

UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

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In the Matter of:

:

: Docket No. 05-16

LYLE E. CRAKER, Ph.D.

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VOLUME 9

Friday, December 16, 2005

DEA Headquarters
600 Army-Navy Drive
Hearing Room E-2103
Arlington, Virginia

The hearing in the above-entitled matter
convened, pursuant to notice, at 9:04 a.m.

BEFORE:

MARY ELLEN BITTNER
Chief Administrative Law Judge

APPEARANCES:

On Behalf of the DEA:

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On Behalf of the Respondent:

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MR. JACOBOWITZ, ESQ.

C O N T E N T S

WITNESS	DIRECT	CROSS	REDIRECT	RE CROSS
Eric A. Voth, M.D.	1855	1919	1967	1972
David E. Auslander, M.D.	1974	2020	2029	2032

E X H I B I T S

EXHIBIT NOS.	MARKED	RECEIVED
GOVERNMENT ' S		
No. 25	--	2038
No. 36	--	1891
No. 40	--	1883
No. 41	--	1883
Nos. 53 and 53	--	1841
RESPONDENT ' S		
No. 41 (in part)	--	2059
No. 54 (in part)	--	2044
No. 55	--	1849
No. 57	--	2053

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

2 JUDGE BITTNER: On the record. Mr. Bayly?

3 MR. BAYLY: Good morning, Judge Bittner.

4 Dr. Eric Voth is here, ready to testify, but we
5 have just a few evidentiary, or document submission
6 issues that I think we need to clear up. It
7 shouldn't be too long.

8 JUDGE BITTNER: Do you want to be on the
9 record or off?

10 MR. BAYLY: Oh, no, we definitely need to
11 be on.

12 JUDGE BITTNER: Okay.

13 MR. BAYLY: The first thing I'd like to
14 submit is Government 53. Wednesday, Judge Bittner,
15 you said this would be not admitted until we got
16 the contextual document to which 53 was responding.
17 I got that this morning. I'll give Your Honor a
18 copy.

19 JUDGE BITTNER: Okay.

20 MR. BAYLY: I just gave a copy to
21 Respondent's counsel just a few minutes ago. If
22 counsel needs more time to respond, that's fine,

1 but I do want to say that when we admit what I've
2 marked now as 53A, I want to submit it for the
3 context of 53 without being for the truth of the
4 matter asserted necessarily therein. There are a
5 couple of reasons I say that.

6 This is a request by Americans for Safe
7 Access, so it's like a petition or like a brief, an
8 advocacy thing. If you look on page two, they lay
9 out the particular issues that they're complaining
10 about. Apparently, to give some context to the
11 process, there is a statute that allows certain
12 parties to have HHS, quote, "correct" documents
13 that they may put out as policy statements. They
14 may publish them in the Federal Register without
15 knowing the actual details of that statute.

16 The Americans for Safe Access in 53A made
17 a request for corrections of information, so they
18 disagreed with what HHS did. I think they refer to
19 some of the information put in the Gettman
20 petition. As you can see on pages one to two, the
21 issues that they raise go to the efficacy of
22 marijuana, the treatment of nausea, loss of

1 appetite, pain, and spasticity. They talk about
2 whether the chemistry of marijuana is known and
3 reproducible, a consensus among experts. And then
4 the last issue that they want HHS to address is
5 marijuana has a currently accepted use in treatment
6 in the United States. I think that one was kind of
7 trumped by the statute.

8 In any event, I submit that if this does
9 go into evidence, to get Government Exhibit 53 into
10 evidence, that it should be just for its context as
11 opposed to getting into the merits of what's
12 written, and this request.

13 Of course, the other issue is, at this
14 point, I don't know if, one, if HHS made some kind
15 of ruling or finding on this, and two, if they did,
16 what it says. I don't know that we could really
17 trump whatever HHS says in that regard, anyway.

18 So that's my reason for wanting to qualify
19 the admission of 53A with 53.

20 JUDGE BITTNER: Ms. Carpenter?

21 MS. CARPENTER: Yes, two things. First of
22 all. We, I guess, spoke with the President of

1 Americans for Safe Access yesterday and there has
2 been no action by HHS on this, so for what that's
3 worth.

4 Secondly, it seems to me what's good for
5 the goose is good for the gander. The response
6 that the Government wants to submit is the same
7 kind of information as is contained in the
8 petition. So if the Government if wants to accept
9 that not for the truth of the matter asserted, then
10 we'll accept the restriction on the first part.
11 But the Government can't have it both ways and have
12 only their section accepted for the truth of the
13 matter asserted and not what's in the petition, as
14 well.

15 JUDGE BITTNER: I may be corrected. My
16 vague recollection--after all, it was two whole
17 days ago--was that the point of getting Americans
18 for Safe Access's document, Government 53A, was to
19 provide the context for Government 53.

20 MS. CARPENTER: That's true, Your Honor.

21 JUDGE BITTNER: I mean, both of these--one
22 is from Americans for Safe Access. The other one

1 is from G.W. Pharmaceuticals. Neither is a
2 disinterested party, right?

3 MS. CARPENTER: Quite right.

4 JUDGE BITTNER: I mean, nobody's going to
5 argue to the contrary. And so I'm not really--and
6 my recollection about Government 53 was that it
7 provided some explanation of side effects.

8 MS. CARPENTER: In addition to a number
9 of--a lot of other information, such as whether or
10 not their research would support herbal--marijuana
11 as an herbal medicine, and so--

12 JUDGE BITTNER: Right, but what I'm not
13 taking any of this for is back to the marijuana is
14 or is not medicine issue.

15 MS. CARPENTER: That's fine, Your Honor.

16 JUDGE BITTNER: Okay.

17 MS. CARPENTER: I just don't think half
18 the exhibit should be qualified if the other half
19 is not similarly qualified.

20 JUDGE BITTNER: I'm qualifying the whole
21 thing.

22 MS. CARPENTER: That makes sense.

1 JUDGE BITTNER: With that, then,
2 Government 53 and 53A are received.

3 [Government's Exhibit Nos. 53
4 and 53A were admitted into
5 evidence.]

6 MR. BAYLY: Thank you, Judge Bittner.

7 JUDGE BITTNER: You're welcome.

8 MR. BAYLY: I was writing on the original,
9 so if you want to white it out or pretend it's not
10 there, I just--

11 JUDGE BITTNER: Okay.

12 MS. CARPENTER: Oh, that's the original?
13 I see.

14 MR. BAYLY: Yes, and I've got a yellow
15 copy here, a yellow stick-em copy for 53A.

16 Then, Judge Bittner, Wednesday and
17 yesterday, there were three new exhibits that the
18 Respondent has submitted and the reason I'd like to
19 clear that up now is because if any or some of
20 these are admitted into evidence, then we'd be
21 able--or we may be able to address them--I think we
22 can--with Dr. Voth and/or Dr. Auslander, although

1 we don't want to waive the right to put in rebuttal
2 arguments, testimony, letters, what have you, since
3 we just got them either Wednesday or yesterday.

4 So at this point, I would request that we
5 go through these three exhibits and if the
6 Respondent could tender them for the purpose for
7 which they want to be admitted, and then I'd like
8 to have just a brief chance to respond. I've got
9 them marked--well, I'm sorry. I'll let you guys
10 take the ball.

11 MS. CARPENTER: Thank you.

12 JUDGE BITTNER: Are we having fun yet?
13 Ms. Carpenter?

14 MS. CARPENTER: Yes, Your Honor. That
15 would be Respondent's 54, 55, and then the one I
16 sent you yesterday, is that correct, Mr. Bayly,
17 which has not been marked yet? Is that what you're
18 talking about?

19 MR. BAYLY: I call it 56.

20 MS. CARPENTER: Okay. That would be my
21 inclination. And, Your Honor, let me give you a
22 copy of--

1 JUDGE BITTNER: Fifty-four--

2 MS. CARPENTER: Fifty-four is the
3 testimony of Mr. Meyer, Dr. Meyer.

4 JUDGE BITTNER: Right.

5 MS. CARPENTER: Fifty-five is the letter
6 to Mr. Eggertson dated September 9 from Chemic
7 Labs.

8 JUDGE BITTNER: Okay. And I don't have
9 that, right?

10 MS. CARPENTER: You should have that, Your
11 Honor. I think we submitted that, or at least
12 marked it. No? Let me see if we've got--we'll get
13 copies of that.

14 JUDGE BITTNER: I don't think I've got it.
15 I don't have it in my book. Let's put it that way.

16 [Pause.]

17 JUDGE BITTNER: And then the other one is
18 56?

19 MS. CARPENTER: Yes, Your Honor, and I
20 have not given you that one yet.

21 JUDGE BITTNER: Okay.

22 [Pause.]

1 MS. CARPENTER: And then let me just go
2 ahead and give you 56 so we can have them all.

3 [Pause.]

4 MS. CARPENTER: Respondent's Exhibit 54 is
5 the testimony by Robert J. Meyer with the FDA
6 before the House of Representatives on April 1,
7 2004. We had intended to cite this in our briefing
8 to you, and given what the Court has said about
9 having information in that's not readily
10 accessible, we thought it might make sense to go
11 ahead and try and put this in, recognizing that we
12 did not put it in the pre-hearing statement.

13 JUDGE BITTNER: Okay. And Mr. Bayly, what
14 was your position on 54?

15 MR. BAYLY: That perhaps in the brief,
16 this can be cited as legislative history. If it's
17 appended to the brief, then for convenience, that's
18 all right. But at this point, I would object to
19 this being admitted for the truth of the matter
20 asserted in the testimony on the timeliness. As
21 Ms. Carpenter pointed out, you can see the date is
22 April 1, 2004, and it looks like, I believe, this

1 is one we got Wednesday, just this past Wednesday.
2 The other thing, this issue is always lurking, does
3 it get into this medical marijuana issue and is
4 marijuana--i.e., is marijuana a good medicine.

5 But in any event, I really do think it
6 should not be admitted as an exhibit. If it is,
7 and I really don't want it to be, but if it is
8 admitted, then, of course, the Government, being
9 that it just got this the day before yesterday,
10 would like a chance to rebut, supplement the
11 record, or what have you. But I think once these
12 things start getting in late, we start spinning out
13 of control and getting into rebuttal and
14 surrebuttal and what have you. So for that reason,
15 I would object to Respondent's 54.

16 JUDGE BITTNER: Ms. Carpenter? I wouldn't
17 consider it on the medical issue. We know that.
18 But on the timeliness issue, Ms. Carpenter?

19 MS. CARPENTER: Your Honor, we didn't know
20 it at the time, and we also, I think--this is in
21 part of rebuttal to what we anticipate Dr. Voth's
22 testimony will be. So if you want us to hold off

1 and do it as rebuttal to Dr. Voth in terms of--then
2 we could do that, which is what we had planned to
3 do, so--

4 JUDGE BITTNER: All right. I am somewhat
5 more lenient on rebuttal because one doesn't know
6 exactly what the other party's case in chief is
7 going to be, so let's just hold off on this--

8 MS. CARPENTER: That's fine.

9 JUDGE BITTNER: --because it isn't timely.
10 That's my main problem with it.

11 MS. CARPENTER: I understand.

12 JUDGE BITTNER: Okay. With respect to
13 Respondent's 55--

14 MS. CARPENTER: Fifty-five--

15 JUDGE BITTNER: First of all, Mr. Bayly,
16 do you have any--since this obviously was not
17 available prior to our hearing beginning.

18 MS. CARPENTER: No, it was not, and it was
19 dated September 9, which was, as Your Honor will
20 recall, just before the second week of the hearing
21 was to begin, and so at the time, we thought we
22 would just be introducing at the hearing and would

1 not file a supplemental. We had also assumed that
2 Mr. Bayly had seen this, since Mr. Eggertson was a
3 witness who was noticed and was to appear.

4 What this does is basically to complete
5 the record, if you will, with regard to the denial
6 of the Chemic protocol that Dr. Doblin testified.
7 We do have that denial in the record. We have Dr.
8 Doblin's response, or Dr. Chemic's response to Dr.
9 Doblin. This is simply Chemic's response to HHS
10 about that protocol, and I would submit it should
11 come in for that reason.

12 JUDGE BITTNER: Mr. Bayly?

13 MR. BAYLY: Well, aside from the
14 timeliness issue, putting that aside just for the
15 moment, it seems like this Chemic is what I'll call
16 a silent partner in this litigation and it is very
17 collateral. But I do realize that the denial came
18 in. So on this one, I will not argue timeliness,
19 but--

20 JUDGE BITTNER: That's probably good.

21 MR. BAYLY: Pardon?

22 JUDGE BITTNER: That's good.

1 MR. BAYLY: Oh, okay. Well, it might make
2 it a little easier. But I certainly don't want to
3 waive the Government's right to argue and give
4 notification to Respondent that we are going to
5 object on a number of grounds, probably more in
6 detail in the brief, since you probably don't want
7 to listen to me too much here today. We want to
8 get the witnesses on and off. But it is a
9 collateral issue, it's not a DEA issue, and there
10 are other problems with this. So with that, I will
11 ask the Judge for a ruling.

12 JUDGE BITTNER: Okay. I'll overrule the
13 objection because I think since it wasn't available
14 earlier, there's not a timeliness question, and I
15 think it does pertain to some of the testimony that
16 we've heard from the Government. But I do have a
17 problem, which is I don't know what all these
18 abbreviations mean. There's a bunch of them in the
19 letter. So I would ask the parties to stipulate
20 what they are so that I don't have to guess.

21 MS. CARPENTER: Okay.

22 JUDGE BITTNER: So with that, I will

1 receive Respondent's 55.

2 [Respondent's Exhibit No. 55
3 was admitted into evidence.]

4 JUDGE BITTNER: And 56?

5 MS. CARPENTER: Fifty-six, Your Honor, is
6 a letter that was sent yesterday, and it's on the
7 very same subject. It was sent by essentially a
8 peer reviewer of the Chemic protocol, and again, it
9 was not available until yesterday and we would
10 simply add that to the Chemic pile.

11 And with regard to the argument that it's
12 collateral, I think in our view, it is not
13 collateral. MAPS has been trying to do research
14 using marijuana from NIDA in a number of different
15 ways, some of them clinical, some of them using
16 this vaporizer, which is an important part of the
17 research, and they have not been able to get it.
18 So in that sense, it's not collateral at all. It's
19 a clear indication of the difficulty of researchers
20 getting marijuana to do research.

21 JUDGE BITTNER: Mr. Bayly?

22 MR. BAYLY: Big problem with this.

1 Definitely timeliness, and this looks like it's for
2 the purpose of litigation. It's not one of those
3 documents where you're waiting interminably for an
4 agency to come out with something and you have no
5 control. This is a document that is solicited to
6 litigate this Chemic issue, and if you look at the--and I do
7 appreciate the Respondent putting in this
8 fax cover sheet. It shows where it comes from--

9 JUDGE BITTNER: Actually, I don't have a
10 fax--it's an e-mail cover sheet, right?

11 MR. BAYLY: I'm sorry.

12 MS. CARPENTER: Right.

13 JUDGE BITTNER: Okay. I just want to make
14 sure we all have the same thing.

15 MR. BAYLY: I get e-mail and faxes mixed
16 up. I guess I'm old fashioned in that regard. But
17 at any rate, reading the letter, it is addressed to
18 Mr. Eggertson, and I think he's the fellow that did
19 write the letter to Chemic and then Chemic wrote
20 back to Eggertson, but this is somebody that is
21 clearly just jumping into the litigation and there
22 was no reason that we have on the record why this

1 person had to do it December 15.

2 The Chemic rejection letter from Joel
3 Eggertson was dated July 27, '05, and I realize we
4 put that into evidence because maybe Chemic didn't
5 disclose it until right before the August hearing,
6 but we've got this Chemic issue is on the table
7 since mid- or, I guess, the latter part of August,
8 when we had the first hearing, and this is, of
9 course, very much sought to be admitted to support
10 the Chemic position. And so we've got--this should
11 not come in on timeliness and for what it's
12 tendered for.

13 JUDGE BITTNER: Ms. Carpenter?

14 MS. CARPENTER: Yes, ma'am. We had
15 extensive testimony yesterday from Dr. Gust about
16 the back and forth between the PHS Committee and
17 that how when the PHS Committee denies something,
18 it's not really denied. They're issuing an
19 invitation for back and forth.

20 This is a peer review, which takes quite
21 some time to get somebody to agree to in the first
22 place, and then sometime to accomplish. It's a

1 peer review rebuttal of the comments that Mr.
2 Eggertson and the PHS Committee made about the
3 Chemic protocol. So this is--Mr. Bayly's
4 assumptions notwithstanding, this was designed to
5 address the Chemic issue before the PHS Committee.
6 It was not gotten for litigation purposes. Even if
7 it were, I'm not sure that would disclude it or
8 disqualify it.

9 But the point is, this was filed
10 yesterday. We had no control over the peer
11 reviewer, when they would finish their research or
12 when they would write the letter. They sent it
13 yesterday. It can hardly be a timeliness problem,
14 Your Honor.

15 JUDGE BITTNER: My concern is if we put
16 this in, then it seems like I'd need the entire
17 Chemic file. In other words, we have a letter in
18 support of Chemic. We don't know what else. I
19 feel like I'm getting part of what Mr. Eggertson
20 got, and I don't know what else he got and I don't
21 really want to get into that.

22 MS. CARPENTER: Part of what Mr. Eggertson

1 got from who?

2 JUDGE BITTNER: In other words, what we
3 have is, if I recall correctly--

4 MS. CARPENTER: A denial from Mr.
5 Eggertson.

6 JUDGE BITTNER: Right. And now we've got
7 Chemic's response, which I just received.

8 MS. CARPENTER: And then a peer review of
9 that protocol.

10 JUDGE BITTNER: And I guess what I'm
11 concerned about is I don't see anything in
12 Respondent's 56 saying that it's a peer review.
13 What we've got is Dr. Hasecamp saying, I support
14 Chemic, but it doesn't appear to have been
15 solicited by the PHS Committee.

16 MS. CARPENTER: No, certainly not, Your
17 Honor. It was solicited by Chemic in order to
18 establish to the PHS Committee that their critiques
19 were--

20 JUDGE BITTNER: Right, and so what I'm
21 concerned about is I don't know what else there
22 might be. In other words, we've got a letter in

1 response to a solicitation from Chemic. I don't
2 know what else--I mean, I'm not going to second-guess HHS.

3 MS. CARPENTER: Certainly not.

4 JUDGE BITTNER: I guess what I'm trying to
5 say is I don't see what this letter adds to the
6 record that wouldn't require me to have every other
7 letter. I mean, Chemic's response makes sense. To
8 have it in evidence makes sense to me. But to have
9 somebody now coming forward right now, three months
10 after Chemic's response to Mr. Eggertson, saying,
11 oh, by the way, I support Chemic, it just doesn't
12 help me any, I don't think.

13 MS. CARPENTER: I would just represent for
14 the record, Your Honor, I don't believe there are
15 any other letters, so I think this is the complete
16 package, certainly in terms of what Chemic--

17 JUDGE BITTNER: Well, at this point, I
18 will reject it but will keep it in the file and
19 send it to the Deputy Administrator.

20 MS. CARPENTER: Thank you, Your Honor.

21 JUDGE BITTNER: So 56 is rejected, but I

1 won't read it, but I'll hang on to it.

2 MR. BAYLY: And if I may add one more
3 ground for the objection, because they may appeal
4 it to Your Honor, as well as the Deputy
5 Administrator, using the generic term "rebuttal"
6 doesn't mean that you can get in documents late.
7 It just doesn't work that way. Otherwise, this
8 process never stops, because certainly, given that
9 we got this yesterday, and if it did come in, we
10 certainly would want to rebut it, so we want to
11 preserve that argument, as well.

12 With that, we're finally ready to call Dr.
13 Eric Voth, please.

14 JUDGE BITTNER: Okay. Doctor?

15 Whereupon,

16 ERIC A. VOTH, M.D.
17 was called as a witness, and after being first duly
18 sworn, was examined and testified as follows:

19 JUDGE BITTNER: Please be seated. There
20 should be water in the carafe there.

21 DIRECT EXAMINATION

22 BY MR. BAYLY:

1 Q Please say your name for the record.

2 A Eric A. Voth, M.D.

3 JUDGE BITTNER: And would you spell both
4 your first and last name for me?

5 THE WITNESS: First name is E-r-i-c, and
6 last name is V as in Victor-o-t-h.

7 JUDGE BITTNER: Thank you.

8 MR. BAYLY: Your Honor, I'd like to
9 present the witness with Government Exhibit 33.
10 That's the CV for Dr. Voth. I don't think we have--no, we
11 have not admitted it yet.

12 JUDGE BITTNER: I think that's correct.
13 Yes, we did. No, wait a minute. That's not
14 Government 33. I'm sorry. What number was it, Mr.
15 Bayly?

16 MR. BAYLY: Thirty-six.

17 JUDGE BITTNER: Ahh, okay. Thirty-three
18 is admitted, but it's not the right exhibit.
19 Thirty-three has not been offered. Ms. Carpenter?

