

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 19, 2024

700 Army Navy Drive
Arlington, Virginia

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

BEFORE: THE HONORABLE PAUL E. SOEFFING,
Administrative Law Judge

APPEARANCES:

On Behalf of the Government:

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ALSO PRESENT:

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

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

2 (9:04 a.m.)

3 JUDGE SOEFFING: We are back on the
4 record.

5 Good morning, everyone.

6 Mr. Mann, is the Government ready to
7 make its closing statement?

8 MR. MANN: We are, Your Honor.

9 JUDGE SOEFFING: You may proceed.

10 CLOSING STATEMENT ON BEHALF

11 OF THE GOVERNMENT

12 MR. MANN: Thank you.

13 May it please the Court, Your Honor,
14 we spent six days now presenting what appears to
15 be a very complicated case full of confusing
16 scientific terminology.

17 But in truth, this scheduling matter
18 is quite simple: DOI and DOC are powerful and
19 potent hallucinogens. They produce profound
20 effects that last for hours, sometimes as long as
21 36 hours.

22 They fully substitute for other
23 hallucinogens such as DOM, also known as STP;
24 DOB; and, of course, LSD. And we all know the
25 horrors of LSD.

1 They fully substitute for these
2 controlled drugs and, as a result, they must be
3 placed in one of the five schedules. Because
4 they have no currently acceptable medical use --
5 I'm sorry, because they have no currently
6 accepted medical use, they can only be placed in
7 Schedule I.

8 In my opening statement I quoted from
9 the man who synthesized DOI and DOC because he
10 actually took it himself. Now I'm going to quote
11 from two of the people who made up much of the
12 Petitioners' case, Dr. Alaina Jaster and Dr. de
13 la Fuente Revenga.

14 First, Dr. de la Fuente Revenga:

15 Psychedelics such as DOI are
16 psychoactive compounds that profoundly affect
17 various mental domains, particularly sensory
18 perception and thought processes.

19 Dr. Jaster:

20 Classical psychedelics such as LSD and
21 DOI have been recognized for their capacity to
22 profoundly disregulate various mental domains,
23 particularly sensory perception and thought
24 processes.

25 Sound similar?

1 Just like these drugs substitute for
2 other controlled substances, these experts say
3 almost the same thing. And these were the people
4 who adamantly got up here and told you this
5 scheduling action has no merit.

6 Dr. de la Fuente Revenga:

7 Their acute abuse potential precludes
8 the routine use of daily -- in daily clinical
9 practice.

10 Dr. Jaster:

11 Even with the growing evidence for
12 their therapeutic potential, the behavioral
13 disruptive effects associated with the use of
14 these drugs may limit their future success in
15 clinical practice.

16 The similarity is eerie.

17 And once again Dr. Jaster:

18 The commonly reported subjective
19 effects of psychedelics include visual
20 hallucinations, euphoria, loss of sense of self.
21 They were noted to produce effects similar to
22 symptoms reported in schizophrenia patients.

23 Reading these words, the Government
24 finds it incredible that these people took the
25 position they took. Dr. Jaster said DOI was

1 perfectly safe, yet, at the same time,
2 acknowledged that it could cause harm. She
3 denied the term "bad trip" and refused to equate
4 it with suffering.

5 Look at Government Exhibit 17. It
6 tells you all you need to know about that.

7 Dr. de la Fuente Revenga told you that
8 no one is using DOI, no one ever will. I don't
9 know how he knows that. He didn't read any of
10 the DEA Bulletins, didn't listen to the
11 Government's case, and he wouldn't even
12 acknowledge the simple fact that a drug
13 administered on blotter paper may be indicative
14 of abuse.

15 He even disowned parts of his own
16 article in order to prove his point, putting his
17 entire professional credibility on the line
18 because why? Because controlling DOI and DOC
19 might result in him having to complete an
20 application and send a protocol to DEA so he can
21 continue his work?

22 Well, the Petitioners' witnesses
23 should have done the work to refute the
24 Government's analysis of the Eight Factor Test.
25 Not a single one did. They might have picked at

1 the methodology, which we've shown is used and
2 approved by FDA.

3 Dr. Jaster pulled a page out of a long
4 paper out of context to confuse you, claiming she
5 could produce that and nothing else.

6 Dr. de la Fuente Revenga attacked the
7 idea of drug discrimination. But when -- he had
8 very little to say when I asked him about his own
9 article, which stated that drug discrimination
10 can be used to analyze the effects of
11 psychedelics.

12 Drs. Cameron and Elder told you that
13 drug discrimination tests that DEA relied on were
14 inadequate. Yet, they offered no tests of their
15 own, no results, no studies to refute the fact
16 that DOI and DOC are so similar to LSD, DOM, and
17 DOB that their similarities cannot be ignored.

