:1
247:6 253:8 254:3
255:16
works 25:2 28:15 79:4
263:3
world 117:4 128:17
238:8
worms 258:12
worst 71:1
Worth 55:24
wouldn't 48:2,18
165:13 194:17 197:18
199:20 226:6 233:9
245:3 249:5 261:5
268:14,22
wow 239:6
wrap 227:5
write 67:20 104:24,25

246:19
writes 233:4
writing 9:22 104:19
written 23:1 64:20
128:21 202:20
wrong 27:1 234:18
wrote 28:8 66:9 75:10
75:17 94:23 104:8
105:18 132:22 134:19
134:25 171:22 232:15
246:7 277:11
www.regulations.gov
40:9

X

Y

yeah 72:7,7 78:6 109:2
116:21 120:1,25
122:17 140:15 156:2
156:6 158:14 174:17
182:16 190:23 227:6
244:10 261:2 271:2,4
year 32:18 56:23 65:5
67:7 138:13 165:10
165:25 206:14 214:3
258:8
years 56:18 61:7,11
181:4 183:21 188:13
206:6,9,13,23 213:25
236:20,25 237:14
yes-or-no 174:17 177:8
189:25 191:19,25
yield 239:12

Z

zero 167:5 206:5
210:15 214:18,21
256:4
zeros 214:21
Zhang 66:12
zoom 121:6,7

0

1

1 3:11 12:2,5,8,11,14,19
34:13 35:24 36:4,6,9
39:13 78:20 95:4
138:11 142:21 147:19
1-3 159:21
1-5 3:18
1-71 3:9
1:15 153:17
1:27 153:21
10 128:23 129:19 202:9
212:5 228:18
10:26 77:2

10:45 77:3
100907 111:2
11 132:10
11:59 40:21
12 1:10 3:9,11,11,12,13
3:14,14,15,15,16,16
3:18,18,19,19,20,20
3:21,21,22,22,23
265:20
12:12 153:20
12:30 10:24
123431-31-2 231:2
128 18:16
12th 4:9 35:5,17 40:20
40:21
13 3:12 5:3 12:15,20
1301.43(d) 24:7
1316.59(f) 12:1
139 3:16
13th 35:1 36:16 37:11
38:2,15 40:19
144 3:6
15 18:1 79:12 80:25
223:10
15-minute 76:24
151 35:9
152 48:1
16 12:15,20 116:14
128:24 241:23 242:12
16-22 3:19
16s 67:4
17 89:15
17th 2:16 8:18
18-year-old 137:2
1917 2:11 8:9
1971 29:5 91:6 92:10,17
1991 179:21 180:6
181:5
1995 18:13

2

2 3:11 35:7 38:8 39:7,12
39:20,22,25 79:11
80:24 92:3 106:15
114:3 138:11 143:6
143:15 178:24
2,5-4-bromoampheta...
89:2
2,5-dimethoxy-4- 1:6,7
2,5-dimethoxy-4-chlo...
4:7 6:7 27:9
2,5-dimethoxy-4-iodo...
4:6 6:2 27:8
2,5-dimethoxy-4-met...
88:25
20 56:2 62:17 206:13,23
252:14
20-year-old 135:13