20 MS. CARPENTER: Thirty-six, Your Honor?

21 JUDGE BITTNER: Yes. You haven't actually
22 offered it yet. Does the witness have it?

1 MR. BAYLY: Yes. We'll go through it in a
2 minute, here.

3 BY MR. BAYLY:

4 Q Start from the face, Dr. Voth, of your CV.
5 We've always had to clarify this in the past, so I
6 see no reason to change our protocol here, but what
7 does M.D. stand for?

8 A It's medical doctor, physician.

9 Q And then we see the initials F.A.C.P. on
10 the face of your CV. Can you tell us what that
11 stands for and what it means?

12 A That stands for Fellow of the American
13 College of Physicians.

14 Q Does that have anything to do with board
15 certification?

16 A No, not really. The Fellowship in the
17 American College of Physicians is bestowed by the
18 American College of Physicians essentially for
19 academic and professional accomplishments.

20 Q All right. And can you tell us why you
21 have this designation, what your accomplishments
22 are, just generally?

1 A More or less, this is a nomination by
2 peers and then looked at by the Fellowship
3 Committee at the American College of Physicians
4 relative to academic accomplishments, teaching
5 accomplishments, professional accomplishments,
6 those kind of things. I think that most of what
7 they looked at in that regard was my work in drug
8 abuse.

9 Q Right now, I'd ask you to turn to page
10 three, please, of your CV. It's marked both on the
11 top and the bottom of the right--

12 A Yes, I have it.

13 Q We see that--I want to refer you to the,
14 quote, "Board certification, American Board of
15 Internal Medicine, 1985." Can you tell us what
16 Board certification means?

17 A Board certification for internal medicine
18 is a process that's been set up by the Academy,
19 more or less, that sets up a testing process, and
20 if you pass that testing, then you become board
21 certified.

22 Q Is your Board certification current?

1 A Oh, yes.

2 Q I'd like you to flip back to page two.

3 A Okay.

4 Q The CV bio summary starts out, "Dr. Voth
5 is a specialist in internal medicine and addiction
6 medicine, working at Stormont-Vale Health Care in
7 Topeka, Kansas." First of all, can you just give
8 us a general description, Dr. Voth, of your
9 internal medicine practice?

10 A Sure. About two-thirds to 70 percent of
11 my time is in the practice of internal medicine,
12 which for all intents and purposes is adult
13 medicine, taking care of heart disease, lung
14 disease, cancer, that kind of thing. I don't do
15 surgery and I don't deliver babies and really don't
16 take care of young children, but other than that,
17 it's more or less adult medicine. And that's the
18 internal medicine part of it.

19 The addiction medicine part has been kind
20 of a broad spectrum of areas. That involved
21 actually being the medical director of a chemical
22 dependency unit for ten years. I continue to do

1 consultation, recommend treatment, detoxification
2 and a lot of drug policy work.

3 Q Have then you in your practice actually
4 treated patients for either addiction or abuse of
5 controlled substances?

6 A Oh, yes, certainly.

7 Q Can you give us an estimate of how many
8 patients you've treated in this regard?

9 A Well, when I finally quit counting, it was
10 about 4,000. We used to keep pretty close track of
11 that for some period of time, and since probably
12 the early '90s, I've not actually tracked that. So
13 at least 4,000, but certainly more than that by
14 now.

15 Q Now, these patients that you testified
16 about, Dr. Voth, have they entailed patients who
17 have had either abuse or addiction problems with
18 marijuana?

19 A Certainly, yes, they have.

20 Q Can you give an estimate of about how many
21 of all these various patients that you have treated
22 for abuse or addiction had marijuana issues?

1 A It's a little hard to guess, but as a
2 general guess, since we didn't track it in those
3 kind of terms, about half of them had some element
4 of marijuana abuse, whether that was along with
5 other drugs or primary marijuana abuse, and
6 somewhere in the neighborhood of, say, a quarter,
7 roughly, would have been strictly marijuana abuse.

8 Q Let me just ask you, when did you first
9 become interested in studying marijuana?

10 A Well, probably well back into the '70s,
11 even in college, before I was involved in medicine.

12 Q Have you become familiar with marijuana
13 research issues, as well?

14 A Most certainly. Absolutely. I started
15 really paying close attention to that in probably
16 the mid-'70s.

17 Q Okay. So when did you start learning
18 about marijuana research?

19 A I think it would be safe to say around
20 1974, 1975, really started closely studying and
21 following marijuana research.

22 Q Have you ever studied marijuana policy

1 issues?

2 A Absolutely, yes.

3 Q And how long have you studied marijuana
4 policy issues?

5 A Pretty much hand-in-hand that whole time,
6 following the research and also the drug policy
7 issues and implications, so probably since
8 certainly the mid-'70s, about 30 years.

9 Q All right. Now, Dr. Voth, I'd like you to
10 please turn to page four.

11 A Okay.

12 Q Listed under positions held, we see
13 Chairman, Institute on Global Drug Policy.

14 A Right.

15 Q My first question is, when was this
16 Institute founded?

17 A I actually helped found that Institute in
18 the year 2000.

19 Q And what is the Institute's function?

20 A The best way to characterize it is that
21 we're really a drug policy think tank.

22 Q What is the role in the Institute? What

1 is your role in the Institute?

2 A Well, I'm Chairman of it, and as such, I
3 try to organize policy issues, statements, put
4 together position papers, those kind of things. I
5 guess I also work on putting membership together
6 and recruiting new members, that kind of activity.

7 Q All right. I'm now still on page four,
8 Dr. Voth, of your CV, and if you could just very
9 briefly give us an idea of what you did as a
10 Clinical Associate Professor of Internal Medicine,
11 Department of Medicine, University of Kansas School
12 of Medicine, 1999 to current? That's about the
13 sixth one down on positions held. Do you see that
14 one?

15 A Yes, I do.

16 Q All right.

17 A As a Clinical Associate Professor, that's
18 more or less a clinical teaching position. I may
19 have residents or medical students or various
20 students from the university working with me,
21 rotating with me for part of their educational
22 processes.

1 Q All right. Next, I'd like to briefly
2 describe your duties or what you do on number nine,
3 and that's the--I've listed it as nine, they're not
4 numbered, but I'll quote it so we know where we're
5 at--alcoholism and drug abuse consultant, Kansas
6 State Board of Healing Arts, current.

7 A With some regularity, our State Board of
8 Healing Arts may have issues involving physicians
9 and their use or handling of alcoholism issues or
10 drug abuse issues, or for that matter, physicians'
11 individual problems, so a physician may be addicted
12 to some substance and how to deal with them.

13 Q And then drop down two more. I think I've
14 got it numbered as 11, but let me quote it here.
15 It's the consultant, National Institute of Drug
16 Abuse, Epidemiology, and Preventative Review. Can
17 you tell us what this organization is and what your
18 duties or functions are in relation to it?

19 A Those functions were actually back in the
20 probably mid- to late '80s when I served on
21 committees to oversee some of the grants that NIDA
22 was looking at relative to prevention programs and

1 maybe even some treatment programs at that point in
2 time. But that was probably two to three years,
3 I'd say, in the mid- to late '80s.

4 Q Okay. So how long were you on this
5 committee, then?

6 A I think it was two to three years. I've
7 not been involved since the late '80s.

8 Q I'd like to ask you now to please flip
9 back to page three of your CV there, Government
10 Exhibit 36. It looks like it's the next-to-last
11 entry there on page three, Dr. Voth. I'll quote it
12 so we make sure we're all together on this.

13 "Member, Advisory Committee, Centers for Substance
14 Abuse Treatment, U.S. Health and Human Services
15 Administration, 2003-," end quote. First of all,
16 can you tell us what this committee is?

17 A Right. The National Advisory Committee
18 for--this is CSAT, or Centers for Substance Abuse
19 Treatment, oversees virtually all the grants that
20 the Centers for Substance Abuse Treatment hands
21 out. We look at research, kind of the general
22 direction for the Centers for Substance Abuse

1 Treatment. And this also, just parenthetically,
2 was appointed by the Secretary of Health and Human
3 Services.

4 Q And Dr. Voth, what do you do in your
5 capacity as an advisor for this committee?

6 A Oh, we attend a number of meetings and
7 also do a lot of grant review, looking at research
8 grants and also treatment grants to communities and
9 different organizations for drug abuse treatment.

10 Q Now, I'd like to ask you to please flip
11 back to page four, and I'm on entry number 12, so
12 let me quote that so that we are all on the same
13 page, so to speak. Quote, "member and former
14 Chairman, Committee on Impairment and Advocacy,
15 Kansas Medical Society." First of all, tell us
16 when you were the Chairman of the Committee.

17 A That was roughly the early '90s, about
18 roughly 1990 or 1992, along in there. There were a
19 couple of years when I sat in oversight of that
20 Committee, which is essentially in some States
21 called the Physician Impairment Committee or the
22 committee that liaisons with physicians that have

1 chemical dependence problems and help them get
2 treatment and that kind of thing.

3 Q And are you now a member of this committee
4 still?

5 A Yes, I'm still involved, but I'm not
6 Chairman.

7 Q And, first of all, tell us--just describe,
8 please, what your function was on this committee,
9 first of all, as Chairman.

10 A Probably the best way to describe that
11 would be coordinating services for impaired
12 physicians, so if a physician was reported, rather
13 than reporting to the State Board of Healing Arts,
14 Kansas allows physicians to be able to be reported
15 to this committee. We would then establish an
16 intervention or evaluation and see about arranging
17 treatment for them and follow-up services and then
18 reintroduction back into practice.

19 Q Next, Dr. Voth, I'd like to refer you to
20 the next entry on page four. That's the Chairman,
21 St. Francis Stormont-Vail Hospital, Physician
22 Impairment and Advocacy Committee, 1990 to 1994, as

1 well as take you over to page six. I think the
2 cross-reference there would be the last one, or the
3 last two, I think. Page six, Chairman, Physician's
4 Health and Advocacy Committee, Stormont-Vail, 2002
5 to current, and Chairman, Physician Risk Management
6 Committee, Stormont-Vail, 2003 to current. Those
7 three entries, can you tell us, describe what you
8 do for those?

9 A The involvement for the Impairment and
10 Advocacy Committees was pretty similar to that
11 Kansas committee. In other words, if a physician
12 has a chemical dependency problem, it's our job to
13 deal with that and help them get treatment or
14 intervene on them and then see to it that they're
15 reinstated back into practice.

16 The Risk Management Committee is a little
17 more along the lines, really, in terms of looking
18 at physician practice patterns, behaviors, things
19 that might result in litigation or malpractice
20 cases, those kind of things.

21 Q All right. Thank you. Now, I'd like you
22 to move to page five and look at the entries. I'm

1 going to kind of roll these into one here to
2 expedite things. But if you'll look on page five
3 at the entries, the first one is book reviewer for
4 the American Journal of Addiction, 1994-dash-current. And
5 then we go down to six and the last
6 one is peer reviewer, Archives of General
7 Psychology--Psychiatry, excuse me--2004 to current.
8 Can you describe what your duties or what you do in
9 terms of the book reviews and peer reviews for
10 these journals that you've listed that I've noted
11 on page five of your CV?

12 A These journals are all major medical
13 journals and my review there, or my function there
14 is when papers are submitted to these journals,
15 they are then--I will be sent papers to evaluate
16 for their content, for their usefulness to be
17 published, et cetera, and then comment back to the
18 editor about accepting them or changing them or
19 that kind of thing. So this is really--when you
20 term a peer review journal, I'm serving as a peer
21 reviewer for those journals.

22 Q Dr. Voth, have you been a consultant and

1 reviewer for the National Academy of Sciences?

2 A Yes, I was.

3 Q And what was the function of that
4 organization in relation to marijuana?

5 A In 1997, they came out with the big review
6 called the IOM Study that has been referred to
7 relative to medicinal uses of marijuana. I was a
8 consultant to that review, testified to it and also
9 was a reviewer of the final product of the IOM
10 Study.

11 MR. BAYLY: Your Honor, I'd like the
12 witness to be shown Respondent's Exhibit 1, and
13 I'll absolutely promise I'm not going to have him
14 go through that.

15 [The document was shown to the witness.]

16 BY MR. BAYLY:

17 Q Thank you. But for the record, Dr. Voth,
18 I want to ask you if this--if you just look at the
19 cover sheet and maybe peruse the first few pages,
20 the title page, what have you, and ask if this is
21 the study that you're referring to.

22 A Yes, it is.

1 Q All right. Thank you. I guess you can
2 put that aside now and back to some of these peer
3 review and book review functions that you've listed
4 on your CV. Did any of these articles you review
5 pertain to marijuana?

6 A Yes, some have.

7 Q Did any of these articles you review
8 pertain to marijuana abuse and addiction?

9 A I believe so. I don't recall
10 specifically, but I generally believe that to be
11 the case, yes.

12 Q And any of these articles you review
13 pertain to marijuana's potential medical use?

14 A Yes, I believe they have.

15 Q And in the course of these peer reviews,
16 have you reviewed marijuana in terms of its
17 constituents and its use and abuse?

18 A Oh, certainly. Yes.

19 Q All right. And I'm going to ask you--let's see, I
20 think we're still on page five. The
21 entry there, it looks like it's the third from the
22 bottom, Consultant to the International Task Force

1 on Strategic Drug Policy sponsored by the United
2 States Department INL and Drug Prevention Network
3 of the Americas, 2001 to current. First, in regard
4 to that entry, what does INL stand for?

5 A It stands for International Narcotics and
6 Law Enforcement.

7 Q And can you tell us what your function is
8 in this organization, Dr. Voth?

9 A In a general sense, we have provided drug
10 policy recommendations and review of drug policy in
11 various parts of the world and may make
12 recommendations about changes or processes that are
13 taking place in various countries.

14 Q And I'd like to refer you to page seven,
15 where you've listed some of your scientific
16 publications.

17 A Correct.

18 Q Are some of these articles--do they
19 pertain to marijuana?

20 A Yes, some of them do.

21 Q Are the articles listed here under this
22 section here, are they subject to peer review?

1 A Most of them are subject to some form of
2 peer review. Letters to the editor would be
3 reviewed by an editor. They may or may not
4 actually go out to a specific peer reviewer. The
5 papers listed certainly are under peer review.

6 MR. BAYLY: Your Honor, I'd like the
7 witness to be given Government Exhibits 38 and 40.

8 MS. CARPENTER: She doesn't have them.

9 MR. BAYLY: I'm sorry, we've got them. If
10 I may approach. Thirty-eight--I think we're going
11 to hold off on 38, but I'm going to at least ask
12 Dr. Voth about Government Exhibits 40 and 41, so
13 I'd like to give Dr. Voth these exhibits.

14 JUDGE BITTNER: Okay.

15 [The documents were shown to the witness.]

16 BY MR. BAYLY:

17 Q Dr. Voth, I've just given you Exhibits 40
18 and 41. Can you, first of all, identify those
19 exhibits for the record?

20 A Exhibit 40 is titled "Medical Marijuana:
21 A Survey of Teenagers and Their Parents," by Dr.
22 Richard Schwartz. And 41 is "The Use and Toxicity

1 of Cannabis in Teenagers," by Dr. Richard Schwartz
2 and co-authored by me.

3 MR. BAYLY: Your Honor, I'd like to
4 introduce Exhibits 40 and 41 into evidence.

5 JUDGE BITTNER: Ms. Carpenter?

6 MS. CARPENTER: Let me just check 41, Your
7 Honor. I'm sorry.

8 [Pause.]

9 MR. JACOBOWITZ: We accept that with the
10 note that we had previously discussed this exhibit
11 and I believe Your Honor has ruled that it is
12 excluded to the extent that it discusses the risks
13 of cannabis smoking.

14 JUDGE BITTNER: No, I don't think so. I--

15 MR. JACOBOWITZ: That may overstate it a
16 little. I'm sorry.

17 JUDGE BITTNER: Whatever I ruled, I'll
18 probably still rule, we hope. But I'm a little
19 unclear. Mr. Bayly, do you have someplace a cover
20 sheet from the journal or something so I can cite
21 it correctly if I need to, or is it in your exhibit
22 list cited?

1 MR. BAYLY: Was it listed as an exhibit?

2 Yes.

3 JUDGE BITTNER: Okay. So Clinical
4 Pediatrics was 40 and Advances in Pediatrics--is
5 this a book or a journal or part of a book, with
6 respect to 41?

7 MR. BAYLY: Could I ask--could the witness
8 address that?

9 JUDGE BITTNER: Sure.

10 THE WITNESS: That was part of--I think
11 that was a chapter in a larger book, Recent
12 Advances in Pediatrics.

13 JUDGE BITTNER: Okay.

14 THE WITNESS: The chapter was, "The Use
15 and Toxicity of Cannabis in Teenagers" on this
16 cover sheet.

17 JUDGE BITTNER: Okay. Then--

18 MS. CARPENTER: Your Honor?

19 JUDGE BITTNER: I'm sorry?

20 MS. CARPENTER: I should be clear about
21 something first. Mr. Jacobowitz is going to be
22 doing the cross-examination today of Dr. Voth.

1 JUDGE BITTNER: Okay.

2 MS. CARPENTER: If I may, could I just
3 make one objection, and then I'll not make any more
4 the rest of the time.

5 JUDGE BITTNER: Mr. Bayly, do you have any
6 objection to Ms. Carpenter making an objection when
7 she's not cross-examining the witness?

8 MR. BAYLY: I object to the objection.

9 [Laughter.]

10 MR. BAYLY: No, I don't.

11 JUDGE BITTNER: Okay. Thank you. Go
12 ahead, Ms. Carpenter.

13 MS. CARPENTER: This is just, I think, to
14 set a groundwork for where we're going today. I
15 guess for the record we should say we do object to
16 Government's Exhibit 41, and the reason is that
17 Your Honor has excluded evidence relating to the
18 therapeutic uses and the risks of marijuana use
19 with regard to medical marijuana. This testimony
20 is one-half of that equation. You're now allowing
21 testimony as to the risk of using marijuana,
22 although it sort of comes in, I guess, under the

1 abuse, which I presume is relevant to diversion,
2 and I guess I'd like to talk a little bit about
3 that.

4 So two objections. One is that it allows
5 in evidence that Your Honor had previously excluded
6 and only one-half of that evidence, so that what's
7 now before Your Honor are only the risks, whether
8 it's medical use or otherwise, and not the other
9 side of that evidence, which would be the benefits
10 of medical use.

11 The second part of it is I understand, and
12 Mr. Bayly can correct me if I'm wrong, that his
13 notion is that this is relevant to diversion.
14 Maybe you should just be clear about that now. Is
15 that correct, Mr. Bayly?

16 MR. BAYLY: That's one reason for
17 admitting it, not necessarily the only one, but
18 yes, definitely.

19 JUDGE BITTNER: Okay. And the other or
20 others is/are? Reasons for admitting.

21 MR. BAYLY: As I recall, these were not--there was
22 a motion in limine filed by Respondent

1 and these were not rejected under that motion, but
2 there's a couple of reasons. Number one, it goes
3 to diversion, and number two, it goes to abuse, and
4 those issues are definitely on the table. I think
5 as with the case of the IOM report, Judge Bittner,
6 if some of these admissible exhibits do spill over
7 into the issue that marijuana as a herbal plant, or
8 any other form, I suppose, is good medicine and
9 should be rescheduled as Schedule I, then certainly
10 we would have to say that any and all exhibits are--can't
11 and shouldn't get into that issue.

12 MS. CARPENTER: Well, I guess similarly, I
13 would say that can't and shouldn't get into the
14 issue of that it is bad medicine and shouldn't be
15 used because of the risks, and that seems to be
16 exactly the point.

17 JUDGE BITTNER: Okay. First of all, let
18 me see if I can find what I did. This is all--well, in
19 theory, it's useful.

20 [Pause.]

21 JUDGE BITTNER: I have the Government's
22 objections. Where are Respondent's?

1 [Pause.]

2 JUDGE BITTNER: Okay. Let's see.

3 [Pause.]

4 JUDGE BITTNER: Well, I'm confused. This
5 is bad. We don't want me confused. The reason I'm
6 confused is the reference that I have to Government
7 Exhibit 41 was the Government's motion back in July
8 to file it two days late, which is not the issue we
9 have right now. Was there an objection to it back
10 then?

11 MS. CARPENTER: I don't--to them filing it
12 late?

13 JUDGE BITTNER: No, no, no. I'm just
14 saying that's the only reference I have. I didn't
15 mean to get off on a tangent here.

16 MS. CARPENTER: No, I don't think so. I
17 think this comes in from Your Honor's order back
18 in, what was it, July, where the Government had
19 moved to exclude much of our evidence and Your
20 Honor held that rescheduling was not before the
21 Court and so you were not going to hear evidence
22 about the therapeutic benefits or the risks of--

1 JUDGE BITTNER: The August 12 memo--

2 MS. CARPENTER: --medical use, and based
3 on that, we then talked to Mr. Bayly and to Ms.
4 Paredes and this is one of the documents that we
5 thought ought to be removed. They did not. I
6 think we then moved to exclude--did we include this
7 one in a motion to exclude?

8 MR. JACOBOWITZ: I thought we had.

9 MS. CARPENTER: But in any event--

10 JUDGE BITTNER: That's what I'm not
11 finding. It doesn't mean you didn't do it. I just
12 haven't found it.

13 MR. BAYLY: If I may hopefully add some
14 elucidation to this, what I'm looking at is
15 Respondent's motion to exclude some of the
16 Government's proposed testimony and exhibits. So
17 that was the Respondent's--

18 JUDGE BITTNER: And when was that? Do you
19 have a date on that?

20 MR. BAYLY: --and then, even better yet,
21 to find your order on that. But this--Respondent
22 filed the motion September 16, 2005.