18 Drs. Elder and Palamar both tried to
19 convince you that online posts about DOI use are
20 fake. Yet, both admitted they use online posts
21 in their own research.

22 The point is, pick at it all you want,
23 none of these Petitioners' witnesses did a
24 complete analysis. The only person who did the
25 actual work in this entire matter is Dr.

1 Carbonaro who, without hesitation, defended her
2 Eight Factor Analysis brilliantly. And she did
3 this while counsel insidiously insinuated that
4 she was manufacturing online posts. And then
5 dragged her into an inane argument about
6 scheduling alcohol.

7 Dr. Carbonaro is the only one who did
8 the work. The rest basically painted a doom and
9 gloom picture about how controlling DOI and DOC
10 would strip research. But you'll notice not a
11 single soul came in here and told you they would
12 stop their research if DOI or DOC were
13 controlled, even Dr. Ramos, who is in the middle
14 of a 4-year project.

15 Only Dr. Carbonaro did the work. She
16 did the Eight Factor Analysis to show you DOI and
17 DOC should be scheduled. And she did the Three
18 Factor Analysis to show you why it should be
19 placed in Schedule I. And that included looking
20 at the five factors DEA uses for determining that
21 DOI and DOC have no currently accepted medical
22 use, a fact that no one disputed.

23 Certainly these Petitioners are
24 advocates for the free use of these powerful
25 psychedelics because they want to use them in

1 their research. I get that. They don't want DOI
2 to be controlled because they would have to do a
3 little more work to be able to use it. They'd
4 have to submit an application and a protocol.
5 But, as Dr. Carbonaro testified, those protocols
6 are likely done already.

7 And DOI -- and DEA's process likely
8 takes no more than 3 months. And registrations
9 for researchers are going up.

10 In fact, I like how Dr. Nichols,
11 despite his joining the doom and gloom crowd,
12 seemed to really put this into perspective.
13 Devoted, dedicated scientists, he said, won't let
14 scheduling get in the way of their goals. It
15 certainly didn't stop him. He never quit. I
16 appreciate him making that point.

17 These are powerful hallucinogens. The
18 evidence indicates that they should be
19 controlled. To schedule a drug DEA doesn't have
20 to wait for someone to die or be rushed to an
21 emergency room. No one should have to be
22 sacrificed just to justify the application of
23 safety and common sense.

24 Thank you.

25 JUDGE SOEFFING: Thank you, Mr. Mann.

1 Who's making the closing statement for
2 Petitioners?

3 MR. RUSH: I am, Your Honor.

4 JUDGE SOEFFING: All right, Mr. Rush.

5 CLOSING STATEMENT ON BEHALF OF PETITIONERS

6 MR. RUSH: May it please the Court,
7 every morning we've been walking in here we go
8 through security, we clear security. And every
9 morning we walk through, I walk past the wall of
10 the Faces of Fentanyl. And every morning I look
11 at those faces, and I look at each one.

12 I look at those faces, I see those
13 faces, and I think about all the families that
14 are missing people. And I think about the
15 holidays coming up and I think about the empty
16 chair sitting there without the person in it.
17 And I think about that, and the harms.

18 I think about my own family. And I
19 think about attending a funeral, watching my
20 niece's husband be buried, and his 7- and
21 9-year-old children, standing there looking at
22 him in the coffin as he lays there. And I think
23 about that. And that's burned in my memory.

24 And that's why I'm here. And that's
25 why I do this. And I don't do this because, as I

1 said in the beginning, this is something
2 cavalier. And none of the people I've worked
3 with think this is something cavalier, and this
4 is something just minor, or this is something
5 that we are doing for some sort of self-interest
6 for them.

7 It's because we think that DOI holds
8 real importance, and it holds real value and
9 possibility in solving some of the most difficult
10 problems facing this country, including
11 addiction, including mental health issues,
12 serious issues. We don't even know the potential
13 of this substance. But it has been used for
14 decades with no problem whatsoever, helping us
15 learn and unlock serious answers to serious
16 questions.

17 And I see these down there and then I
18 think, Why are we here? Why are we here? We
19 have a substance where the Government's
20 demonstrated no real evidence of it being, of it
21 being, being used outside of research.

22 The substantial evidence? Mere
23 scintilla? I haven't seen any evidence, real
24 evidence of it being used outside of legitimate
25 research.

1 I think when you look at the CSA and
2 we look at laws, we have view it as we're
3 interpreting what those laws are, what they're
4 meant for, why they were created. What's the
5 purpose of them?

6 Not to sit and have arguments delving
7 into minutia and just an overly-granular analysis
8 and circular reasoning, often leading to absurd
9 results. And this is something when I started
10 working with scientists trying to explain to them
11 the law, well, they said to me the facts are
12 here, they just demonstrate that this isn't, this
13 isn't being abused. And it's value is so
14 important. Why is this happening?