2004 134:25
2005 130:17 165:10,21
 220:12
2006 56:2 132:13
 165:23
2007 133:8 166:5
2008 241:23
201 2:18
2012 32:8 56:4 60:21
2013 32:13 45:9
2014 136:19
2016 214:18
2017 63:19 214:16
 241:23
2018 55:5 63:19 64:8
 214:13
2019 167:23 205:13,25
 206:2 214:5,10
2020 214:6 215:3,4,4
2021 23:11 32:17 45:9
 50:10 81:20 82:25
 83:1,16,19 212:9
 213:14,22,25 215:4
2022 50:13 83:20
2023 3:12 5:3 23:12
 36:16 37:11 38:15
 39:1 83:3,7,17,23,23
 205:25 212:24 213:15
 213:22 214:1,8 236:3
2024 1:10 4:9 5:8,13,18
 10:5 15:24 35:17
 167:23
21 6:5,10 12:1 28:18
 68:12 86:2 146:23
22 12:15,20 135:19
22152 2:6 7:4,8,12
2252 54:5
23rd 5:13,18
24 12:15,20 28:14
 115:15
24-24 1:6 4:8
24-26 3:19
26 3:2 12:15,20
2600 8:19
28 3:20 12:15,20
2800 2:17
2A 89:9,18 99:15,16
 107:4,7 109:12
 110:25 111:5,13
 112:2 116:3 117:22
 140:8 177:15 192:15
 194:16 196:14 200:13
 258:1 259:13 263:5
 267:15
2C 239:22

3
3 3:12 42:21 43:13,18

43:20,23 95:5 96:1
 118:8,13 143:12
 144:5,13 159:1,3
 230:20,20 235:10
 236:5 240:10 275:15
3.5 107:21
3:03 223:13
3:25 223:14
30 116:15 188:13
300 246:15
30th 15:24
31 3:5
32 3:20 12:15,20
321.16 232:10 233:10
33 3:20 12:16,21 107:21
35 12:16,21 75:14
35-42 3:20
36 3:11
362-7908 2:7
37-year-old 136:20
39 3:11

4

4 3:13 10:5 18:17 57:6
 58:12,18,20,24
 125:17,18 162:7
 177:17 240:12
4:53 279:20
4:54 279:21 280:9
40 130:17 206:12
 220:11
42 12:16,21
42203-78-1 230:23
425-5129 2:13
43 3:12
44 3:5
46 3:21 12:16,21
48 41:19
49 12:16,21
49-55 3:21

5

5 3:14 12:14,19 75:5,8
 75:15,24 76:13,15,19
 103:22 107:20 129:13
 145:13 149:10 178:24
 202:8,11 203:10
 228:19
5-methoxy-DMT 124:12
5:00 10:21 279:8,23
50 181:4 257:6,7
505 2:13
51 3:5
54 3:6
55 12:16,21
57 3:22 12:16,21
571 2:7
58 3:13

6

6 3:14 78:18,21 79:23
 80:4,6,9 93:16,18
 134:10 145:22 154:19
 158:15,18 205:2
60 18:16
600 2:16 8:18 54:9
61 12:16,21
61-71 3:22

7

7 3:15 12:11 14:2 23:8
 23:11,16 81:12,15
 82:3,12,14,17,22
 85:11 112:4 139:14
 146:14 158:12 212:3
 212:8 265:19 267:2
700 1:11
70s 187:2
71 12:3,5,17,22
72 41:19
73 12:17,22
73-87 3:23
759-1493 2:18
76 3:14
790 130:19
7A 3:15 12:11 14:2 23:7
 23:13,16 81:9 83:2,6
 84:1,9 85:1,3,6,12,22
 85:25 86:7 94:21
 112:4 119:6 122:12
 122:20,23,25 128:23
 158:12,22 177:17
 184:8 202:10 212:3
 212:21 228:18 230:20
 238:2 265:20 276:19

8

8 3:16 5:7 12:11,14,19
 114:22 137:23,25
 138:2,25 139:5,7,10
 142:5 165:4 230:19
8-13 3:18
80 3:14
800 204:5
80202 2:17
80s 187:2
811 6:5,10
811(c) 28:18 86:2
812 150:2
812(b) 68:12 146:23
812(b)(1) 6:6,11 28:23
82 3:15
85 3:15
87 12:17,22
870 7:7
8701 2:6 7:2,7,11 54:4
87701 2:12 8:10

9

9 3:16 12:8,12 91:15
 93:1,6,8,11 119:5
 122:24 123:1
9:00 1:13 10:20 280:7
9:02 4:2
90s 179:19
93 3:16

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Before: US Drug Enforcement Administration

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