1 JUDGE BITTNER: Oh, okay. Thank you.

2 MR. BAYLY: I know I filed a response.

3 JUDGE BITTNER: Yes. I was looking at the
4 August 12 ruling, which doesn't apply to this.
5 But, you know, I'm going to paper clip it.

6 MS. CARPENTER: Your Honor, I don't know
7 that we included this one.

8 JUDGE BITTNER: Okay.

9 MR. BAYLY: That's your order.

10 JUDGE BITTNER: Yes, it is.

11 MS. CARPENTER: That was Exhibit 41, and I
12 think Your Honor--right, and that's the one that
13 Your Honor limited, I believe, in your order.

14 JUDGE BITTNER: That's what I'm trying to
15 find.

16 MS. CARPENTER: Okay.

17 MR. BAYLY: I found it.

18 JUDGE BITTNER: Okay. What's the date,
19 since mine are filed by--

20 MR. BAYLY: November 8, 2005. It's
21 entitled--it should be a Memorandum of Accounts and
22 Ruling on Motion to Exclude Evidence. Yes, that's

1 it.

2 JUDGE BITTNER: Okay.

3 MS. CARPENTER: Page five of that order.

4 MR. BAYLY: Okay. So 41 was on the table--

5 JUDGE BITTNER: I'm sorry, what was the
6 date of it?

7 MR. BAYLY: November 8, 2005.

8 JUDGE BITTNER: Aha. Okay.

9 MS. CARPENTER: Page five, at the very
10 bottom.

11 JUDGE BITTNER: Okay. So what I said was
12 just that I would limit--I may as well quote
13 myself. Suppose Government Exhibit 41 discusses
14 both the risks of smoking marijuana and the extent
15 of use. I shall not exclude the article, but to
16 the extent it discusses risks, I conclude that it
17 pertains to whether marijuana has the potential for
18 use as medicine and shall not consider it. So I
19 will adhere to that.

20 I think that there is kind of a fine line
21 between risks and diversion, and I also don't think

1 that I'm in a position to draw that line now. I am
2 aware of it, and I know you will all brief it and I
3 know you will all tell me that I should consider
4 certain things and not consider other things
5 because of that line, wherever it may be.

6 MS. CARPENTER: Okay.

7 JUDGE BITTNER: So with that, I'll
8 overrule the objection to 40 and 41 with this
9 caveat. So 40 and 41 are received, finally.

10 [Government's Exhibits Nos. 40
11 and 41 were received into
12 evidence.]

13 MS. CARPENTER: Your Honor, I just have
14 one follow-up question to that. Then the risks--we
15 just want to understand for purposes so we're not
16 jumping up and down and objecting continuously.
17 But by diversion, Your Honor means the risk that
18 something will go out into the illicit market from
19 the manufacturing market, is that correct?

20 JUDGE BITTNER: No.

21 MS. CARPENTER: No?

22 JUDGE BITTNER: I think, and I may--since

1 I wasn't expecting this question, I may modify it,
2 but I think of diversion somewhat more broadly,
3 that a substance will be used for other than a
4 legitimate use, okay?

5 MS. CARPENTER: Okay.

6 JUDGE BITTNER: In other words, off the
7 top of my head, I would say that a consumer, for
8 example, an individual consumer who is prescribed a
9 narcotic for pain relief and who then continues to
10 use that drug after the pain is gone is diverting.

11 MS. CARPENTER: Okay.

12 JUDGE BITTNER: Okay?

13 MS. CARPENTER: And that's the sort of
14 diversion you're considering relevant for this
15 hearing, where you talk about a manufacturer of
16 something that's not--

17 JUDGE BITTNER: Well, you asked broadly
18 about what diversion is--

19 MS. CARPENTER: Right.

20 JUDGE BITTNER: --and I think my
21 definition of diversion--and there may be another
22 one someplace that I should be applying, I'd have

1 to look--is the use of any controlled substance for
2 other than a legitimate use. Note that I didn't
3 say legitimate medical use.

4 MS. CARPENTER: Okay. But it's the risk
5 of that happening and not the risk of--and not the
6 harm caused by that, because that's the reason it's
7 in the controlled substance in the first place.
8 I'm just trying to understand whether that includes
9 harm caused by that substance, which I think you've
10 excluded by your--

11 JUDGE BITTNER: If it's harm caused by--there's
12 risk and risk, I guess, and Dr. Voth knows
13 a lot more about this than I do--at least I hope
14 you do--that there's the harm that comes from--that
15 could come--potential for harm from using anything,
16 right? I mean, you take too much pain killer for
17 pain, you can have side effects and you could have
18 other issues. And then there's harm associated
19 with the non-legitimate use and what I'm trying to
20 do is draw that line, but I haven't gotten there
21 yet.

22 MS. CARPENTER: Then we'll just try and

1 draw it as we go.

2 JUDGE BITTNER: Yes. Now that I've
3 totally confused the issue, would you like to go
4 on, Mr. Bayly?

5 MR. BAYLY: At the risk of--

6 JUDGE BITTNER: Oh oh--

7 MR. BAYLY: --muddying up the waters, I
8 just want to put in a response to Ms. Carpenter's
9 concerns. And I think I should put this on the
10 record because we're going to get into this on our
11 brief, and I think, Judge, you should know, and
12 Respondent should know, too, where we're coming
13 from, and that is the problem is that somebody that
14 uses a drug legitimately, whether it's prescribed
15 by a physician or whether it's in a proper IND
16 study or any other legal circumstances, those drugs
17 have some kind of an effect. Of course, if the
18 persons use them outside of these legitimate
19 avenues, the drugs still have an effect. It's just
20 that the effects can be even worse if they're not
21 controlled by a limited or a lawful-type setting.
22 But the problem is, and this is why I think the

1 effects of marijuana or really any controlled
2 substance would be relevant because the effects are
3 going to occur in a diversion-type setting.

4 So, in other words, if an article talks
5 about toxic effects, say, of any drug, those toxic
6 effects may occur in a diversion context. They may
7 occur even in a legitimate medical setting where a
8 doctor has got some pretty weighty issues and has
9 got to weigh it on kind of a cost-benefit analysis.
10 So that's, I think, why we contend that maybe some
11 of these articles were relevant whereas maybe Your
12 Honor perhaps excluded them or Respondents argue
13 that, well, the effects should not be considered
14 because they're effects in a clinical or legitimate
15 context. For whatever that's worse, I just want to
16 get that on the record.

17 JUDGE BITTNER: That's the line I'm going
18 to have to draw.

19 MS. CARPENTER: Right.

20 JUDGE BITTNER: But I'm not drawing it
21 now.

22 MS. CARPENTER: I understand. Thank you.

1 JUDGE BITTNER: Okay.

2 MS. CARPENTER: The statute 823(a), you
3 know, it's in the context of manufacturing and it
4 says the DEA shall consider maintenance of
5 effective controls--this is the context of a
6 particular license--maintenance of effective
7 controls against diversion of particular controlled
8 substance, you know, the ones for which the license
9 will be granted. So I think it's getting very far
10 afield to say the fact that at one point, FDA may
11 make this into medicine and it may be usable and
12 somebody may misuse it, that's really an issue for
13 the FDA to decide at the point where they're
14 deciding whether or not it's going to be permitted
15 to be used as medicine. One of the things they'll
16 consider is what the risks are.

17 So I think looking that far down the road
18 and talking about the risks of that sort of use,
19 anybody else using it, and not looking at the risks
20 of diversion from the granting of this license, it
21 goes way beyond what the statute allows the DEA--

22 JUDGE BITTNER: Right, but there is also

1 the other--the catch-all phrase, and--

2 MS. CARPENTER: But--

3 JUDGE BITTNER: --I think, also, there is
4 the issue that the same harm, whatever that might
5 be, that might be incident to legitimate use could
6 also be a reason for illegitimate use. That's
7 where the line gets fuzzy.

8 MS. CARPENTER: Okay.

9 JUDGE BITTNER: I don't think I want to go
10 beyond that. So we're just going to have to leave
11 it where it is and I'll do the best I can. Okay.

12 MR. BAYLY: I think all these will be
13 briefed, so--

14 JUDGE BITTNER: I think the briefs will be
15 fascinating.

16 MR. BAYLY: The brief will be, I am sure,
17 a misnomer, but if I may continue, Your Honor,
18 questioning.

19 JUDGE BITTNER: Yes, please.

20 MR. BAYLY: Thank you.

21 BY MR. BAYLY:

22 Q Dr. Voth, based upon your experience and

1 education, have you studied and learned about
2 marijuana and its constituents?

3 A Yes, I have.

4 Q And based upon your experience and
5 education, have you studied and learned about the
6 physiological and psychological effects that
7 marijuana and its constituents has on a human?

8 A Yes, I have.

9 Q Have you testified in court as an expert
10 about marijuana before?

11 A Yes, I've testified not only in Federal
12 court, but some State courts, as well.

13 Q Roughly how many times have you testified
14 as an expert on marijuana?

15 A Maybe three or four or five, along in--three to
16 five times.

17 MR. BAYLY: All right. Your Honor, I now
18 want to move Government Exhibit 36 into evidence.

19 That's Dr. Voth's CV.

20 JUDGE BITTNER: Mr. Jacobowitz?

21 MR. JACOBOWITZ: No objection, Your Honor.

22 JUDGE BITTNER: Okay. Government's 36 is

1 received.

2 [Government's Exhibit No. 36
3 was received into evidence.]

4 MR. BAYLY: Based upon the CV and Dr.
5 Voth's testimony and the articles mentioned in the
6 CV and the two articles actually admitted, I'd like
7 to now request that the Court qualify Dr. Voth as a
8 medical expert in internal medicine and as an
9 expert in marijuana as it pertains to its effects,
10 abuse, and potential medical use on humans.

11 JUDGE BITTNER: Mr. Jacobowitz?

12 MR. JACOBOWITZ: Dr. Voth appears
13 qualified as an expert in these matters, but we
14 remain objecting that the potential effects on
15 humans of medical use of marijuana is not relevant
16 in this hearing. It's been excluded.

17 JUDGE BITTNER: Okay. We'll hope that I'm
18 consistent in my rulings. The question is whether
19 Dr. Voth is an expert, and I gather you don't
20 dispute that he is.

21 MR. JACOBOWITZ: I don't dispute that he's
22 an expert. I--

1 MR. BAYLY: Your Honor, if I may cut this
2 short, we tendered him as an expert on medical use.
3 We also tendered Dr. Voth as an expert on
4 marijuana's effects and abuse on humans. So let me
5 cut down the proffer here and offer Dr. Voth as an
6 expert in marijuana as it pertains to its effects,
7 abuse, and constituents on humans--well, effects,
8 abuse on humans, and its constituents. We won't
9 get into the medical use issue.

10 JUDGE BITTNER: Okay.

11 MR. JACOBOWITZ: No, Judge.

12 JUDGE BITTNER: Okay. Then you're still
13 an expert, Dr. Voth.

14 BY MR. BAYLY:

15 Q Dr. Voth, could you generally tell us,
16 what is a constituent?

17 A Well, in all drugs, whether they be plant
18 or otherwise, there are substances that constitute
19 the drug, and in marijuana's case, there are a
20 number of substances that have been identified in
21 the plant marijuana.

22 Q And can you generally tell us what

1 substances have been identified in the plant
2 marijuana?

3 A There are approximately 480-plus
4 substances. About 66 of those are cannabinoids, so
5 when I use the term "cannabinoids," I just want to
6 be clear that that means the substances that
7 resemble the major active ingredient Delta 9 THC,
8 or Delta 9 tetrahydrocannabinol. So in other
9 words, 66 cannabinoid-related substances and then
10 400-plus other substances that have been
11 identified.

12 Q All right. Why segregate the cannabinoids
13 from the 488 other substances identified?

14 A Well, primarily because they're
15 structurally related. They're very similar in
16 structure, but they're not identical.

17 Q You're talking about the cannabinoids?

18 A Cannabinoids, correct. The others, there
19 are groupings, but not the same in the
20 cannabinoids. They don't resemble the
21 cannabinoids. They're other things like tars and
22 that kind of thing.

1 JUDGE BITTNER: Do cannabinoids appear in
2 any other plant product--in any other plant, I
3 should say?

4 THE WITNESS: That's an interesting
5 question. I don't know the answer to that.

6 JUDGE BITTNER: Okay.

7 THE WITNESS: Interesting question,
8 though.

9 JUDGE BITTNER: I only get to ask one or
10 two a hearing.

11 THE WITNESS: It would seem reasonable
12 that they would. Off the top of my head, I can't
13 think, though, of others that they would exist in.

14 JUDGE BITTNER: Okay.

15 THE WITNESS: Naturally occurring, anyway.

16 JUDGE BITTNER: Right. Okay.

17 BY MR. BAYLY:

18 Q Dr. Voth, when you're talking about the
19 cannabinoids, the 66 cannabinoids, are you talking
20 about some of them being active as opposed to
21 inactive ingredients, or how would you characterize
22 that?

1 A Well, that's an interesting point, because
2 really, they've not all been studied in detail as
3 far as their activity. I mean, there's a sense
4 that there are certain ones that are more active
5 than others. Certainly Delta 9 THC, Delta 8 THC,
6 cannabidiol. The drug Sativex, for instance, works
7 with Delta 9 THC and cannabidiol. So there has
8 been some look at those. But to the best of my
9 knowledge, there's no one that said that one
10 through 66, certain ones absolutely are active and
11 certain absolutely aren't active. I think they
12 probably all have relative degrees of activity, is
13 the best way to put that.

14 Q But it's relative, then?

15 A Relative, yes.

16 Q How about the 488 other constituents? How
17 would you describe those in terms of active versus
18 inactive?

19 A Just to be clear, there would be
20 approximately 420, not that it makes any
21 difference, but just to be clear. That's again
22 another interesting question, because I'm unaware

1 that anyone has looked in detail at every one of
2 those. Many of them are the kind of things like
3 turpines and tars and et cetera that one has to be
4 concerned about activity, but I don't think that's
5 been well defined. Certainly, there's a lot of
6 similarity between tobacco smoke and marijuana
7 smoke. We know that tobacco smoke is very active.
8 So I guess that's a larger area of concern, what
9 happens in that mix of 400-plus other substances
10 that's sucked into people's lungs. Don't know.

11 Q But do some of these 420 other substances,
12 then, do you say they have some parallel active
13 activities similar to tobacco?

14 A Well, it's probable that there are
15 physiologic effects from them. Whether any of them
16 have any kind of intoxicating effects or mood
17 altering effects is less likely, but certainly
18 physiologic effects.

19 Q Now, you've already mentioned, I think,
20 one of the cannabinoid constituents. I think you
21 characterize it as one of the main ones, as Delta 9
22 THC. Do you recall that testimony?

1 A Yes.

2 Q All right. Can you tell us what the
3 effect of the--I'm just going to call it THC for
4 shorthand purposes, but what is the effect of THC
5 on a person in the short term?

6 A In the midst of that cough, did you say in
7 the short term?

8 Q Yes.

9 A So the acute effects, more or less, just
10 to be clear?

11 Q Yes.

12 A To the best of what I'm aware of, the
13 primary effect is a sense of intoxication, a sense
14 of feeling stoned. So to some extent, a change in
15 mood and those behaviors that go along with
16 intoxication, such as coordination, concentration,
17 short-term memory involvement, driving skill
18 abilities. Interestingly, dysphoria, panic
19 attacks, psychotic episodes can occur with that.
20 Some sedation. So in terms of--I guess those are
21 the effects that would most typically be associated
22 with some acute use.

1 Q Could you tell us some of the effects on
2 humans of THC in the long term? I guess I'd
3 characterize that as chronic use?

4 A Yes. With chronic use--well, one of the
5 big areas of concern is habituation or dependence,
6 and some refer to this as addiction, certainly
7 worsening of memory disorders, concentration
8 ability, short-term memory, increasing risk of
9 psychotic and other psychiatric disorders, for that
10 matter. And depending on age groups particular,
11 but especially in young people, productivity,
12 school performance, cognitive abilities, those kind
13 of things.

14 Q Dr. Voth, can a person suffer--is a
15 possible for a person to suffer an acute lethal
16 dose from ingesting too much THC from marijuana?

17 A No, it's not, because THC doesn't really
18 affect the brain stem and drugs that cause
19 overdoses that way, like alcohol and some of the
20 sedatives, will suppress the activity in the brain
21 stem and stop people's breathing, but marijuana
22 does not affect that part of the brain.

1 Q But what are some of the effects of a
2 person ingesting higher levels of THC from
3 marijuana just at one time, for example, compare
4 somebody who smokes a marijuana cigarette with just
5 four percent THC potency as opposed to a marijuana
6 cigarette that has THC potency of 15 percent.

7 A So you're talking about a roughly three-time--a
8 factor of three intensity. Well, certainly
9 the high, the intoxication potential, is greater.
10 I would say the risk of dysphoria is certainly
11 greater. Panic attack, certainly greater.
12 Clearly, coordination, driving skills. One effect
13 that I had failed to mention earlier is the effect
14 on heart rate, heart rate being increased. I can't
15 honestly say that I'd be aware of studies that
16 looked specifically at changes in heart rate
17 relative to concentration. Theoretically, perhaps.
18 But I think that would pretty well encapsulate it.
19 Essentially, any effect at a low dose is enhanced
20 at a three times or three-fold factor higher dose.

21 Q Dr. Voth, what would one potential--let me
22 rephrase the question here. Would one potential

1 benefit of marijuana be that if one smokes a higher
2 level of THC, then wouldn't that person need to
3 smoke less of the carcinogen constituents in
4 marijuana in order to get, quote, "high"?

5 MR. JACOBOWITZ: Objection, Your Honor.

6 JUDGE BITTNER: Grounds?

7 MR. JACOBOWITZ: This goes directly, I
8 think, to the medical effects. We are speaking now
9 of the carcinogenic effects. This goes directly to
10 side effects as a medical use.

11 JUDGE BITTNER: Overruled, but if I decide
12 I was wrong, I won't consider it.

13 MR. BAYLY: For the record, I'm talking
14 about and I asked specifically about abuse, so
15 that's the--

16 JUDGE BITTNER: Okay.

17 BY MR. BAYLY:

18 Q Do you want me to repeat the question?

19 A No, I think I understand it. The real
20 question would be--

21 MR. JACOBOWITZ: Objection to a lack of
22 foundation, also, I think, about carcinogenic

1 effects.

2 JUDGE BITTNER: Would you rephrase the
3 question, Mr. Bayly?

4 BY MR. BAYLY:

5 Q We can back up here. In smoking
6 marijuana, are there carcinogenic effects from
7 that?

8 A Well, there are certainly carcinogens that
9 are inhaled. There is concern in the literature
10 about damage to the lungs and airways. There is
11 some conflict in the literature about whether there
12 is actually a causality for lung cancer, mouth
13 cancer, that kind of thing. So yes, carcinogens
14 are inhaled. What happens with those carcinogens
15 is hard to say for sure. There is certainly
16 irritation in the airways, certainly things like
17 bronchitis and airway changes and all of that.

18 Now, relative to carcinogens, one has to
19 consider what effect you're talking about. If it's
20 to become intoxicated, the literature has actually
21 looked at this and not found a consistent pattern
22 in the use of a higher drug--the use of a higher

1 THC concentration and inhaling less, necessarily,
2 and that's only relative to intoxication.

3 Now, you're talking about a three times
4 higher concentration and I don't think that's been
5 studied nor looked at. But for lower
6 concentrations, the literature has been very
7 inconsistent in that regard. In other words,
8 whether a user would smoke less just because it's
9 stronger. A user may very well smoke more because
10 he's getting more stoned, or smoke differently. So
11 it's very inconsistent as to what's actually seen
12 in the literature. Relative to your specific
13 question of four percent versus, I think you said
14 15 percent, I don't know, and I don't think that's
15 been defined in the literature.

16 Q All right. But let me ask you just
17 generally, Dr. Voth. What is tolerance?

18 A Tolerance is more or less a biochemical
19 process and a brain process that the user develops
20 an ability to be exposed to a dose of any medicine,
21 narcotic or whatever, marijuana, to be exposed to
22 that at increasing levels without experiencing a

1 side effect from it, particularly the intoxication
2 side effect. An example would be alcohol. A
3 person who drinks a significant amount can, quote,
4 "hold their alcohol" better than a person who
5 doesn't. The same way with narcotics. Marijuana
6 is very much the same.

7 Q Can this phenomena of tolerance, as you've
8 described it, occur with the THC in marijuana?

9 A Certainly it can, yes.

10 Q Do you, in your expertise, Dr. Voth, make
11 any distinctions between marijuana in its herbal
12 plant form and its constituents?

13 A I'm not sure I understand that question.

14 Q Okay. Is there a difference between the
15 plant marijuana and the isolated individual
16 constituents?

17 A Oh, absolutely, because the plant
18 marijuana, of course, has that milieu of 400-plus
19 substances, 66 cannabinoids, and the individual
20 constituents are just that, individual
21 constituents--Delta 9 THC, Delta 8 THC, et cetera.