15 Don't we have to just tell them,
16 provide them the evidence, show them, like, what
17 exactly, how is this used, how it's not being
18 abused, the critical nature of the research? And
19 I'm sure it will be obvious.

20 And then I have to explain, no, that's
21 not the way the law works. And I do honestly
22 believe when the CSA was enacted it was enacted
23 with the idea that there would be checks and
24 balances within the CSA. There are multiple
25 agencies involved.

1 The DEA is a law enforcement division
2 fundamentally. The FDA is supposed to be health
3 focused. And it's supposed to be checks and
4 balances.

5 And, instead, we come, due to the law
6 and due to the inability to review administrative
7 rule decisions, we've seen a process that's
8 amounted to nothing more than a rubber stamp for
9 the DEA's decision for decades.

10 I don't believe this is the best
11 reading of the statute, the way it's applied, the
12 way it's been applied.

13 And, and I think we really need to
14 also look at the quality of the evidence
15 presented.

16 I don't, I don't -- quite frankly, I
17 don't know where -- what hearing the Government
18 attended that they found that Dr. Carbonaro's
19 done the work but our scientists haven't. Our
20 scientists have done the work. They've done the
21 work. They are peer-reviewed scientists. Their
22 work is reviewed, torn apart. They have to
23 defend it. It is analyzed and it is defended,
24 and their reputations depend on it
25 professionally.

1 We presented real evidence, scientific
2 evidence. People who conducted evidence. Dr.
3 Carbonaro's done the work. Really? Because when
4 we asked confirmation on anything regarding the
5 analysis, any really -- substantiate how is this,
6 why is this? That's what HHS gave me, and I
7 confirmed it. That's what we got.

8 I'm not law enforcement, I can't
9 answer that. We even got, I'm not a chemist, I
10 can't tell you about that. But, yet, you're
11 presenting the professional opinion, and the
12 opinion we're supposed to rely on.

13 Yeah, our witnesses as being
14 unreliable or self-interested, or somehow that
15 they are somehow disingenuous in presenting
16 testimony, I just didn't witness that. I
17 witnessed people who are honest. I witnessed
18 people who are telling the truth, and people who
19 are trying to protect research from real harm.

20 And maybe you can believe the
21 narrative that this is just a simple form you
22 fill out. And it's three months. And it's very
23 simple, and it can be done very simple. But I,
24 what I heard from everyone else other than the
25 Government was that it takes a lot longer than

1 that. It's a lot more complicated, and it would
2 really interrupt their research.

3 And, also, too, we've heard testimony
4 how it would derail people on their paths, their
5 career tracks, the work they're on, how it would
6 be interrupted, and not cause -- we heard Dr.
7 Nichols tell how, because his ability to just do
8 this fundamental mechanistic research into how
9 things work, that would not have been done if
10 this was scheduled, that one of the most powerful
11 anti-inflammatories known was discovered not
12 because it was they filled out a form and they
13 created a study to try to study the
14 anti-inflammatory effects of it. And they
15 submitted it, and then it went there.

16 No. No, it was because you're allowed
17 to conduct research when it's not a Schedule I
18 drug, applying that research you're allowed to
19 conduct research into investigating possible
20 theories.

21 And you find things that you didn't
22 know, like the amazing anti-inflammatory effects.
23 And we don't know how many drugs will come from
24 this and how important they'll be.

25 And Dr. Nichols even said two

1 companies came from this. And this would have
2 never happened if it was scheduled.

3 That was the testimony I heard.

4 And what evidence did we get of its
5 use? What evidence did we get of the use of DOI?
6 We got social media posts, Reddit posts. And
7 then we get Reddit posts that were offered that,
8 quite frankly, it would be absurd to believe.

9 In my opinion it's an affront to this
10 tribunal to sit and look and say that it's
11 possible that 100 or 200 people were using DOI at
12 a PTA meeting, and to sit and say that is
13 possible? That has, that has evidence of use? I
14 mean, it's just, it's just -- it strains the
15 imagination.

16 We have this very simplistic analysis
17 that's applied that because of this, this has to
18 be scheduled. And it's a much more complicated,
19 it's much more complicated than that.

20 And when one talked about suffering
21 they heard, and the horrors of LSD, I think we
22 really need to look at really the modern take on
23 science and psychedelics. And, yeah, we've been
24 hearing for the 50 years of the CSA, we've been
25 hearing from DEA the horrors of LSD, the horrors

1 of psychedelics. We've been hearing that for
2 decades.

3 And what we've seen through real
4 science, through real research is we've seen
5 tremendous medical potential, tremendous benefits
6 and possibilities, including solving the
7 addiction problems that are facing this country.

8 You want to talk about suffering, as
9 I heard, as I heard the Government just say, they
10 said, look downstairs. That's suffering.