22 Q Dr. Voth, in terms of the abuse of

1 marijuana, what is the common form of marijuana
2 that is abused? Is it the plant material itself or
3 is it any of its constituents?

4 A Well, the most common abuse is with the
5 plant form. In fact, I have not been able to
6 determine any significant abuse listed out there
7 for Drabinol or Marinol, which would be the only
8 prescribable form of Delta 9 THC available on the
9 market, that I'm aware of--in the U.S., anyway.

10 Q Right now, let's turn to another subject.
11 Dr. Voth, are you familiar with a product called
12 Sativex? I'm going to spell that for the record
13 and the court reporter. That's S-a-t-i-v-e-x.

14 A Yes, I am familiar with it.

15 Q Okay. Can you tell us what your
16 understanding of what this product is, generally?

17 A To the best of my knowledge in regards to
18 Sativex, it's been a highly hybridized and worked
19 on product that has created a hybrid so that Delta
20 9 THC and cannabidiol are in pretty much a one-to-one ratio
21 rather than the very low ratios seen
22 typically in leaf marijuana as we know it.

1 Q I just want to back up to get some other
2 information about it before we get into more
3 details on that subject, Dr. Voth, and ask you, are
4 you aware of who is the manufacturer of this
5 product?

6 A I believe G.W. Pharmaceuticals is the
7 manufacturer of it.

8 Q And are you aware of how this product is
9 administered?

10 A I believe they have an inhaler--well, the
11 substance is more or less extracted and refined and
12 then administered via a small inhaler.

13 Q Are you aware in what country or countries
14 that Sativex is marketed a lawful prescription
15 medicine?

16 A To the best of my knowledge, I think that
17 Canada is the only one where it's readily legally
18 available at this point.

19 Q Can you tell us what the difference is
20 between the crude plant marijuana and Sativex?

21 A Well, quite a few things, really. The
22 biggest one is that there is a difference between

1 the THC and cannabidiol ratios. G.W., in their
2 research, has found that this one-to-one ratio of
3 Delta 9 THC to cannabidiol is more effective for
4 the things that they're using it or suggesting it
5 to be used for than the higher Delta 9 and very low
6 cannabidiol concentrations.

7 The other difference is that, well,
8 marijuana, of course, is marijuana. It's got all
9 of the other substances associated. What I am not
10 clear on is how much of that other mix of stuff,
11 we'll call it, the other 400-plus substances is
12 represented in Sativex when it's extracted, and I
13 don't--I haven't seen good data as to what all is
14 in that. So there is probably some difference
15 between that and leaf marijuana, but I can't recite
16 to you the differences exactly. I think that may
17 be one of the failings, unfortunately, of Sativex,
18 too, is that there's this sort of unknown stuff
19 that hasn't been clearly defined.

20 Q Well, when you say "stuff," are you
21 referring back to the cannabinoids or are you
22 referring back to the other 400-and-so

1 constituents?

2 A All substances, because I have not seen a
3 clear definition of what other cannabinoids are
4 present, what their activities are, and what of the
5 other 400-plus substances exist and what their
6 activities are, and that's probably, if I were
7 guessing, why it's having difficulty in the U.K.--

8 MR. JACOBOWITZ: Objection.

9 JUDGE BITTNER: Sustained.

10 BY MR. BAYLY:

11 Q Are you familiar with a product called
12 Marinol?

13 A Yes, I am.

14 Q Have you ever used it in your practice,
15 Dr. Voth?

16 A I have occasionally, yes.

17 Q Do you know what it's made from?

18 A It's a synthetic form of Delta 9 THC
19 called Drabinol.

20 Q Any other constituents in it?

21 A There are inert constituents, but I
22 believe it's all Delta 9.

1 Q Okay. And what is Marinol designed to do
2 in terms of treatment?

3 A Its primary indications are for appetite
4 enhancement and nausea, and there is some use now
5 for nursing home patients in agitated states and
6 also to stimulate appetite in cachexia or people
7 that are not eating well in nursing homes.

8 Q Is there a benefit medically of smoking
9 marijuana over the oral administration?

10 A I've certainly never seen any, I mean,
11 benefit-wise. The only potential benefit-wise
12 might be the rapidity in absorption. However, that
13 has some downside to it, too.

14 Q Dr. Voth, does smoking marijuana lead to
15 problems with the harshness on the throat and
16 lungs?

17 A Certainly, it does.

18 Q Would such problems be related to the
19 amount of THC or the potency of the THC in the
20 marijuana?

21 A Not necessarily. It's really just due to
22 the fact that it's a smoked substance, that there

1 is a lot of irritant in that smoke.

2 Q Would such problems be related to the
3 amount of stems and seeds in the marijuana?

4 A I think there is old street rumor about
5 being down to seeds and stems again, but I've never
6 seen anything systematic that said that seeds and
7 stem constituents necessarily cause greater or less
8 irritation.

9 MR. BAYLY: Your Honor, I'd like to
10 request that the witness be handed--I think it's
11 Respondent's Exhibit 92A. That's the entitled,
12 "Guidance for Industry: Botanical Drug Products."
13 I want to make sure that's right for the record.

14 JUDGE BITTNER: I'm sorry, Government--did
15 you say Respondent--

16 MR. BAYLY: Is it Government?

17 JUDGE BITTNER: Well, it's not Respondent
18 92.

19 MS. CARPENTER: No.

20 MR. BAYLY: Okay, it's Government 92.

21 [The document was shown to the witness.]

22 BY MR. BAYLY:

1 Q Dr. Voth, now that we've cleared that up,
2 you've got Government Exhibit 92A?

3 A Yes, I do.

4 Q Please turn to page 21.

5 A I'm at page 21.

6 Q I'd like you to go down toward the bottom
7 of the page, but you should see four bullets, four
8 paragraphs.

9 A Yes, I see them.

10 Q All right. Third from the bottom, it
11 starts out, "The quantitative description
12 (strength) of the drug substance." Can you read
13 that entire paragraph to yourself, please, and let
14 us know when you have looked at that paragraph.

15 [Pause.]

16 THE WITNESS: Okay, I've read it. Yes.

17 BY MR. BAYLY:

18 Q All right. And how would this paragraph
19 relate to marijuana as a botanical?

20 A Well, it would say that with the known
21 ingredients, in other words, we've got 400-plus
22 substances and we have a pretty good sense what

1 they are and we know that they're measurable, the
2 amount--it says in this, the amount in which they
3 are present in the botanical should be declared,
4 and for a multi-herb substance, should be declared
5 in terms of relative ratio of the individually
6 processed botanical drug substances. So in other
7 words, relative to marijuana, Delta 9 THC and Delta
8 8, cannabidiol, blah, blah, blah, that should be
9 clearly delineated and, let's see, I think that's
10 pretty much all it would say. So, essentially,
11 you've got to know what's in your botanical and
12 what its ratios are.

13 Q In terms of the marijuana herbal or plant
14 material, is its chemistry, in your opinion, known
15 and reproducible?

16 A Well, I think the chemistry is known, but
17 it's reproducible is a very, very difficult
18 question. I don't think that the chemistry in
19 marijuana is easily reproducible. Again, you've
20 got 488 substances that have to be clearly
21 reproduced and defined in a predictable manner to
22 fulfill these criteria. So yes, the chemistry is

1 defined, but reproducible, it is not.

2 Q I'd like you to turn to page 22--

3 A Okay.

4 Q --of this Government Exhibit 92 here, the
5 botanical guidelines.

6 A I'm there.

7 Q Please look at the three paragraphs under
8 "Appearance." It's about in the middle of the
9 page. Do you see where I'm talking about?

10 A Yes, I do.

11 Q If you would look at paragraph one, it
12 starts, "Chemical identification by spectroscopic
13 and/or chromatographic fingerprints," and just read
14 that paragraph to yourself, please, and let us know
15 when you have completed reading that.

16 A I want to be sure which one you want me to
17 read. Everything under "Appearance"?

18 Q Just the first paragraph. It ends, "two-
19 dimensional--TLC and gas chromatography."

20 A Okay.

21 [Pause.]

22 THE WITNESS: Okay. I've--

1 BY MR. BAYLY:

2 Q All right. Can you tell us how marijuana
3 relates to this paragraph?

4 A Well, essentially, it would say that a
5 marijuana specimen would need to undergo these
6 chemical identification processes to see exactly
7 what's in it, exactly the constituents and they
8 need to be characterized and defined, in other
9 words.

10 Q Now, I'd like you to look at the second
11 paragraph. It starts, "Chemical assay--"

12 A Right.

13 Q --and it ends, "amounts should be
14 defined." Do you see that paragraph?

15 A Yes.

16 Q If you'd please read that and then just
17 let us know when you've completed reading that.

18 A Sure. I've read it.

19 Q How does plant marijuana relate to this
20 paragraph?

21 A Well, again, per their last comment, when
22 multiple active constituents or markers are known,

1 they should be chemically characterized and their
2 relative amounts should be defined. So with
3 marijuana, 400-plus substances, those need to be
4 defined, marked, characterized, and the amount of
5 them need to be present, and especially in light of
6 the fact that from growth to growth, grower to
7 grower, those are going to change, that could be a
8 fairly--that's quite a process. Just a
9 parenthetical comment, but it's 400-plus
10 substances.

11 Q And then, Dr. Voth, I want to refer you to
12 the last paragraph. It starts, "Biological assay,"
13 and ends with, "should be performed." Please read
14 that and then let us know when you've done.

15 A Yes, I have.

16 Q And how does marijuana in its plant form
17 relate to this paragraph?

18 A Well, it particularly relates to the
19 second sentence, which says if the botanical drug
20 substance is considered potent, toxic, addictive,
21 or has abuse potential, an assay for biological
22 activity and/or a chemical assay for the active

1 constituents should be performed. So at least the
2 cannabinoids in that regard.

3 Q Now, Dr. Voth, I want to ask you to please
4 turn to page 24 of Government Exhibit 92A,
5 Botanical Guidelines.

6 A Yes, I'm there.

7 Q Again, we're down toward the middle of the
8 page under, you see "Appearance," and then it's
9 three paragraphs down. Let me identify that for
10 you. The paragraph starts, "Biological assay (when
11 the active chemical constituents are not known or
12 quantifiable)." How does the plant marijuana
13 relate to this one phrase, whether the active
14 chemical constituents are not known or
15 quantifiable?

16 A Well, that's very similar to that last one
17 that we reviewed. In other words, when there's a
18 segment of the chemistry that we really don't know
19 necessarily what they are, but yet the drug itself
20 is potent, addictive, abuse potential, then there
21 needs to be biological activity and chemical assay
22 for the active constituents. So certainly that

1 relates to marijuana. It's toxic, addictive, and
2 has abuse potential, so therefore there needs to be
3 biological activity and chemical assay for those
4 active constituents.

5 MR. BAYLY: That's all for now.

6 JUDGE BITTNER: Dr. Voth, if you know, can
7 something be addictive and not have abuse
8 potential?

9 THE WITNESS: Well, by definition, really,
10 if you're talking about addictive, dependence
11 formation, virtually every substance that I can
12 possibly think of that would have dependence
13 potential would also have abuse potential, and that
14 would cross into narcotics and virtually any other
15 drug I could possibly think of.

16 JUDGE BITTNER: But something could have
17 abuse potential but not be addictive?

18 THE WITNESS: I'd say they go very hand-in-glove.
19 Now, whether a person--no, I think
20 they're very hand-in-glove. I think a person can
21 abuse a drug and not necessarily become dependent
22 upon it, but having become dependent upon it,

1 certainly, that drug can be abused, also. If you
2 want me to go on, I mean, I could give you some
3 examples, because that's really a much broader
4 answer than it might seem.

5 JUDGE BITTNER: Yes, please.

6 THE WITNESS: Narcotics, for instance, may
7 not be abused at all, but they are very dependence
8 forming. However, they certainly can be abused and
9 that's a great area of misunderstanding in the pain
10 management world right now, is if a person takes a
11 certain high dose, are they taking it because their
12 body is physically dependent on needing that
13 medicine for its therapeutic effects, yet they are
14 not actually abusing the drug. So they are
15 somewhat hand-in-glove, but they are not
16 necessitating of each other.

17 JUDGE BITTNER: Okay. Mr. Bayly?

18 MR. BAYLY: I have no follow-up, Your
19 Honor, and I am done with direct.

20 JUDGE BITTNER: Oh, okay. I thought you
21 were just done with that one exhibit. I was all--okay. Mr.
22 Jacobowitz? Do you want a short break?

1 MR. JACOBOWITZ: We would like a short
2 break, please.

3 JUDGE BITTNER: Ten minutes. Off the
4 record.

5 [Recess.]

6 JUDGE BITTNER: On the record.

7 MR. BAYLY: Judge Bittner, I just want to
8 make one quick scheduling announcement. I just got
9 cell phoned here. Fortunately, it was before we
10 were on the record, but right before. Dr.
11 Auslander's train should get him in here so that he
12 should be at DEA headquarters by 1:15.

13 JUDGE BITTNER: Okay. Mr. Jacobowitz?

14 MR. JACOBOWITZ: Thank you.

15 CROSS EXAMINATION

16 BY MR. JACOBOWITZ:

17 Q Dr. Voth, as regards reproducibility,
18 would you agree that the primary factors that
19 control the cannabinoid content of marijuana, of
20 marijuana plant, are genetics and environmental
21 influences?

22 A I think that's fairly stated, yes.

1 Q Environmental influences would include
2 such things as light and heat and nutrition,
3 humidity?

4 A Correct, yes.

5 Q And, in fact, also potency can be
6 affected, as well, by the stage of growth, I
7 believe?

8 A Yes, that's correct.

9 Q And also by the specific plant part used,
10 that leaves from one part of a plant will be
11 consistently higher in THC and perhaps in other
12 cannabinoids than leaves from another part of the
13 plant?

14 A It is possible, yes.

15 Q Also, there are hundreds of different
16 strains of cannabinoids with different genetic
17 qualities--sorry, of marijuana, I mean to say?

18 A I believe that's correct, yes.

19 Q Now, you referred to, I believe, to
20 studies showing great variation in marijuana. Do
21 you know that those studies did control for each
22 one of those separate variables?

1 A Well, I think my comment was really more
2 to your prior question along that line of the
3 different variant species, et cetera. I mean,
4 there's a broad spectrum of THC content and
5 certainly percentage content of the various
6 cannabinoids and things. So I don't know that any
7 specific studies that was looking at that was
8 necessarily controlling those variables. No,
9 specifically to your question. But I think my
10 point was really more to the issue of you can't
11 just say, quote, "marijuana." I mean, you're
12 really referring to a very broad representation of
13 plants.

14 Q Now, are you familiar with the term
15 "vegetative propagation"?

16 A Yes. I mean, I've heard it. I'm not sure
17 I can give you a definition of it, but go ahead.

18 Q Do you know of plant cuttings, growing a
19 plant from cuttings?

20 A Yes, I do.

21 Q Now, would you be satisfied to call
22 growing a plant from cutting vegetative

1 propagation?

2 A I don't know that I have the botanical
3 expertise to say one way or the other, honestly. I
4 wouldn't necessarily comment one way or the other,
5 no.

6 Q Are you aware that a plant grown from a
7 cutting is genetically identical to the parent
8 plant?

9 A Well, it certainly makes sense, yes. It's
10 like a stem cell phenomenon, more or less.

11 Q So a grower could grow genetically
12 identical plants rather than genetically varying
13 plants if he grew from cuttings?

14 A Theoretically, I'd have to say that would
15 be correct, yes.

16 Q And are you aware of Dr. Craker's
17 application to--

18 MR. BAYLY: Objection; out of the scope.

19 MR. JACOBOWITZ: I think it's what the
20 entire hearing is about. I think all of his
21 comments are related to Dr. Craker's application.

22 JUDGE BITTNER: Right, but that's not the

1 issue. Sustained.

2 BY MR. JACOBOWITZ:

3 Q Have you seen Dr. Craker's application?

4 MR. BAYLY: Same objection.

5 JUDGE BITTNER: Sustained.

6 BY MR. JACOBOWITZ:

7 Q Could a grower of marijuana grow his
8 plants in a greenhouse or a growth room or an
9 environmental chamber?

10 A In a theoretical sense, yes. That's
11 frequently how marijuana is grown, whether legally
12 or illegally.

13 Q In such an enclosure, environmental
14 factors could be tightly controlled?

15 A I believe that that's certainly viable,
16 yes.

17 Q Just a moment.

18 [Pause.]

19 BY MR. JACOBOWITZ:

20 Q In general, plants are not of a single
21 chemical compound, are they?

22 A Are we talking about botany in general, or

1 marijuana--

2 Q Botany in general, if you know, plants--

3 A Well, most plants have many chemicals in
4 them, yes.

5 Q Possibly many hundreds of chemicals even?

6 A Certainly. I mean, that's what we see
7 with marijuana, of course. Right.

8 Q And turning your attention, if I may, to
9 Government's Exhibit 92A, which you discussed on
10 direct--

11 [The document was shown to the witness.]

12 BY MR. JACOBOWITZ:

13 Q Now, if you could look to page two, to the
14 second paragraph under the heading "Background"--

15 A It starts, "For the purposes of this
16 document," is that correct?

17 Q Mm-hmm.

18 A Okay.

19 Q And it continues, the term botanicals
20 includes plant materials.

21 A Yes.

22 Q And turning to page one, under

1 "Introduction," that first paragraph, if you could
2 look at that.

3 A I'm on page one.

4 Q Page one indicates that this will provide
5 guidance for submitting what are called INDs,
6 Investigational New Drug applications, for, among
7 other things, botanicals.

8 A Yes.

9 Q And that is the term defined as including
10 plant material?

11 A That's correct.

12 Q So this guidance, then, would go to
13 submitting INDs for materials that include hundreds
14 of chemical compounds, possibly, or certainly more
15 than one or a couple?

16 A Well, first of all, I've only seen this
17 this morning. It's my--I'm assuming by botanical
18 compounds we're talking about plants, as we've
19 mentioned, and as we've also discussed, plants may
20 contain hundreds of compounds. So I think my
21 answer to your question is yes.

22 Q Now, if you could turn to page nine, at

1 the first paragraph under the italicized list--

2 A It starts, "Section 312"?

3 Q Exactly. Now, do you see the sentence
4 that begins, "A sponsor need not differentiate the
5 clinical effects of each molecular entity--"

6 A Yes, I do.

7 Q "--in a botanical product"?

8 A Right.

9 Q And that sentence says that the sponsor
10 does not need to make clear which effects are
11 caused by exactly which of each separate molecular
12 entity in a botanical product for purposes of
13 submitting the IND, is that right?

14 A Specifically, it says a sponsor need not
15 differentiate the clinical effects of each
16 molecular entity in a botanical product derived
17 from a single part of a plant, okay.

18 Q And if you could also go on and tell me
19 what the next sentence indicates.

20 A Even where the components of a combination
21 product must be studied under the statute, initial
22 control studies could be used to evaluate the

1 entire combination product.

2 Q By combination product, that would mean
3 the combination compounds of botanical material?

4 A I think that's a fair assumption.

5 Q Now, you read earlier, I believe, from
6 pages 21 and 22, and just to make clear, could we
7 look at page 19, the beginning of the section in
8 which those pages appear.

9 A Page 19, Section 8, is that correct?

10 Q Mm-hmm.

11 A Okay.

12 Q And this is the section for Phase I and
13 Phase II clinical studies for non-marketed
14 botanical products and products with known safety
15 concerns?

16 A That is correct, yes.

17 Q And as you discussed before, this section
18 specifically discusses marijuana as such a
19 compound?

20 A I don't believe it specifically named
21 marijuana.

22 Q If you could look at page 24, I believe we

1 discussed this paragraph on direct.

2 A --marijuana, sure enough. Okay.

3 Q And at page 22, also a section you were
4 looking at on direct, I believe.

5 A Yes, I'm on page 22.

6 Q The fourth indented paragraph.

7 A That says "Chemical Assay"?

8 Q "Biological Assay."

9 A "Biological Assay," okay.

10 Q And that also specifically refers to
11 marijuana?

12 A It gives as an example marijuana, yes,
13 ephedra marijuana. Right.

14 Q Now, when you were discussing that
15 paragraph earlier--I may be confusing it actually
16 with the nearly identical paragraph on page 24, so
17 I hope this will apply to both of these very nearly
18 identical paragraphs--I believe you indicated that
19 the requirement may only apply to the cannabinoids?

20 A No, I don't think so. I think I was
21 giving the cannabinoids as an example. In other
22 words, one of the things that might be looked at

1 would be a biological assay of what cannabinoids
2 and what their concentrations were, for instance,
3 and that was more of an example, I think, than my
4 interpretation of statute or of the statements.

5 Q Are there inactive--I'm sorry. Let me go
6 back. This paragraph and the one on page 24, the
7 ones you discussed from these two pages, discuss
8 active constituents?

9 A I believe they do. To the best of my
10 recollection, I believe they do. I'm not sure
11 where it's specifically stated, but nonetheless--

12 Q Well, let's take a look. On page 22, that
13 paragraph beginning, "Biological Assay," could you
14 look at just the last, say the last clause of the
15 last sentence, an assay for biological activity?

16 A For the active constituents, right.

17 Q And on the paragraph just before that,
18 could you read the first sentence of that
19 paragraph?

20 A "Chemical assay for active constituents
21 were characteristic markers," right.

22 Q Now, are there such things as inactive

1 constituents of plants?

2 A Oh, certainly there are, mm-hmm.

3 Q Are there inactive constituents of the
4 marijuana plant?

5 A I would assume there are, and there are
6 different types of activities of the active
7 constituents. In other words, psychoactive,
8 physiologically active, inactive, et cetera. So
9 there are a whole host of those things.

10 Q So not every one of the 420 or 480
11 compounds in marijuana would have to be--would be
12 covered by these two paragraphs, which refer to
13 active constituents?

14 A That's a reasonable assumption. The
15 problem is, unfortunately, knowing which are active
16 and which are inactive, and that's kind of a
17 difficult question. I mean, there's psychoactive,
18 there's physiologically active, and then there's
19 inactive, and I don't think that's been well
20 defined. There's certainly a lot of substances
21 that need to be looked at and defined.

22 Q More research would be needed?

1 A Yes.

2 Q And that's a determination that the FDA
3 would make under this guidance if an application
4 were submitted under this--

5 A I assume they would. I can't speak for
6 them, but I don't know. I would assume they would
7 make that determination.

8 MR. JACOBOWITZ: Now, could the witness be
9 given a copy of Respondent's Exhibit No. 54.

10 JUDGE BITTNER: Are you through with
11 Government 92A?

12 MR. JACOBOWITZ: I believe we are. Thank
13 you.

14 JUDGE BITTNER: And so you believe not?

15 MR. JACOBOWITZ: I believe we are.

16 JUDGE BITTNER: Just trying to figure out
17 what books I can close up.

18 BY MR. JACOBOWITZ:

19 Q Dr. Voth, let me ask you, I had the
20 impression from your testimony about
21 reproducibility that it is your understanding that
22 marijuana is not chemically reproducible. I

1 believe you testified to that.

2 A If that's--well, I don't think that's
3 exactly what I said. I said reproducibility is a
4 difficult part, making a substance always
5 reproducible in the same percentages, the same
6 constituent states, et cetera, because there's a
7 lot of substances herbally and botanically to
8 reproduce.

9 Q But not impossible?

10 A It's not impossible, no.

11 Q And the FDA would be open to considering
12 whether marijuana is reproducible?

13 A Beats me.

14 MR. BAYLY: Objection, Your Honor. First
15 of all, there's a lack of foundation. Secondly,
16 Dr. Voth has already testified he can't speak for
17 them, and indeed, he can't. He is a private
18 doctor. So I definitely think he's not qualified
19 or should answer that question.

20 MR. JACOBOWITZ: I believe he's testified
21 as to what the FDA guidance suggests to him and
22 what it means.

1 JUDGE BITTNER: Ask him if he knows, Mr.
2 Jacobowitz.

3 BY MR. JACOBOWITZ:

4 Q Do you know whether the FDA would consider
5 marijuana a reproducible substance for these
6 purposes?

7 A I have no idea. I have had no
8 communications with them, nor would I guess.

9 Q But you have no reason to believe that
10 they would not do so, would not consider it?

11 A I have no reason to believe either way. I
12 mean, I've seen nothing in either regard.

13 Q Are you familiar with the, what are called
14 Drug Master Files?

15 A Vaguely. I mean, I know that they exist,
16 but I really don't know a heck of a lot about them.

17 Q Are you aware that the Drug Master Files
18 are filed with the FDA as a part of applying for
19 Phase I or Phase II clinical trials?

20 A That wouldn't surprise me, no.

21 Q Are you aware that Dr. Elsohly of the
22 University of Mississippi has filed such a Drug

1 Master File for marijuana with the FDA?

2 A I don't believe I was aware of that, no.

3 Q Are you aware that the FDA has approved
4 Phase II clinical trials for Dr. Elsohly based on,
5 among other things, this Drug Master File?

6 A I have no knowledge one way or the other
7 in that regard, no.

8 Q You are unaware of Dr. Elsohly's medical
9 trials with marijuana? I'm sorry, of any Phase II
10 clinical trials with marijuana?

11 A No. I think it was specific to Elsohly.
12 I'm unaware that he's filed and I'm unaware that
13 there's any such master file at the FDA for
14 marijuana. I'm not sure--I mean, I just am
15 unaware.

16 Q Going to Sativex, would it be correct to
17 say that you're skeptical of the concept of whole
18 plant use as a medication?

19 A Yes. I think that's a fair statement.

20 Q But it's--these are herbal remedies of the
21 sort we used before we progressed to modern
22 medicine.

1 A Well, certainly not Sativex. Sativex is
2 probably a generation beyond that. I do think,
3 relative to marijuana, that that is sort of a
4 throwback to the days of herbal remedies and
5 witches' brews, yes.

6 Q Would that apply to other plant compounds,
7 as well, well, to other plant products, I guess I
8 should say?

9 A That's an awfully broad question. I mean,
10 there's a lot of things in medicine that have plant
11 origins that we use on a regular basis.

12 Q St. John's Wort, for example.

13 A St. John's Wort, sure.

14 Q That could be used as a medication?

15 A I'm aware that some people do that, yes.

16 Q It is prescribed in some countries as a
17 medication?

18 A I believe it is, yes.

19 Q And it is a whole plant product?

20 A That's correct.

21 Q Just a moment. I'm sorry.

22 [Pause.]

1 BY MR. JACOBOWITZ:

2 Q Are you aware that the DEA recognizes that
3 the interaction among cannabinoids in marijuana may
4 be a critical factor in how marijuana affects the
5 body and the brain?

6 A I'm not sure that I have any opinions
7 about what the DEA is or isn't aware of. I--if
8 there's a specific thing you'd like me to comment
9 on, I'd be happy to do that.

10 Q I'm sorry. Just a moment, please.

11 [Pause.]

12 MR. JACOBOWITZ: Could the witness be
13 given Government Exhibit 25?

14 MR. BAYLY: I just want to confirm, Your
15 Honor, that for the record, I don't believe this
16 was admitted, is that correct?

17 MS. CARPENTER: That was one of the things
18 withdrawn yesterday.

19 MR. JACOBOWITZ: Oh--

20 JUDGE BITTNER: Let me look. Hold on.

21 MR. BAYLY: Yes, I believe that's--

22 MR. JACOBOWITZ: Then by all means, don't

1 give the witness Government Exhibit 25.

2 JUDGE BITTNER: Let me just double-check,
3 since I, in theory, kept detailed notes of all of
4 these things. We're about to test that premise.
5 Yes, it was withdrawn on Wednesday.

6 BY MR. JACOBOWITZ:

7 Q Are you aware that researchers who wish to
8 use controlled substance in the research must apply
9 to the DEA for a registration number permitting
10 that?

11 A Yes, I'm aware of that fact.

12 Q And specifically if they wish to conduct
13 research on a Schedule I substance, they must
14 submit a written application with the protocol of
15 the study?

16 A Yes, I'm aware of that fact.

17 Q And is it correct that such an application
18 will describe exactly how much of the substance
19 they want and in what dosage they will apply it?

20 A I've not actually read the requirements
21 for that. I have a general sense that that is
22 correct, but I've never actually read any

1 regulations in that regard.

2 Q Are you aware that the application must
3 also state for the DEA's consideration the security
4 precautions to be used in the study to guard
5 against diversion?

6 A Again, I have a general awareness of that
7 fact, but I have not specifically read it nor been
8 aware of regulations in that regard.

9 Q Are you aware that manufacturers, as well,
10 must submit an application to the DEA to
11 manufacture bulk drug products that are on Schedule
12 I?

13 A I believe that's correct, yes.

14 Q And manufacturers also must take security
15 precautions against diversion?

16 A To the best of my recollection and
17 knowledge, yes.

18 Q As an expert in drug abuse, do you think
19 that the DEA fulfills its duty in ensuring the
20 safety of controlled substances that are used in
21 such research programs?

22 MR. BAYLY: Objection. There's a scope, a

1 foundation, and it's kind of unclear where the
2 question is going to.

3 JUDGE BITTNER: Sustained. I'm not sure
4 that being an expert in drug abuse necessarily
5 leads to knowledge of whether DEA controls
6 diversion in research, plus I think this goes
7 beyond the scope of direct.

8 MR. JACOBOWITZ: We may get to scope a
9 little more.

10 JUDGE BITTNER: Okay.

11 BY MR. JACOBOWITZ:

12 Q Are you aware of the University of
13 Mississippi's cannabis cultivation program?

14 A Yes, I am.

15 Q And that it cultivates and supplies
16 marijuana for research purposes?

17 A Yes, I am aware of that.

18 Q Are you aware that its cultivation site is
19 an outdoor site?

20 A Is a--

21 Q Is an outdoor site?

22 A Yes, I am aware of that.

1 Q Are you aware that it employs temporary
2 workers, not permanent staff, sometimes for tenting
3 and harvesting?

4 MR. BAYLY: Objection. This is getting
5 out of the--definitely out of the scope of the
6 direct. I don't think the witness on direct ever
7 testified about Dr. Elsohly or any other cultivator
8 or manufacturer of marijuana.

9 MR. JACOBOWITZ: I wasn't going to go too
10 far more with this. I had one more question.

11 JUDGE BITTNER: I'll provisionally allow
12 it, but I might end up not considering it. I'll
13 change my ruling. Overruled, sort of.

14 THE WITNESS: I have no knowledge of that
15 element of how the Mississippi marijuana project is
16 run.

17 BY MR. JACOBOWITZ:

18 Q Are you aware of any incidents of
19 diversion from that program or the research from
20 that program?

21 MR. BAYLY: That, I would object.

22 JUDGE BITTNER: Sustained.

1 BY MR. JACOBOWITZ:

2 Q Marijuana is a very commonly used illicit
3 drug in the United States, is it not?

4 A Yes, it is.

5 Q In fact, it's the most readily available
6 illicit drug in the United States?

7 A I think it's fair to say. Actually,
8 probably alcohol is among teenagers, but it would
9 be a very close second.

10 MR. JACOBOWITZ: Could the witness be
11 given Government Exhibit 45, please.

12 JUDGE BITTNER: That was Government
13 Exhibit 45?

14 MR. JACOBOWITZ: Yes.

15 [The document was shown to the witness.]

16 MR. BAYLY: Your Honor, I'd like to
17 confirm that it's been admitted. I think it has.

18 JUDGE BITTNER: It has.

19 MR. BAYLY: Yes. Okay.

20 THE WITNESS: I have it in front of me,
21 yes.

22 BY MR. JACOBOWITZ:

1 Q Thank you. Could you, looking at the
2 first page, could you just identify this for the
3 record?

4 A This is the National Drug Intelligence
5 Center National Drug Threat Assessment 2005.

6 Q For what drug?

7 A For marijuana.

8 Q Thank you. If you would look at page six--

9 A I'm on page six.

10 Q On the second paragraph under the
11 "Availability" section.

12 A Okay.

13 Q The first sentence of that indicates that
14 at some DEA field offices and HIDTA offices,
15 marijuana is the most available illicit drug?

16 A I suspect that's accurate, but not being
17 looked at relative to alcohol, but I'll agree with
18 you. I think it's widely available.

19 JUDGE BITTNER: Do we know what DEA means
20 by the term "illicit drugs"? I'm asking anybody.
21 I don't know. I don't know if in preparing this

1 document, DEA was considering controlled substances
2 only or if they were considering alcohol.

3 MS. CARPENTER: I don't think it includes
4 alcohol.

5 BY MR. JACOBOWITZ:

6 Q In fact, if the witness could look at page
7 31, at the final paragraph on that page, it's not--it speaks
8 somewhat to it.

9 A A specific area of this page, or what
10 would you--

11 Q At the final paragraph, please. I believe
12 there is a sort of comparison there--

13 JUDGE BITTNER: Oh, okay.

14 MR. JACOBOWITZ: --between marijuana and
15 illicit alcohol.

16 JUDGE BITTNER: Okay.

17 THE WITNESS: Well, but this says easier
18 to obtain, but if you look at things like National
19 Household Survey or Monitoring the Future, I think
20 you'll find as far as abuse, alcohol is about two-to-one
21 over marijuana. So I'm not going to split
22 hairs. I mean, it's a widely used, abused, and

1 widely available drug.

2 BY MR. JACOBOWITZ:

3 Q Actually, could you read that sentence you
4 were just paraphrasing from?

5 A "Among established users, particularly
6 among older teens and young adults--"

7 Q I'm sorry, I believe it's the sentence
8 before that.

9 A Oh. "Indeed, reporting from some areas
10 has suggested that marijuana is easier for youths
11 to obtain than alcohol or cigarettes."

12 Q I'm sorry, one moment, please.

13 [Pause.]

14 MR. JACOBOWITZ: Could the witness be
15 given Government Exhibit 43, please.

16 [The document was shown to the witness.]

17 THE WITNESS: And I have in front of me
18 43, which is "Office of Rare Diseases Reports."

19 BY MR. JACOBOWITZ:

20 Q Who is that?

21 A "Office of Rare Diseases Reports, Report
22 on Rare Diseases Research Activities."

1 Q And who is the issuer of that report?

2 A National Institute on Drug Abuse.

3 Q And if you would turn to page nine of that
4 report, which I believe has been admitted--rather,
5 a part of page nine has been admitted--looking at
6 the Section 4, the first paragraph.

7 A Okay.

8 Q Could you tell me what the estimate of
9 marijuana use made there is?

10 A That 14.6 million users in the past month
11 and particularly heavy use occurring in adolescent
12 populations, over 20 percent of all high school
13 seniors.

14 Q Mm-hmm.

15 A Is that the sentence you were after?

16 Q And the sentence after that?

17 A "Approximately 2.4 million people use
18 marijuana for the first time every year. Two-thirds of them
19 are between 12 and 17 years of age."

20 Q And turning back to Exhibit 45--

21 A I think I gave it back to her.

22 Q Oh, okay. I'm sorry. I didn't mean to

1 make you go back and forth.

2 [The document was shown to the witness.]

3 THE WITNESS: That's kind of an
4 interesting paragraph right underneath that, too,
5 but I guess you didn't ask me to read that one, so--

6 BY MR. JACOBOWITZ:

7 Q No thank you. Putting this aside for the
8 moment, would you have an estimate of the number--of the
9 tonnage of marijuana made available in the
10 United States over an average year?

11 A Oh, gosh, I--

12 MR. BAYLY: Objection. This gets out of
13 the scope, too. I don't think we got into the
14 numbers.

15 JUDGE BITTNER: Sustained.

16 MR. JACOBOWITZ: I'm sorry. Excuse me for
17 a moment.

18 [Pause.]

19 BY MR. JACOBOWITZ:

20 Q One other question about diversion. You
21 testified, I believe, that one concern with respect

1 to diversion is dependency and habituation.

2 A I'm not sure what the context exactly was,
3 but that would be a reasonable concern, that people
4 who would divert it would abuse it or become
5 dependent or sell it or involve people who had
6 become dependent on it, yes.

7 Q Now, isn't it true that marijuana has been
8 found in studies to cause dependency in only 0.5
9 percent of people who begin use after the age of
10 21?

11 A That wouldn't surprise me, because after
12 the age of 21, the instance of use drops quite a
13 lot. But in earlier ages, 14, 15, whatever,
14 incidence of dependence is extremely high.

15 Q Would that be as high as five percent?

16 A I think that's certainly compatible,
17 certainly five to ten. There are some people who
18 believe that as high as 30 percent of people who
19 use it at an early age continue using it. But I
20 think it's fair to say. I mean, that's a
21 reasonable estimate, five to ten percent of overall
22 users. Realize that the earlier a person uses a

1 drug, the more likely they are to become addicted
2 to it. If they don't use any intoxicant until
3 after age 21, their instance of addiction drops way
4 off. I'd be tickled pink if kids never got exposed
5 to pot until after 21. That doesn't seem to
6 happen, though.

7 Q Now, dependency occurs with prescription
8 drugs, does it not?

9 A Now, let me be very clear. When you're
10 talking about dependence, you're talking about
11 physical dependence in the sense that is a
12 physiologic process? You're not talking about
13 abuse or addiction. You're talking about physical
14 dependence?

15 Q Physical dependence.

16 A Physical dependence does occur with some
17 prescription drugs, like narcotics, for instance.

18 Q Addiction also occurs with some
19 prescription drugs, does it not?

20 A Addiction, which I'm going to be very
21 clear is the sociologic phenomenon of illegal use,
22 misuse, acceleration of use, buying it illegally,

1 et cetera, can occur with some prescription drugs,
2 yes.

3 Q And THC is, you testified, is the primary
4 active ingredient in marijuana?

5 A I believe I did. I think I said it's been
6 the most recognized active ingredient, and
7 generally--

8 Q I accept that correction.

9 A Right.

10 Q The most recognized active ingredient.

11 A Right.

12 Q And THC is the active ingredient in the
13 drug Marinol?

14 A Correct.

15 Q Is THC an important factor in producing
16 marijuana dependence?

17 A Well, I don't know that it's--well, it's
18 the major--probably the major factor as far as the
19 exposure to a substance that creates the
20 physiologic response that is called dependence,
21 yes.

22 Q And I may have already asked this. THC is

1 the primary active ingredient in Marinol?

2 A That's correct.

3 Q And you have prescribed Marinol to
4 patients--

5 A Absolutely.

6 Q --when it seemed indicated?

7 A Absolutely.

8 Q Have you prescribed other drugs in which
9 dependency has been known to occur?

10 A Yes. A big part of my practice involves
11 pain management, so I use a whole host of narcotic
12 pain substances, yes.

13 Q The withdrawal process for narcotic pain
14 medication dependency or addiction is fairly
15 intense, is it not?

16 A It certainly can be, yes.

17 Q What are some of the symptoms that are
18 associated with that?

19 A "That" being what?

20 Q With the withdrawal process?

21 A Of any drug or specific--

22 Q Specifically the narcotic drugs, narcotic

1 pain reliever drugs.

2 A Now, let's be very clear. Are you talking
3 about stopping it cold turkey or are you talking
4 about a withdrawal process that I would supervise,
5 or--because if a person just stops it cold turkey,
6 they become very agitated, salivate, their skin
7 crawls, they may have diarrhea. They're very
8 uncomfortable. If they're tapered off of it, then
9 hopefully those would be completely mitigated.

10 JUDGE BITTNER: I've got another problem,
11 which is the definition of narcotics. When you say
12 narcotics, Mr. Jacobowitz, what do you mean?

13 MR. JACOBOWITZ: Well, I think it actually
14 was Dr. Voth who introduced narcotics, but let's
15 see if we can make a definition.

16 BY MR. JACOBOWITZ:

17 Q Narcotics are analgesics used to relieve
18 pain and they include such medicines as codeine,
19 hydrocodone, Oxycontin?

20 A Yes, I would say opiate--

21 JUDGE BITTNER: Is it opiates?

22 THE WITNESS: Opiate pain relief

1 medications, yes, and I'll--

2 JUDGE BITTNER: Okay. That's fine, as
3 long as you agree and I know what you agree on.

4 THE WITNESS: Narcotic, opiate pain
5 medications.

6 BY MR. JACOBOWITZ:

7 Q Have you ever prescribed benzodiazepine to
8 a patient?

9 A Well, that's a group of drugs and I have
10 prescribed benzodiazepines, yes.

11 Q One benzodiazepine, I believe, is
12 Lorazepam, is that correct?

13 A That is correct, yes.

14 Q And Lorazepam is used as an anti-medication for
15 cancer patients?

16 A Pretty rarely. It has been used. It's
17 more an anti-anxiety, but you can add it to an
18 anti-medication regime, yes.

19 Q And an anti-medication for cancer patients is
20 also one use for which medical marijuana has been
21 proposed?

22 A I'm not sure I'm understanding--well,

1 Lorazepam is a benzodiazepine. It's a sedative.
2 It has some anti-medic effects in cancer
3 chemotherapy patients, and it is also true that
4 marijuana has been proposed as an anti-medic, yes.

5 Q Withdrawal symptoms from benzodiazepines
6 are also quite intense, are they not?

7 A Assuming that you mean abrupt withdrawal
8 from them, yes, that is correct. However,
9 scheduled, tapered withdrawal usually is not that
10 difficult.

11 Q And benzodiazepines can also cause
12 dependency and even addiction?

13 A In a general sense, that's correct, yes.

14 Q Symptoms for withdrawal might include in
15 some cases convulsions for this class of drug?

16 A For benzodiazepines, it is true that,
17 again, upon abrupt discontinuation, and usually
18 from fairly severe doses, seizures or convulsions
19 can occur, yes.

20 Q Is withdrawal a factor in--withdrawal is a
21 factor, is it not, in how intense the dependency
22 is?

1 A Oh, not necessarily, because, for
2 instance, with marijuana, you do have withdrawal
3 symptoms that occur, but because it's such a--and
4 you can be severely dependent on it, but because
5 it's such a fat-soluble drug and removes itself
6 from the system slowly, withdrawal is often fairly
7 benign compared to some of the other drugs. So you
8 can be severely dependent, but withdrawal is not
9 necessarily a one-to-one correlation. You can also
10 precipitate marijuana withdrawal. There are drugs
11 that can do that in experimental populations.
12 Rimonabant, for instance, boy, you can have
13 somebody pretty uncomfortable in a very real hurry
14 if you block that. So I guess your point is, is
15 withdrawal necessarily related to the intensity of
16 addiction or dependence, and I would say, maybe in
17 a general sense, but not totally.