11 Who talked to the families who've lost
12 people? That's suffering.

13 I know that. I feel that.

14 Dr. Jaster felt that. Dr. Jaster
15 feels that.

16 Yeah, that's, that's the real deal.
17 And so, based upon some online posts we're
18 supposed to schedule this and shut down all
19 research?

20 And, yeah, maybe it will be, yeah,
21 years later or months later, at the discretion,
22 also, of the DEA whether this license is granted.
23 At the discretion, then of what research will
24 continue. We're supposed to believe that and
25 view it as there's not going to be harm. There

1 will be harm if this is scheduled. We don't know
2 what the harm is, but there will be harm.

3 And we believe that based upon the
4 value, the possibilities that a substance that --
5 that we can help stop those harms and have less
6 of those faces down there.

7 And I believe that the best reading of
8 this statute, the only logical, real reading of
9 this requires that DOI not be scheduled. And I
10 think, and we will explore that in our brief, but
11 we think that at a basic level it's just wrong to
12 do this. And it doesn't make sense.

13 I think under the law in the best
14 reading, it's going to require that DOI not be
15 scheduled because I don't think the Government
16 has demonstrated a potential for abuse. It's
17 just, this isn't being abused. It's not something
18 that's abused. It's not something people will
19 want to abuse.

20 I think we presented a ton of evidence
21 from very qualified people at the very pinnacle
22 of science. And we've gotten, in answer to that:
23 social media posts, I read the report, and I
24 adopted its conclusions.

25 I think the law, under the law I

1 think, I think you should rule that DOI should
2 not, and DOC also. I don't think they, they
3 demonstrated an adequate potential for abuse.

4 And we've heard that even no use
5 whatsoever, that's good enough to schedule a
6 drug. That's not the good reading of this
7 statute, a logical, sensible reading.

8 So, in the end I just, I think that
9 the law requires that DOI and DOC not be
10 scheduled, especially DOI.

11 But also just, you know, I hope the
12 Court, the tribunal will do what I think the law
13 requires.

14 But, also, I hope that this tribunal
15 will do what's right, and will do what's right
16 and help protect science, and help make less of
17 those faces down there.

18 Thank you, Your Honor.

19 JUDGE SOEFFING: Thank you, Mr. Rush.

20 I want to thank counsel for the
21 presentation of your respective cases and for
22 your patience throughout these proceedings.

23 The tribunal will provide a transcript
24 of this hearing to the parties in electronic form
25 and in hard copy after it is received from the

1 court reporter.

2 In addition, there were multiple
3 exhibits introduced by both parties at the
4 hearing that were not part of the prehearing
5 disclosures. I would ask that the parties upload
6 those exhibits to JEFS.

7 For the Government, that would be 7A
8 and 10 through 18. That's what I have.

9 And for the Petitioners, that would be
10 88, 89, and 90.

11 You can talk to the law clerk
12 afterwards if there's any question about
13 identification assigned to each of those exhibit
14 numbers.

15 I will issue a post-hearing order with
16 the following dates:

17 The expected date of the final
18 transcript is December 4, 2024.

19 The parties shall file any exceptions
20 to the transcript by December 17th, 2024.

21 The parties shall file their proposed
22 findings of fact and conclusions of law, also
23 known as post-hearing briefs, by January 6th,
24 2025.

25 In their post-hearing briefs the

1 parties should add what amount of weight, if any,
2 I should give to the evidence regarding research
3 harm that may occur if DOI and/or DOC are
4 scheduled.

5 I will issue my recommended rulings,
6 findings of fact, conclusions of law, and
7 decision as expeditiously as possible after
8 receiving the parties' proposed findings of fact
9 and conclusions of law.

10 Thereafter, the parties may file
11 exceptions in accordance with 21 CFR section
12 1316.66.

13 The Administrator will issue a final
14 order that will be published in the Federal
15 Register.

16 Does any party have any further
17 matters?

18 Mr. Mann?

19 MR. MANN: No, Your Honor.

20 JUDGE SOEFFING: Mr. Phelps, Mr. Rush?

21 MR. PHELPS: Yes. Just one, one quick
22 question to clarify.

23 Our witnesses are now allowed to
24 discuss their testimony as this is the conclusion
25 of the hearing?

1 JUDGE SOEFFING: That's correct.

2 MR. PHELPS: Okay. Thank you.

3 No further questions, Your Honor.

4 JUDGE SOEFFING: Thank you.

5 We are off the record.

6 (Whereupon, at 9:28 a.m., the

7 above-entitled matter was concluded.)

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This is to certify that the foregoing transcript

In the matter of: Schedules of Controlled Substances

Before: US Drug Enforcement Administration

Date: 11-19-24

Place: Arlington, Virginia

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