18 Q But there is some connection, some
19 correlation?

20 A Some potential correlation, yes.

21 Q I'd like to address one comparison that
22 you made on direct between, I believe you said

1 marijuana smoke was similar to tobacco smoke.

2 A Yes.

3 Q One important difference would be, would
4 it not, that tobacco smoke has been proved
5 substantially to cause lung cancer--

6 A Oh, certainly.

7 Q --whereas marijuana has not?

8 A Well, the constituents are very similar.
9 It is probable that the smoking patterns are
10 different, which, it would be my guess. The
11 particular study I was referring to didn't have a
12 lot of statistical power in the heavy marijuana
13 smokers, so I'm not sure where that all is going.
14 I know that Dr. Tashkin, who did that study, was
15 absolutely surprised and thought that there would
16 be a connection to lung cancer. We'll see. I
17 don't think the final chapter is written on that
18 yet.

19 Q In Dr. Tashkin's study, he--actually, let
20 me go back a little since you mentioned Dr.
21 Tashkin. Dr. Tashkin, I believe, is a researcher
22 at UCLA, is he not, who did a NIDA-funded study on

1 the effects of marijuana vis-a-vis lung cancer?

2 A That's correct.

3 Q And, in fact, he found that marijuana had
4 a minimizing effect on lung cancer, a protective
5 effect, isn't that right?

6 A I don't think that completely states his
7 findings. There was one of the groups that there
8 was a slight reduction in the instance over the
9 placebo population.

10 Q Are you aware that marijuana research has
11 shown--some research has shown anti-tumor
12 properties in marijuana?

13 A That's a very broad statement.

14 Q Or, I'm sorry, I should say in
15 cannabinoids?

16 A Let's say cannabinoid research, sure.
17 There is some very preliminary research in that
18 regard.

19 Q And tobacco smoke or nicotine does not
20 have that property?

21 A Well, tobacco smoke is a known carcinogen,
22 right, or has known carcinogens and certainly

1 causes lung cancer.

2 Q And nicotine does not, then, have anti-tumor
3 properties?

4 A No, in fact--

5 Q Definitely not--

6 A --it has pro-tumor properties. But there
7 isn't nicotine in marijuana. That's one big
8 difference there, just to be clear.

9 Q I'm sorry, just a moment.

10 [Pause.]

11 BY MR. JACOBOWITZ:

12 Q You testified as to some of the short-term
13 effects of marijuana.

14 A Yes.

15 Q Other short-term effects would be to
16 relieve nausea?

17 MR. BAYLY: I'm going to object here. We
18 are getting into the medical efficacy issues--

19 JUDGE BITTNER: I know, but we also got
20 into risks. It's really quite tricky. I'll allow
21 the question, but I don't want to set a dangerous
22 precedent.

1 THE WITNESS: If you really look closely
2 at the studies that have been done, first of all,
3 let's talk about marijuana. One of the best was
4 the Vinciguerra study and, in fact, 25 percent of
5 those folks wouldn't smoke it because they didn't
6 like the smoke effect and a fairly significant
7 percentage didn't get a beneficial effect. Now, in
8 a general sense, there is the allegation that
9 people who have nausea and smoke marijuana get some
10 benefit to that. But there's also a very high
11 percentage of people who get acutely dysphoric and
12 don't like that effect.

13 BY MR. JACOBOWITZ:

14 Q And, of course, many more who get somewhat
15 euphoric--

16 A Well, I don't know that that's necessarily
17 the case. I mean, is that the intent, because
18 again, that's one of the pivotal discussions here,
19 is is it euphoria or is it reduction of nausea, and
20 if you're after nausea reduction, you're not after
21 euphoria. I think that's a fundamental issue, and
22 if you want to open that door, I'll walk right

1 through it. But that is a fundamental issue. And
2 yes, they acutely get euphoric. They acutely get
3 dysphoric. And they may or may not get benefit to
4 their nausea.

5 Q But in Vinciguerra's study, in fact, it
6 did show that some patients who did not respond to
7 standard anti-medic medicine did receive benefit,
8 anti-medic benefit from the use of marijuana, smoke
9 marijuana?

10 A There were some, and generally, those were
11 people who had some history with marijuana
12 themselves.

13 JUDGE BITTNER: Would you define, Doctor,
14 euphoria, dysphoria for me?

15 THE WITNESS: Euphoria, Your Honor, I
16 define as being a pleasurable intoxicated response.
17 Dysphoria, meaning an unexpected panic, agitated
18 kind of feeling, potentially hallucinatory or even
19 trantially psychotic in some circumstances.

20 JUDGE BITTNER: So are they opposites?

21 THE WITNESS: Absolute opposites, yes.

22 JUDGE BITTNER: Okay. And my other

1 question, when you talked earlier about dependence
2 and you defined it, and then you talked a little
3 bit about addiction and defined it, is there some
4 other condition, as well? Is there something
5 between the two or connected to the two, because--in other
6 words, you talked about a physical
7 condition of dependence and a sort of psycho-social
8 addiction. Is there something else, as well, or
9 are those it?

10 THE WITNESS: I think the spectrum we'd be
11 talking about would include abuse and there would
12 be the issue of therapeutic use. So the spectrum
13 would be this, and this is any drug of abuse. It's
14 not necessarily narcotics or marijuana or whatever.
15 But in the general sense, a therapeutic use that
16 results in a physical dependence does not
17 necessitate abuse. It just is a physiologic
18 response. If I gave a person morphine long enough,
19 they would not necessarily abuse it, but they would
20 become physiologically dependent upon it, and in
21 order to discontinue it, I'd have to slowly taper
22 it off. Otherwise, they'd be uncomfortable.

1 On the other hand, whether prescribed or
2 not prescribed, they may abuse a drug and become
3 dependent upon it, and that's where we talk about
4 the psycho-social or the sociologic elements of
5 addiction, which means illegality, abuse,
6 escalation of dose, selling on the street, buying
7 on the street, that kind of thing. So it's kind of
8 a spectrum and abuse does not necessarily mean
9 dependence and abuse does not necessarily mean
10 addiction, but you can't have addiction without
11 abuse.

12 JUDGE BITTNER: Okay.

13 THE WITNESS: Okay? That was clear as
14 mud, I think, but--

15 JUDGE BITTNER: Suppose an initial use,
16 therapeutic or otherwise, and then at some point
17 dependence.

18 THE WITNESS: Right.

19 JUDGE BITTNER: If a drug--I wish I could
20 phrase the question better. Does physical
21 dependence always have a component of tolerance?
22 In other words, if you're physically dependent on

1 something, can you remain dependent on that same
2 amount, that same dosage on a daily level, let's
3 say, for the rest of your life, or will you always
4 build up a tolerance--

5 THE WITNESS: For the most part, if you're
6 physically dependent, you will develop some degree
7 of a tolerance. Most of the pain community and
8 addiction community will tell you that in the
9 addict, that you rarely see an end to tolerance,
10 that that dose just keeps going up and up and up
11 and up, whereas in the legitimate using, let's say
12 pain medicine, and the people who become somewhat
13 physically dependent, they may develop tolerance to
14 a point, but often it will plateau, and that's one
15 of the differential points that's often the case,
16 is you'll see an addict just continue to just ramp
17 it up as far as they can go as long as--

18 JUDGE BITTNER: There's no bliss point?

19 THE WITNESS: Well, there's limitation by
20 dose. At some point, you can just--you finally
21 shut down. But usually, the end point for an
22 addict is what they can obtain, what they can buy

1 or be given.

2 JUDGE BITTNER: Whereas for a dependent
3 person, it can be just what's necessary to maintain
4 the--

5 THE WITNESS: That's correct.

6 JUDGE BITTNER: --some sort of state--

7 THE WITNESS: It typically plateaus more.

8 JUDGE BITTNER: Okay. Go ahead, Mr.
9 Jacobowitz.

10 BY MR. JACOBOWITZ:

11 Q In that context, I believe you testified
12 that you're not aware of any abuse of Marinol?

13 A I've not personally witnessed abuse of
14 Marinol, and I also, with my law enforcement
15 contacts have no awareness of any substantial abuse
16 population of Marinol.

17 Q And you're aware that Marinol was
18 rescheduled by the DEA to Schedule III in 1999?

19 A Yes, I'm aware of that.

20 Q And are you aware that at that time, the
21 DEA determined that there was little evidence of
22 either abuse or trafficking?

1 A Yes, I'm aware of that.

2 Q You've spoken about the short-term effects
3 of marijuana smoking. Now, the--you're not,
4 however, I believe, familiar with the short-term
5 effects of vaporized marijuana?

6 A No, I don't--I've really not--I have a
7 vague awareness of it, but I've not studied it in
8 great detail, no. I mean, relative to the bong
9 that we're talking about, no, I've not really
10 studied it. I mean, I have an awareness, but I've
11 not really sat down and dug just line by line
12 through it, no.

13 Q There aren't many studies, are there, of
14 the differences between vaporized marijuana and
15 smoked marijuana?

16 A I've not seen them, no.

17 Q But one difference would be that there is
18 no smoke in vaporized marijuana. The effects that
19 are attributable specifically to inhalation of
20 smoke would not be present.

21 A Well, that's kind of an odd thought,
22 because actually what's happened in a vaporized

1 phase is those chemicals are being changed into a
2 different phase, so what I don't know, and what I
3 don't know if there's been studies to look at is
4 where did those chemicals go? I mean, did they
5 just get filtered out? Did they go into liquid
6 phase? Are they now in liquid phase and being
7 inhaled? I don't know that that's been done. I
8 just don't know.

9 Q There's no combustion of the substance in
10 a vaporizer, though. There's a different chemical
11 reaction--

12 A Right. I'd give you that, sure. There's
13 no combustion.

14 Q No pyrolysis.

15 A Right. Okay. Absolutely.

16 A Let's see. I'm sorry, just a moment,
17 please, Your Honor.

18 [Pause.]

19 BY MR. JACOBOWITZ:

20 Q Going back for a moment--and I think we're
21 very near the end--going back for a moment to Drug
22 Master Files, if the FDA has permitted a clinical

1 Phase II trial with a botanical for which a Drug
2 Master File is being submitted, that would indicate
3 that they were--I guess I should say, it was
4 satisfied with the Drug Master File?

5 A I don't know. I mean, I--you could maybe
6 assume that, but, I mean, for whatever purpose,
7 they've let it go through and--I don't know. I
8 don't sit on the FDA and I don't know. I'd have to
9 assume there was at least adherence to whatever
10 their rules and regulations were for such a master
11 file.

12 Q A couple of questions. You, in your
13 professional life, you are opposed to the
14 legalization of marijuana, is that correct?

15 A That is correct, yes.

16 Q And you have testified on this subject, is
17 that right?

18 A That's correct.

19 Q And you've submitted editorials and
20 letters to the editor about the subject?

21 A That's correct.

22 Q And you consider medical marijuana an

1 excuse for legalization of marijuana, is that
2 correct?

3 A Absolutely, I do.

4 Q You are opposed, therefore, to medical
5 marijuana?

6 A Yes, I am, on both a political-social
7 ground and on a medical ground. I mean, they're
8 really kind of two separate and distinct phenomena.

9 Q Do you consider it a stalking horse--I
10 believe you've used the phrase talking horse--for
11 medical marijuana?

12 A Absolutely. I think that the--

13 Q I'm sorry, for legalization of marijuana,
14 I should say.

15 A Right. In fact, I think that NORML
16 referred to it as getting the camel's nose under
17 the tent at one of the NORML meetings, and I agree
18 with that characterization.

19 MR. JACOBOWITZ: I believe we have no
20 further questions, then.

21 JUDGE BITTNER: Okay. Redirect?

22 REDIRECT EXAMINATION

1 BY MR. BAYLY:

2 Q Dr. Voth, you were asked toward the end of
3 the cross-examination if you were opposed to the
4 legalization of marijuana, and I believe your
5 answer was in the affirmative?

6 A That is correct, yes.

7 Q Okay. But I think for the record here, we
8 had better define what you mean by marijuana when
9 you give that answer.

10 A I'm opposed to the gaining of legal status
11 of leaf marijuana, in other words, that it would be
12 a substance that people could smoke at will, just
13 for recreation or whatever purpose they chose.

14 Q Do you have 36 up there?

15 A I don't think so.

16 MR. BAYLY: I think that's been admitted,
17 Your Honor. That's Dr. Voth's CV.

18 JUDGE BITTNER: Yes.

19 BY MR. BAYLY:

20 Q Dr. Voth, one of the articles you
21 submitted, and I'm not finding it right now, maybe
22 you can help me, but I think it's the bottom of

1 page seven, "Guidelines for Prescribing Medical
2 Marijuana"?

3 A Yes, I recall it.

4 Q And you see that on your CV? You listed
5 that on your CV?

6 A Yes.

7 Q Okay.

8 A I don't have the CV in front of me, but I
9 know the article you're talking about, right.

10 Q Well, you may not need this, but let's
11 give it to you anyway.

12 [The document was shown to the witness.]

13 BY MR. BAYLY:

14 Q I believe you just got Exhibit 36. That's
15 your CV. And if you'll turn to page seven, it
16 looks like it's the bottom entry there underneath
17 your scientific publications.

18 A Correct.

19 Q Can you tell us, just give us a very
20 thumbnail description of what this article is
21 about?

22 A Well, this article was really in response

1 to the fact that so many States have passed these
2 marijuana initiatives and was trying to give
3 especially regulatory boards some sort of a sense
4 of how they can get some reasonable control over
5 that process, because most States don't have any
6 controls for the way those drugs would be used and
7 these specific recommendations were a set of
8 guidelines, such as making sure there were
9 legitimate trials of other medications and the
10 person wasn't an addict and there was drug testing
11 and essentially trying to create a legitimate
12 medical-regulatory framework for physicians who are
13 stuck with having to deal with street marijuana now
14 to be used for medical purposes.

15 Q Dr. Voth, are you opposed to research on
16 the potential use of marijuana cannabinoids in
17 medicine?

18 A Oh, not at all. I'm very supportive to
19 the notion of individual components and
20 cannabinoids for medicine.

21 Q So tell us why the difference. On the one
22 hand, you're opposed to the marijuana plant

1 material being legalized, and on the other hand,
2 you very much support the extraction of
3 cannabinoids for possible medical use.

4 A Well, I think there's clear evidence that
5 individual cannabinoids can and do have some
6 potential medical use. There's a new drug, for
7 instance, called Rimonabant that's sort of an anti-
8 cannabinoid, but it's a spin-off of the cannabinoid
9 research. This is phenomenal stuff. The problem
10 is that I see it with marijuana per se, you have
11 not only potentially useful cannabinoids, but all
12 the other problems associated with it, and what
13 makes this a further complex issue is that the
14 marijuana culture has been driving the issue. It's
15 not a medically-driven issue. It is driven by a
16 marijuana legalization culture. And I'd be just as
17 opposed if someone came forward wanting to legalize
18 tobacco for weight loss or for stress control. If
19 the tobacco industry were behind it, I'd be very
20 suspect, and I think there's enough evidence that
21 this is a self-serving phenomenon that I'm very
22 opposed to that.

1 MR. BAYLY: Thank you. that's all I have,
2 Your Honor.

3 JUDGE BITTNER: Any recross?

4 MR. JACOBOWITZ: Maybe one or two
5 questions.

6 RE CROSS EXAMINATION

7 BY MR. JACOBOWITZ:

8 Q You just testified that the difficulty is
9 the fact that this process as you see it is not
10 driven by medical interests but by non-medical
11 factors.

12 A I rephrased that. I said, not by
13 legitimate medical interests. I said it's driven
14 by a self-serving marijuana culture.

15 Q Does that make it all the more important
16 that the legalization process--sorry, that the
17 medical marijuana process, I should say, be taken
18 through the FDA evaluating process?

19 A Well, you've kind of mixed issues. I
20 think it's very important that all drugs that hit
21 the market go through the FDA, absolutely, and I
22 think that all this ballot initiative process has

1 been a clear end run on the FDA. So yes, drugs
2 need to go through the FDA.

3 Q So isn't it all the more important that
4 the FDA evaluate the medical marijuana research and
5 decide based on the science whether medical
6 marijuana should be a drug?

7 A Well, I would say, in a general sense, the
8 FDA should be the final authority and should
9 evaluate marijuana. I think that's very important.

10 MR. JACOBOWITZ: No further questions.

11 JUDGE BITTNER: Any re-redirect?

12 MR. BAYLY: No.

13 JUDGE BITTNER: Thank you, Dr. Voth. You
14 may step down.

15 [The witness was excused.]

16 JUDGE BITTNER: I suppose you all think
17 that you should somehow get a meal break. Where
18 you get these ideas, I don't know.

19 [Laughter.]

20 JUDGE BITTNER: Let's go off the record.

21 [Luncheon recess.]

1 A F T E R N O O N S E S S I O N

2 JUDGE BITTNER: On the record. Mr. Bayly?

3 MR. BAYLY: Thank you, Judge Bittner.

4 Unbelievably, this worked out perfectly. Dr.
5 Auslander and his wife were here by 1:15, but they
6 actually got a much earlier train. Amtrak was
7 running about, what, two or two-and-a-half hours
8 late, so my pessimism of Amtrak was confirmed, but
9 nevertheless, things worked out, so we're ready to
10 call Dr. Auslander to the stand.

11 JUDGE BITTNER: Okay. Doctor, would you
12 come up, please, and if you would stand right over
13 there.

14 Whereupon,

15 DAVID E. AUSLANDER, M.D.

16 was called as a witness, and after being first duly
17 sworn, was examined and testified as follows:

18 JUDGE BITTNER: Please be seated.

19 DIRECT EXAMINATION

20 BY MR. BAYLY:

21 Q Good afternoon, Dr. Auslander.

22 A Good afternoon.

1 Q Please state your name for the record, and
2 I think you'd better spell your last name, please.

3 A Okay. My name is David E. Auslander, A-u-s-l-a-n-
4 d-e-r.

5 Q And your address, your professional
6 address?

7 A My address is 778 Adams Circle, Yardley,
8 Y-a-r-d-l-e-y, Pennsylvania 19067.

9 Q Thank you.

10 MR. BAYLY: Your Honor, I'd request that
11 Dr. Auslander be given Government Exhibit 83. That
12 one, I don't think, has been admitted.

13 JUDGE BITTNER: Yes, it's been admitted.

14 MR. BAYLY: Oh, it has?

15 JUDGE BITTNER: Mm-hmm.

16 MR. BAYLY: Okay. Thank you.

17 [The document was shown to the witness.]

18 BY MR. BAYLY:

19 Q Dr. Auslander, I'll show you what's been
20 already admitted as Government Exhibit 83, but I'd
21 still like you to please identify this document for
22 the record.

1 A Yes. I know this document. It's
2 basically a summary of my experience in
3 pharmaceutical development. In a sense, it's my
4 CV.

5 Q All right. And did you draft this CV, Dr.
6 Auslander?

7 A Yes, I did.

8 Q All right. And is your CV current?

9 A It should be. It should be current.
10 Well, under work history, it says 1975 to 2000. It
11 should say to present time. But it is current. It
12 reflects my years of experience in drug
13 development.

14 Q Well, let me back up here and then ask you
15 what your present occupation, profession, or
16 business is.

17 A Well, just as it says under "Work
18 History," Deatech Associates. I'm a pharmaceutical
19 consultant, President of Deatech Associates. Just
20 as it states on page two, my responsibilities are
21 in drug development strategy, development. I've
22 done some expert witness work in the past, a fair

1 amount of auditing for CGMP compliance, validation
2 and PAI support. So it really reflects what I do
3 at the present time.

4 Q All right. Well, we're going to just go
5 through a few specifics of your CV here, Dr.
6 Auslander, but let me just ask you, in general,
7 prior to your present profession, what was your
8 occupation, profession, or business?

9 A All my work experience has been in
10 pharmaceutical development, one form or the other.
11 But prior to being a consultant, I was in the
12 corporate world. Immediately prior to consulting,
13 I was Director of Pharmaceutical Development at
14 Wallace Laboratories, as it states here, 1990 to
15 1994. I was a department head responsible for the
16 areas that are reflected on the right-hand side. I
17 don't think you need for me to state that again,
18 but those areas were under my direct supervision.

19 Prior to that, I was at Rorer Group,
20 department head, both areas in international
21 coordination as well as pharmaceutical technology,
22 actually from years 1981 all the way really to

1 1990. The companies had gone through some mergers
2 and acquisitions, but it basically reflected the
3 Rorer Group, Inc., corporate world.

4 Prior to that, I was with Purdue
5 Frederick, a company in New York State. I had
6 those responsibilities as stated there, Director of
7 Pharmaceutical Analysis and Group Leader in
8 Development from 1977 to basically 1981. And prior
9 to Purdue Frederick, I was a senior scientist at
10 the Squibb Institute of Medical Research in New
11 Jersey from 1972 to '77. I had gotten my Ph.D.
12 degree in pharmaceuticals from Rutgers University in
13 1973.

14 Q All right. And I just want to ask you for
15 some clarifications or interpretations on the CV
16 that there are some technical terms that, as
17 laymen, some of us may not know, particularly me,
18 what they mean. So if you'd turn to page one of
19 your CV, Dr. Auslander, under the heading "Primary
20 Expertise."

21 A Okay.

22 Q And then if you'll go down to the second

1 column--

2 A Okay.

3 Q --the phrase, quote, "aseptic
4 pharmaceutical process validation," could you
5 explain what that term means and what your job
6 function was under this designation?

7 A Okay. Sure, I will. The critical phrase
8 really is pharmaceutical process validation.
9 Aseptic validation is really a subset of that. But
10 in terms of validation, I was involved in managing
11 that process. A validation is a requirement that
12 the Food and Drug Administration requires, really,
13 prior to launch of any commercial product. It's a
14 requirement for both drug substances as well as
15 finished products. It's a requirement that the
16 drug company or the sponsor of an application,
17 prior launch, commercial launch, undergo a complex
18 set of exercises to ensure the quality attributes
19 of both the drug substance as well as the drug
20 product to ensure that the quality not only of the
21 commercial materials will meet all quality
22 specifications now and in the future.

1 Aseptic, as I mentioned, is a subset of
2 that. Aseptic processing means producing sterile
3 materials under processing conditions. There are
4 two ways to produce a sterile product. One way is
5 to have a terminal sterilization. Aseptic is
6 applied to materials that cannot be terminally
7 sterilized. It achieves sterilization through
8 actually full control of the processing conditions.

9 Q Now, you were talking about
10 specifications. Is this work with the FDA?

11 A Well, this is work that industry requires
12 and it's certainly work that the FDA necessitates.
13 Any sponsor of a drug, of a pharmaceutical drug,
14 has to develop specifications for that product.
15 FDA, the Food and Drug Administration, mandates
16 that and industry knows that and that's a process
17 that we work together to achieve.

18 Q Dr. Auslander, now let me just take you
19 down to the third section here on page one of your
20 CV under the column labeled, "Primary Expertise."
21 It says, Food and Drug Administration, and then
22 under description, it says, quote, "Dr. Auslander

1 has had significant experience in preparing
2 technical dossiers and CMC implementation for
3 registration and filing purposes for worldwide
4 registration." The first question in relation to
5 that part of your job description, what does CMC
6 mean? What does it stand for?

7 A Well, CMC is an acronym. It stands for
8 chemistry, manufacturing, and control aspects of
9 drug development. It's more the in vitro
10 laboratory aspects of a drug profile as opposed to
11 clinical and safety aspects.

12 Q Dr. Auslander, again referring to the same
13 quote under the job description, can you please
14 explain in a little more detail what you did?

15 A Okay. Essentially, I was a department
16 head during that period of time at Wallace
17 Laboratories. We had teams of people conduct
18 studies to provide data that would generate
19 information regarding the inherent purity, quality
20 aspects of--purity profiles of both drug substances
21 as well as drug products. Basically, we went
22 through the various aspects to ensure that the

1 formulations were adequate, developing the
2 manufacturing process for the various phases of
3 clinical development, developing the technical data
4 to support a formulation and process development,
5 and we, of course, all of it under FDA requirements
6 which has to be documented, of course, properly,
7 and dossiers are basically information packages of
8 technical experiences that we had to prepare and we
9 actually used these technical dossiers or
10 information packages for registration not only in
11 the United States, but also for worldwide
12 implications.

13 Q Now, the next part of the CV that I'd like
14 to refer you to, Dr. Auslander, is the second
15 paragraph from the bottom. Quote, "Dr. Auslander
16 has audited facilities and plants that manufacture
17 the active pharmaceutical ingredient in bulk drug
18 products. He ensures that the substances comply
19 with FDA requirements." And in relation to that
20 description, Dr. Auslander, I'd like to ask you,
21 what did you do to ensure that substances did
22 comply with FDA requirements?

1 A Well, certainly it was a complex set of
2 experiences and activities that were conducted.
3 But let me say up front that the Food and Drug
4 Administration has guidelines, basically more than
5 just suggestions but I would say almost
6 requirements, that a sponsor must have to meet bulk
7 drug substance requirements.

8 So one of the things that I did, or teams
9 of people that I managed, we would actually go into
10 a bulk drug substance facility and evaluate the
11 plants, the personnel, the procedures, the quality,
12 to ensure that the entire facility, the entire
13 plant would meet industry standards as well as FDA
14 requirements. But we'd also help set up analytical
15 procedures, as appropriate, so that we'd have
16 hands-on experience to ensure that the drug
17 substance had proper analytical controls.

18 So it basically was on-site inspections,
19 as appropriate, data documentation evaluations, as
20 appropriate, and in a few cases, we'd actually do
21 the hands-on laboratory work.

22 Q All right. Thank you, Dr. Auslander.

1 Now, I'd like you to refer to page two of your CV
2 under "Work History," and under the heading of
3 "Responsibilities"--I'm looking for the section
4 that--if I may have a moment, Your Honor, I've
5 lost--here it is. Okay. The very bottom right-hand corner
6 of page two of your CV, Dr. Auslander.
7 Are you with me there?

8 A I'm with you.

9 Q I'll quote it. It says, quote, "Drug
10 development strategies, product development, expert
11 witnesses, auditing for CGMP compliance,
12 validation, and PAI support, clinical
13 manufacturing." It goes over to page three.

14 A I see that.

15 Q For that excerpt that I just read, first
16 of all, what does the acronym CGMP stand for?

17 A Okay. Let me start with GMP. GMP stands
18 for Good Manufacturing Procedures, and the "C"
19 stands for Current, so implying or stating--really
20 stating explicitly that GMPs will evolve with time.
21 So GMP processes that we're evaluating compliance
22 for are current. So it's Current Good

1 Manufacturing Procedures, basically as required by
2 the Food and Drug Administration.

3 Q Okay.

4 JUDGE BITTNER: So it's procedures, not
5 practices?

6 THE WITNESS: You're quite correct. It's
7 procedures and practices.

8 JUDGE BITTNER: Oh, okay.

9 THE WITNESS: Procedures and practices,
10 correct.

11 JUDGE BITTNER: Okay. Thank you.

12 BY MR. BAYLY:

13 Q Then the last word, or actually acronym on
14 page two, in the bottom right-hand corner, are the
15 acronym PAI. Can you tell us, Dr. Auslander, what
16 PAI stands for relative to the phrase, quote,
17 "validation and PAI support"?

18 A Okay. The acronym PAI stands for Pre-Approval
19 Inspection. Let me just state that prior
20 to commercialization, the sponsor of the drug
21 development program has to do basically three
22 things. It has to provide a New Drug Application

1 to the Bureau of Drugs.

2 Then subsequent to that, the Bureau of
3 Compliance, is part of FDA, will conduct what's
4 called a PAI, or Pre-Approval Inspection program
5 subsequent to the NDA application. Basically, it's
6 to ensure that the commercial plant as designated
7 in the NDA is ready to produce product under the
8 specifications and quality standards, et cetera, as
9 specified in the New Drug Application.

10 Validation is the third leg of this
11 program. Prior to launch of a commercial product,
12 the sponsor of the application of the new drug has
13 to ensure that there's a satisfactory validation
14 program for the drug substance as well as the drug
15 product, again, to ensure consistent quality for
16 now and in the future.

17 Q All right. Dr. Auslander, if the acronyms
18 CMC and PAI occur in other places in your CV, would
19 you say that they stand for the same phrases that
20 you've already testified about?

21 A Yes.

22 Q Now I'd like to go to page three of your

1 CV, under "Career Accomplishments." This is the
2 first entry under "Career Accomplishments." It
3 says, quote, "Dr. Auslander is a member of the
4 American Association of Pharmaceutical Scientists,"
5 and it ends with the acronym PMA. Can you tell us
6 what PMA means?

7 A That stands for Pharmaceutical
8 Manufacturers Association. That was the
9 association that was in place under that acronym
10 probably until the late '80s, early '90s. At the
11 present time, it has a different--I think it's
12 called PhRMA, but it's a similar idea. It's the
13 association of big pharma, for the most part,
14 association of pharmaceutical companies.

15 Q Dr. Auslander, are you familiar with the
16 term, quote, "IND"?

17 A Yes, I am.

18 Q What does that stand for?

19 A IND is another acronym. It stands for
20 Investigational New Drug.

21 Q Are you familiar with the three phases of
22 clinical studies for an IND?

1 A Yes, I am, very familiar.

2 Q Has your work experience included working
3 with INDs in the three clinical phases?

4 A Yes.

5 Q Have you had experience with developing
6 controlled substances as a marketable drug product
7 under FDA approval?

8 A Yes, I've had some experience with
9 controlled drug substances.

10 Q If we could go now to your CV on pages two
11 to three, under your "Work History." If you would
12 please just briefly describe your work experience
13 for each job listed on your CV as it pertains to
14 developing pharmaceutical drug products.

15 A Where should I start? I'm sorry. Please,
16 once more. Page two, did you say? Page one?

17 Q The bottom of page two, under your work
18 history, and it spills over to page three.

19 A In terms of my work at Deatech Associates,
20 or--

21 Q Yes.

22 A Okay. Again, Deatech Associates is a

1 consulting operation of which I'm President. The
2 responsibilities are very broad-based, but
3 involved, really, in all aspects of drug
4 development, from early stage development--you used
5 the term IND--to IND stages I, II, and III, reflect
6 really the various stages of the evolving program
7 in the clinical aspects of the drug development.
8 But along with each stage I, II, and III, there has
9 to be an evolving CMC, or Chemistry and
10 Manufacturing Control program. So I have been
11 involved in developing strategies to integrate the
12 various requirements to help facilitate and develop
13 more intelligent development programs. I've been
14 involved in product development, drug
15 pharmaceutical development, formulation
16 development, at all stages of the IND program,
17 Phases I, II, and III.

18 I have been an expert witness,
19 particularly in patent litigation matters. I've
20 done that in the past. I've done some auditing to
21 ensure that this compliance with accepted both
22 industry standards as well as FDA requirements.

1 Clearly, there's an awful lot of FDA-industry
2 collaboration, as there should be, so I've done a
3 lot of work auditing for both drug substances as
4 well as drug products to ensure compliance with
5 accepted requirements and expectations.

6 I've been involved in the validation
7 programs that are well understood and also part of
8 an FDA expectation program. I've been involved in
9 Pre-Approval Inspection evaluations to ensure that
10 sites will meet and withstand an FDA audit prior to
11 the full NDA--full product acceptance by the Food
12 and Drug Administration. I've been involved in
13 supporting clinical manufacturing programs to
14 ensure that the clinical supplies, the clinical
15 trial materials, will meet all quality attributes
16 and are made in the facilities that are--made in
17 facilities that are CGMP compliant.

18 Do you wish me to go down the entire list,
19 all the way down to the very end?

20 Q No, that won't be necessary. Have you had
21 any experience with developing a new drug product
22 from a botanical?

1 A I've had experience with botanical
2 products, but I have not had experience, hands-on
3 experience, with a drug, early-stage development of
4 a botanical drug. I've had experience only with
5 commercial products which were of botanical origin.

6 Q All right. Can you give us a little more
7 detail, then, what your actual experience was with
8 botanicals?

9 A When I was at Purdue Frederick back in the
10 period of '77 to 1980-81, I was involved working
11 with Senokot. Senna is a product of biological
12 origin used for GI requirements, bowel issues. I
13 was involved in terms of doing a lot of the
14 analytical work, identifying and evaluating various
15 constituents in senna. Senokot is a product that's
16 on the market presently, as it was then.

17 Q And would you explain, Dr. Auslander, for
18 us what a botanical product is, a botanical drug
19 product?

20 A Botanical product, certainly. A botanical
21 product is a drug product basically of plant or
22 vegetable origin. I think the requirements and

1 definitions are stated by FDA, but it's a drug
2 product, as I understand it, to be of plant or
3 vegetable origin, a complex product of plant or
4 vegetable origin.

5 Q Okay. Now I'd like to ask you to refer
6 back to Government 83. That's your CV. We're on
7 page two here, and it looks like the second
8 paragraph, second column here under "Parentrial
9 Drug Delivery"--

10 A Parentrial, yes.

11 Q Can you tell us in layman's terms what
12 that means?

13 A Okay. Parentrial--well, let me start by
14 saying that there are a variety of ways you can
15 introduce drugs into the body. Most common, of
16 course, is oral, basically tablets or capsules
17 which you swallow. Parentrial means drugs which
18 are administered by way of injection, either
19 intramuscular, intravenous, subcutaneous.
20 Parentrial is the terminology for basically
21 injectable delivery systems.

22 Q All right. If you turn to page--well, not

1 turn to, you're already there--page two on your
2 education, if you would just briefly describe what
3 each degree entailed, starting--I guess you can go
4 from the bottom up, from your Bachelor's.

5 A Yes. Well, all of my education, training
6 and education at the university level has been in
7 schools of pharmacy. I have a Bachelor's degree in
8 pharmacy. Basically, I was trained to be a
9 pharmacist, either in a community setting or a
10 hospital setting. For one reason or another, I
11 decided to go into graduate work. I have a
12 Master's degree in pharmaceuticals from Columbia
13 University. I trained in research, basically, drug
14 development, physical mechanisms of action of a
15 variety of class of drugs, basically was my thesis
16 area. A Ph.D. in pharmaceutical sciences from
17 Rutgers University. I did advanced work in drug
18 development and in understanding basically the
19 interactions of drugs with various chemicals. I
20 did additional work in the area of physical
21 mechanisms of actions of a class of drug products.
22 As you can see, my training has always been within

1 the pharmaceutical world, various colleges of
2 pharmacy from B.S., M.S., and Ph.D.

3 Q Thank you, Dr. Auslander.

4 MR. BAYLY: Judge Bittner, now I'd like to
5 tender Dr. Auslander as a qualified expert in
6 pharmaceutical drug development.

7 JUDGE BITTNER: Who do I address? Mr.
8 Jacobowitz?

9 MR. JACOBOWITZ: We have no objection.

10 JUDGE BITTNER: All right. Doctor, you're
11 an expert.

12 THE WITNESS: Thank you.

13 BY MR. BAYLY:

14 Q Dr. Auslander, I now have a few questions
15 on botanicals, but let me ask you, to start off
16 with here, when you're developing a new drug
17 product, is there a difference between a botanical
18 product versus a pure or synthetic product?

19 A Let me start by saying that my expertise
20 and area of involvement has been in the chemistry
21 and manufacturing control area. I really could
22 speak with expertise to that world. But to answer

1 the question, I'd say, yes, there's definitely a
2 difference between pure synthetic material of very,
3 very established purity, of defined quality
4 attributes, a level of purity as well as impurity
5 degradation products which become quantified over
6 time, maybe not immediately, but can more readily
7 and with greater facilitation be quantified,
8 qualified, and understood over time.

9 A botanical, on the other hand, is clearly
10 much more complex. You're dealing with a variety
11 of constituents that are not easily identified,
12 require tremendously greater effort and time and
13 resources and capabilities to establish, I think
14 the variety of materials within the botanical
15 material. And there's probably a greater variety,
16 at least the potential for greater variety, given
17 the vagaries of Mother Nature.

18 So I think the world of botanicals is
19 clearly much more complex from the point of view of
20 chemistry than they are for a synthetic, pure
21 material, not to diminish the activities involved
22 in a pure material--I mean, a synthetic material.

1 Clearly, there's a whole variety of activities
2 there, as well. But it seems to me that the
3 pathway for a pure drug substance can use more
4 defined classical techniques, as opposed to a
5 botanical, which are a lot more unknown materials.

6 Q Dr. Auslander, are there additional
7 hurdles or problems in going through the three
8 phases of the IND process that you mentioned here
9 in getting FDA to approve a new drug from a
10 botanical substance as opposed to a pure or
11 synthetic drug substance?

12 MR. JACOBOWITZ: Objection; foundation.

13 JUDGE BITTNER: Would you like to rephrase
14 the question, Mr. Bayly?

15 MR. BAYLY: Yes. All right.

16 MR. JACOBOWITZ: I believe he's testified,
17 in fact, that he does not have experience with the
18 early stages, the Phase I, Phase II stages that
19 would be bringing a botanical drug along.

20 MR. BAYLY: If I may?

21 JUDGE BITTNER: Yes.

22 MR. BAYLY: Thank you.

1 BY MR. BAYLY:

2 Q Dr. Auslander, would you be able to
3 testify about comparing--well, first of all, let me
4 back up here. You've taken a pure or synthetic
5 drug through the three IND phases?

6 A Yes, I have. I have with teams of people,
7 personally as well as managing teams that have done
8 that. That's true.

9 Q Are you familiar with botanicals so that
10 you would be aware of what would be needed to take
11 a botanical through the three IND phases?

12 A Well, the answer is yes. I think I am
13 familiar with the guidelines that FDA has
14 documented for botanical products. I feel I know
15 that the FDA has--the guidelines tend to be a
16 little bit more lenient with botanical drugs that
17 they are with pure synthetic materials, but I do
18 have opinions as to what would be required for a
19 botanical drug development.

20 MR. BAYLY: Your Honor, I would ask the
21 witness be shown, is it--I guess it is Government
22 92A.

1 JUDGE BITTNER: Yes.

2 [The document was shown to the witness.]

3 BY MR. BAYLY:

4 Q Dr. Auslander, are these the guidelines
5 that you were referring to?

6 A Yes.

7 Q Now, given your testimony here, are you
8 able to indicate if there are any additional
9 problems or hurdles in going through the three IND
10 phases and getting FDA approval for a botanical
11 substance as opposed to a pure synthetic drug?

12 A Well, it is my opinion, my expert opinion,
13 I guess, that the hurdles that exist are due to the
14 fact that a material of botanical origin is much
15 more complex in terms of variety, the amounts of
16 various constituents, so that the activities to
17 isolate and distinguish the various componentries,
18 the first principles, it clearly will be a much
19 more complex, require higher energy, require a
20 level of resources, capacity. It seems to me that
21 although--and the FDA does recognize this by
22 allowing perhaps a different variety of approaches

1 using fingerprints and markers as opposed to
2 quantifying individual materials. But
3 nevertheless, the evolutionary process to go from
4 an early stage development to a commercial product
5 will require a lot more hurdles, my judgment, with
6 a botanical product than with a material of pure
7 synthetic origin.

8 Q Dr. Auslander, let me ask you this. In a
9 botanical that has many active ingredients but
10 where you only want one active ingredient is really
11 the goal or needed for the development of a drug,
12 how could a pharmaceutical company comply with the
13 FDA guidelines and standards to get a botanical
14 through the system, so to speak?

15 A Not easily. Clearly, if all the active
16 ingredients basically have the same pharmacologic
17 property, it might be a little bit easier. But if
18 they have competing or a variety of pharmacological
19 activities, it would be much more complex because
20 there's a whole--it would have a whole set of
21 different medical or pharmacological responses.
22 But I think it has to--it would be a much more

1 complex process.

2 The FDA does accept the fact that this
3 exists for important botanical product with a--or
4 let me back up a bit. It also depends on the
5 clinical indication. If the benefit of the
6 intended indication is very critical, I think FDA
7 will be more liberal and more lenient. But if the
8 indication is going to be potentially less
9 important, I think they take a different set of
10 standards.

11 Having said that, FDA does, in the course
12 of documents, FDA does accept the fact that this is
13 more complex and will allow a certain amount of
14 fingerprinting. But at the point where you reach a
15 Phase III or almost an NDA program, the FDA will
16 expect, I think, complete evaluation of what's
17 involved in the botanical product. So it seems to
18 me it's going to be much more complex. FDA
19 understands this, but nevertheless is going to be--I think
20 it's a more involved process.

21 Q All right. Dr. Auslander, let me focus
22 here on three issues in this botanical drug

1 development: Potency, safety, and purity. First,
2 what are the additional considerations with which a
3 pharmaceutical company must contend with in
4 developing a pharmaceutical product from a
5 botanical that are not considerations in developing
6 a pure or a synthetic drug in regard to potency?

7 A Well, I think, I guess, potency, some of
8 the potency relates basically to the chemistry and
9 manufacture control world. Potency, in a sense, is
10 a measurement of purity, so that purity both of the
11 direct drug substance as well as the purity or
12 levels of the degradation products, process and
13 purities, basically relate, in a sense, to the
14 potency. So it would be a more complex set of
15 experiences to develop this consistently for a
16 botanical than it would be for a pure synthetic
17 material since it's dealing with basically one
18 commodity in a pure material as opposed to a
19 complex, a more complex set of materials over much
20 greater variety that would exist, I think, in a
21 botanical product, considering the vagaries of
22 Mother Nature and the fact that you get complex

1 materials usually arising in botanical products.

2 Q What are the additional considerations
3 with which a pharmaceutical company must contend
4 with in developing a pharmaceutical product from a
5 botanical that are not considerations in developing
6 a pure synthetic drug in regard to safety?

7 A Well, I think it's--you know, safety and
8 efficacy are basically two legs of one table.
9 Efficacy is the activity of the drug, the
10 anticipated sought after activity is efficacy, what
11 your target is, your desirable pharmacological need
12 or your medical indication. Safety, on the other
13 hand, is to, above all, do no harm, that you do not
14 want to create byproducts or side effects. Side
15 effects can arise from impurities, degradation
16 products.

17 So purity of a drug, if I back up, purity
18 of a drug substance relates again to the standard
19 material as well as any of the byproducts that
20 exist in a drug product or drug substance, so that
21 you would achieve efficacy by having purity,
22 potency, but you want to avoid safety problems that

1 may arise from--that may arise--from degradation
2 products. I mean, safety obviously is not only
3 coming from that, but, you know, when you provide
4 drugs to people, you get a whole variety, a whole
5 spectrum of responses. Not everybody responds to
6 the drug the same way because that's the human
7 condition. But certainly one of the aspects you
8 try to control is safety problems arising from
9 degradation programs.

10 So clearly, from a botanical, it would
11 seem to me, both safety and efficacy, achieving
12 consistent quality that would lead towards efficacy
13 and to lead towards appropriate safety issues would
14 be more complex with a biological because you have
15 a more complicated environment, milieu, which is
16 more difficult to evaluate and to provide, I think,
17 assurance of consistent quality. With a drug
18 substance, a drug product of a synthetic nature,
19 ostensibly, it's purer and more easily--you can
20 more easily establish these facets, these aspects.

21 Q Dr. Auslander, can some of these hurdles
22 or complexities that you've been talking about

1 regarding botanicals as opposed to a pure synthetic
2 drug, could they be circumvented by extraction from
3 the botanical of the active ingredient that would
4 be needed for development of the pharmaceutical
5 product?

6 A The answer to your question is I think so,
7 yes. I think by having controlled extraction
8 procedures, one can more readily obtain materials
9 of a more consistent nature or quality as opposed
10 to processing the bulk botanical material. If one
11 can control the extraction procedure so that the
12 extraction procedure is standardized, it seems to
13 be a better step--a step to better achieve a higher
14 quality, a more consistent quality of material.
15 The answer to your question is yes.

16 Q Dr. Auslander, is the extraction option
17 always feasible for a botanical?

18 A Well, feasible--I'd say the proper word
19 would be theoretically feasible. Feasible means
20 practical. Theoretically, it's possible. I mean,
21 it may require a tremendous effort in terms of
22 scientific input, resources, capability, expenses,

1 budgetary concerns. The answer is, it may be
2 theoretically possible. In practice, it's hard to
3 give you a general answer, but anything is
4 theoretically possible. But it may be easy. On
5 the other hand, it may be a tremendous burden.

6 Q Dr. Auslander, are the number of active
7 constituents in a botanical, is the number a factor
8 in terms of its complexity? In other words, if
9 you've got a botanical that has just two active
10 ingredients as opposed to one that has over 100, is
11 that an issue?

12 A Yes.

13 Q Why is that?

14 A Well, in the first case here, one or two,
15 they're more easily evaluated. The chemistry per
16 se, chemistry requirements are less complex. One
17 can develop classical approaches to isolating and
18 quantifying and understanding, evaluating these
19 materials. When you're dealing with a hundred, so
20 to speak, a hundred materials in a botanical, you
21 can imagine the interactions that take place, the
22 complex chemistry, engineering that's required to

1 isolate, quantify, establish, understand, it's
2 exceedingly complex. I wouldn't think--I think the
3 complexity is more than linear. It can be
4 exponential in terms of going from two to a
5 hundred.

6 Q Dr. Auslander, you still have Government
7 Exhibit 92A up there?

8 A Yes.

9 Q All right. Let me ask you to please turn
10 to page 21.

11 A Okay.

12 Q If you go down to about the middle of the
13 page, you'll see Section 2 and it says, "Botanical
14 Drug Substance." Do you see that?

15 A I see it.

16 Q Okay. And then I'm going to quote
17 underneath that. "The following information should
18 be provided for all botanical drug substances
19 regardless of whether they're prepared from one or
20 more botanical raw materials." Do you see that?

21 A I see that.

22 Q All right. Then I want to quote the next

1 section, or next sentence, so you can comment on
2 that. It starts off, "A qualitative description,"
3 and why don't I just let you read that sentence.
4 You see where I'm going? Do you see where it's at?
5 It starts off with, "A qualitative description,"
6 and then it ends with, "clearly so state."

7 A You'd like for me to read that?

8 Q To yourself, yes, and then let us know
9 when you're done.

10 [Pause.]

11 THE WITNESS: I see that. Yes. Okay.
12 I've read that.

13 BY MR. BAYLY:

14 Q The statement there says, "A qualitative
15 description of the drug substance, including name,
16 appearance, physical and chemical properties,
17 active constituents, if known, biological activity,
18 if known, and clinical indication, if known, of
19 each botanical raw material." Can you explain to
20 us what that means in terms of a drug developer
21 submitting to the FDA?

22 A Okay. Just that one particular sentence?

1 Certainly for a drug substance of synthetic origin,
2 the sponsor facility would put together in the IND
3 basically what would be considered a pre-formulation
4 profile, with a description of the drug
5 substance that's the subject of the clinical
6 program. The qualitative description, I guess,
7 would be essentially a statement about what the
8 material is and what it purports to be, as opposed
9 to a quantitative description of the material. The
10 name, various profile of appearance, physical
11 properties, such as solubility, particle size,
12 density, chemical property, such as stability,
13 active constituent, I guess in parentheses, if
14 known, but clearly with a drug substance of
15 synthetic origin, it's rare that you would not know
16 the active constituent. And biological activity,
17 if known, if it has biological activity in terms of
18 any sort of biological model, and clinical
19 indication, in parentheses, if known, of each
20 botanical raw material.

21 Certainly, it does give allowance that you
22 can, at the early stage of development for a

1 botanical material, you can--you have a bit more
2 leeway, I think. It's known. Certainly, in a drug
3 substance origin where you have a synthetic origin
4 as opposed to botanicals, you wouldn't have the "if
5 known" aspects. But the FDA recognizes the
6 complexity of a botanical program and gives a
7 certain amount of allowance by saying, "if known,"
8 for a botanical material. That's my understanding
9 of that sentence. I don't know if that's what you
10 had--

11 Q Dr. Auslander, you mentioned in the
12 earlier development, in terms of the IND stages,
13 can you say what you meant?

14 A Well, yes. Basically, the two application
15 sponsor files to the government, in terms of
16 applications--there are other activities I talked
17 about before about pre-approval and validation, but
18 in terms of applications, there's an
19 Investigational New Drug application which supports
20 the various stages of clinical development, Phase
21 I, Phase II, and Phase III. At the conclusion of
22 the Phase III program, with concomitant clinical

1 safety and chemistry manufacturing control data,
2 the sponsor submits what's called a New Drug
3 Application. If you'd like me to discuss the
4 various aspects of INDs I, II, and III, or does
5 this suffice to answer your question? Would you
6 like me to continue and discuss the various aspects
7 of Stages I, II, and III?

8 Q No. I'll ask you to turn to page 22,
9 please.

10 A Okay.

11 Q And under--you'll see the first bullet
12 near the top of the page. It says, quote, "Quality
13 control tests performed on each batch of the drug
14 substance."

15 A Mm-hmm.

16 Q And then underneath "Appearance," it
17 starts out with, "a chemical identification by
18 spectroscopic and chromatographic fingerprints."
19 In the context of this paragraph there, would you
20 tell us, explain to us, what these identification
21 procedures are in terms of a botanical?

22 A Well, I think it relates to the fact that

1 these are what we call fingerprints, basically, of
2 a material. Spectroscopic and chromatographic
3 approaches provide unique fingerprints for a
4 substance of, again, in this case, botanic origins.
5 They give examples of spectroscopic procedures,
6 such as ultraviolet, infrared, transformations,
7 infrared mass spec, mass spectroscopy. These are
8 all chemical approaches which give unique
9 fingerprints for a substance of biological origin
10 in this particular case.

11 These are a way of--by doing all these
12 variety of tests, procedures, you get a--let me
13 back up by saying that each of these procedures may
14 provide a different profile, but by doing all of
15 these various procedures, the compilation of all
16 the data from all these procedures provides
17 basically the sum and substance, really, of
18 developing a very accurate fingerprint. Not just
19 one test, but a variety of interesting tests give
20 you a truer understanding of what this material
21 looks like and how it should behave.

22 Q All right. Then if you'd jump down to the

1 next paragraph, it says, quote, "Chemical assay,
2 i.e., assay for active constituents or
3 characteristic markers." Can you explain what
4 those terms mean and how they are used in terms of
5 developing a botanical for a potential drug
6 product?

7 A Well, chemical assay relates to--typically
8 means quantitative as opposed to qualitative.
9 Qualitative just says this material exists. A
10 chemical assay or quantitative assay will give you
11 the evidence this material exists to what extent,
12 how much of it exists. So you're required to do
13 chemical assays, more quantitative assays, for the
14 active constituents. And again, it does state here
15 that if it's infeasible, or not feasible, FDA
16 accepts the fact that it may not be feasible,
17 certainly at the early stage. They certainly allow
18 for a joint determination for several active
19 constituents or markers, you know, especially when
20 you go to the last sentence, they say, or the
21 guidance states where multiple constituents or
22 markers are known, they should be chemically

1 characterized and their relative amounts should be
2 defined.

3 So I guess there's the expectation,
4 certainly the desire of the Food and Drug
5 Administration that definition and chemical
6 characterization and definition should be defined,
7 should be stated, applied, especially when the
8 various constituents are known. They say there is
9 a certain amount of allowance when--they say if
10 it's not known, given the complexity of the
11 biological or botanical, they do allow for, I guess
12 it would be basically a joint determination, which
13 means in my opinion basically saying we have an
14 understanding that A, B, and C materials exist, but
15 we can't really define A, B, or C. It's just that
16 we know A, B, and C exists in this amount as
17 opposed to quantifying or characterizing A, B, and
18 C specifically.

19 Q Now I'd like you to drop down to the next
20 paragraph, where it says, quote, "Biological assay
21 (when the active chemical constituents) are not
22 known or quantifiable, if available." Please

1 explain what a biological assay is in the context
2 of that phrase.

3 A Okay. Again, this relates to, I guess to
4 a botanical drug, but to biological materials, too.
5 Sometimes an assay, chemical assay using chemical
6 approaches, such as techniques mentioned above--
7 spectroscopic procedures, chromatographic
8 procedures, and so on--may not be developed for a
9 biological material. So the FDA accepts--FDA and
10 the U.S. Pharmacopeia accepts alternate approaches
11 to assay materials.

12 One could use what's called a biological
13 assay, which means, in a sense, administering the
14 drug substance, the drug product, in this case,
15 say, of biological or botanical origin to animal
16 species and the animal then responds in a certain
17 quantifiable way. It could be, for example, you
18 may give a product to an animal species and there
19 could be a drop in blood pressure, or it could be a
20 bowel movement, or it could be a certain response
21 to an irritant. A biological assay, it has to be
22 quantifiable and consistent within a variety of

1 statistical approaches. So FDA and the
2 Pharmacopeia accept the use of biological assays
3 when the chemical assay is not available or
4 feasible.

5 Q I'd like to have you look at the next
6 sentence. Let me make sure that we're all on the
7 same page here. It starts off, quote, "If the
8 botanical drug substance is considered potent," and
9 if you just would read that complete sentence to
10 yourself and let us know when you've finished that
11 sentence.

12 [Pause.]

13 THE WITNESS: Yes, I see it. I've read
14 that. Yes.

15 BY MR. BAYLY:

16 Q Okay. My question to you is, why, if a
17 botanical drug substance is considered potent,
18 toxic, addictive, or has abuse potential, why is it
19 necessary for an assay for biological activity
20 and/or a chemical assay for the active
21 constituents, why is that needed?

22 A Well, it's needed or desired in any case.

1 I think the case here is that it's particularly
2 needed here. I think perhaps if the botanical drug
3 substance were not considered potent, I don't have
4 an example offhand, but if a botanical drug
5 substance were not considered potent or toxic,
6 addictive, or had abusive potential, there was a
7 negative situation, FDA may allow the sponsor not
8 to be able to conduct an assay immediately.

9 But it seems to me that my reading of this
10 infers that if the drug substance has indication,
11 medical indication or clinical indication, that
12 it's considered potent, highly active, toxic,
13 addictive, or it has abuse potential, FDA really
14 wants an assay, either a bioassay or a chemical
15 assay. And I guess the operative word is "should"
16 be performed. FDA would like to have it conducted
17 under this procedure.

18 But clearly, I think that's what it's
19 stating in this guidance document, that Food and
20 Drug Administration wants a quantitative assay,
21 either a biological assay or a chemical assay, for
22 a substance that is considered potent, highly

1 active, toxic, addictive, and so on. They may give
2 you more allowance if the drug substance were not
3 in this category, but they're expecting to get for
4 a drug substance that has these attributes.

5 Q All right. Dr. Auslander, now I want you
6 to just please jump up to the second paragraph
7 there. I'm backtracking a little bit, but I'm
8 referring you to the sentence, quote, "When
9 multiple active constituents or markers are known,
10 they should be chemically characterized and their
11 relative amounts should be defined." First of all,
12 can you explain what a marker is in the context of
13 that sentence?

14 A Well, I think what a marker means, in a
15 sense, is that it gives a certain chromatographic--let's say
16 we're using chromatography to evaluate,
17 to assay or to quantify, qualitatively or
18 quantitatively, the assay material. You may get a
19 chromatographic response that is not matched up
20 with an assessment of what that source response is.
21 It may not be matched up or you may not have the
22 actual active constituent quantified or even

1 identified. But we expect the chromatographic
2 profile to be consistent. If you have the
3 scientific intuition and data to believe that this
4 response is coming from some constituency of yet
5 undetermined nature, we call that response a
6 marker. It's a surrogate for some material that is
7 believed to be of active quality, and FDA gives you
8 allowance not to go in at this point in time to
9 identify and quantify what it is, but they would
10 expect that this marker be there, be present, you
11 know, under consistent--consistently.

12 Q All right. And then the next part of the
13 sentence, quote, "They should be chemically
14 characterized and their relative amounts should be
15 defined." In context of that sentence, do the
16 markers need to be consistent?

17 A I would think so, yes. I would think
18 there should be a consistency from experience to
19 experience demonstrating that your processes to
20 measure these materials are consistent, that one
21 day you're not doing an experiment one way, the
22 next day you're doing an experiment another way.

1 It should be--the laboratory approaches have to be
2 consistent and the material under evaluation should
3 be consistent, as well.

4 Q Dr. Auslander, if the markers are not
5 consistent in terms of a botanical product, would
6 that create problems for the FDA in terms of
7 approving the drug?

8 A Well, I'd say that it would provide
9 concern, and certainly I don't know if it would be
10 a problem, but it would be a concern of which it
11 may involve FDA-industry interaction so that the
12 sponsor would have to be able to explain why the
13 inconsistency in marker, what that means. So I
14 think that FDA--it would be my expectation that the
15 FDA would question that and would be a concern or a
16 problem that would necessitate FDA-industry
17 dialogue.

18 Q So would that be a hurdle, then, for the
19 drug company to overcome before FDA would approve?

20 A It could very well be a hurdle, could be.
21 Yes, I would expect it to be a hurdle.

22 MR. BAYLY: Thank you. That's all I have

1 at this time.

2 JUDGE BITTNER: Cross?

3 MR. JACOBOWITZ: Could we just take a
4 minute, Your Honor?

5 JUDGE BITTNER: I'll give you ten.

6 [Recess.]

7 JUDGE BITTNER: Back on the record. Mr.
8 Jacobowitz?

9 MR. JACOBOWITZ: Thank you.

10 CROSS EXAMINATION

11 BY MR. JACOBOWITZ:

12 Q Dr. Auslander, as you may have guessed,
13 I'm counsel for the other side. Now, Dr.
14 Auslander, do you still have a copy of Government's
15 Exhibit 92A there?

16 A No, I don't. I don't have any documents.

17 [The document was shown to the witness.]

18 BY MR. JACOBOWITZ:

19 Q You have that document now.

20 A I do.

21 Q Could you please--I'm going to ask you to
22 turn to page five.

1 A Okay.

2 Q Specifically, the middle paragraph, the
3 one right under the Section B heading.

4 A Okay.

5 Q Now, you'll see a section there that says,
6 "In many cases, the active constituent in a
7 botanical drug is not identified nor its biological
8 activity well characterized. Therefore, the CMC
9 documentation that should be provided for botanical
10 drugs will often be different from that for
11 synthetic or highly purified drugs as active
12 constituents can be more readily chemically
13 identified and quantified. For example, FDA would
14 expect an NDA for a synthetic or highly purified
15 drug to identify the active ingredient. However,
16 it would not be essential for the sponsor of a
17 botanical drug to identify the active constituents
18 (although FDA recommends that this be done if
19 feasible)." Can you tell me what that would mean
20 in relation to botanical drugs and botanical drug
21 development?

22 A Well, it seems to me to be a--reading this

1 guidance document and the particular paragraph that
2 you just read, it's an expression of fact that the
3 FDA recognizes the complexity of identifying and
4 characterizing a drug substance of botanical origin
5 and gives the sponsor certain allowance and that
6 saying it's not essential, although the FDA
7 recommends it be done if feasible, a
8 characterization and identification of the drug
9 substance or drug substances contained within the
10 botanical product.

11 Q Thank you. And going back to page 22,
12 which you discussed before on direct--I'm sorry,
13 tell me when you've got there.

14 A I'm at page 22, yes.

15 Q You identified, based on the guidance,
16 several alternative forms of information, sort of
17 the either/or forms of information that might be
18 submitted to the FDA, is that right?

19 A I'm sorry, please repeat your question.

20 Q You identified several forms of
21 information about the drug, the potential drug
22 product, that would be submitted to the FDA?

1 A Well, I basically--I didn't particularly
2 identify them. I just basically responded by
3 reading the guidance document and explained what
4 the various procedures, what they meant in terms of
5 my experience.

6 Q The information--but this is about
7 developing information about the drug product.
8 That is what these paragraphs refer to.

9 A Well, the drug product as well as the drug
10 substance, as well, but yes.

11 Q Now, all that information would go into a
12 Drug Master File--it's a file with the FDA--is that
13 right?

14 A Well, it could go into a variety of
15 documents, one of which could be a Drug Master
16 File. It could go into a New Drug Application, as
17 well. The answer to your question is, yes, one of
18 the documents it could go into would be the Drug
19 Master File, that's correct.

20 Q If there is a Drug Master File for a
21 botanical drug product, you would expect to see
22 this sort of information in it?

1 A There's a certain amount of allowance,
2 what goes into a Drug Master File. But if a
3 company does provide a Drug Master File--not all
4 companies do Drug Master Files, but if a company
5 does have a Drug Master File, one would expect much
6 of this information to be present within that file.

7 Q And if there is a Drug Master File, it's
8 one of the things that the FDA uses to decide
9 whether to approve the Phase I and Phase II
10 studies, is that correct?

11 A You're making that assertion, but I don't
12 know if that's particularly correct. FDA does not
13 necessarily require a Drug Master File to do a
14 Phase I and Phase II study in all cases if the Drug
15 Master File usually comes from a producer that's
16 different from the sponsor itself. If the sponsor
17 is developing the drug substance and the botanical
18 product themselves, they may not necessarily have a
19 Drug Master File at the moment to target a Phase I
20 and Phase II program is conducted. The sponsor
21 would then provide an Investigational New Drug, or
22 an IND, application, which would contain this

1 information. This information needs to be
2 documented and contained clearly in documentation,
3 not necessarily in a Drug Master File.

4 Q And whichever way it gets to--whichever
5 document that gets to the FDA, the FDA would rely
6 upon that information, not necessarily either/or of
7 those documents, but the information submitted,
8 whichever document it's in, would rely upon that
9 information in deciding whether to grant approval
10 for a Phase I or Phase II study?

11 A Certainly, that information would be
12 important, not to state that this information would
13 be pivotal. But the IND includes not all the
14 chemistry and manufacturing control data, but
15 includes support of toxicological safety data to
16 give FDA the assurance that the clinical program is
17 safe. But this data would be present, presumably,
18 and the FDA would evaluate to assure that the
19 sponsor is capable of producing a consistent
20 product.

21 Q Consistency is important in the FDA
22 approval process.

1 A Yes.

2 Q If the FDA does approve a Phase I or Phase
3 II study, would it indicate that it is at least
4 preliminarily satisfied with the information
5 submitted as to consistency?

6 A To answer your question, I believe so,
7 yes.

8 Q Now, if the sponsor of a proposed new
9 botanical drug product submitted such information,
10 proceeded with its Phase I and Phase II studies,
11 and then switched sources for the raw material for
12 the drug product, could that cause concerns--

13 MR. BAYLY: Objection--

14 MR. JACOBOWITZ: --about consistency?

15 MR. BAYLY: I'm sorry, are you done?

16 MR. JACOBOWITZ: Yes, thank you.

17 MR. BAYLY: I don't want to cut off the
18 question, but I do want to object because this is
19 out of the scope of the direct examination.

20 JUDGE BITTNER: I'm not sure, so I'll
21 overrule.

22 THE WITNESS: Let me respond by giving a

1 little background. The answer is yes. The
2 response would be really stated this way, that the
3 IND collects information that's contemporary to
4 date. If the sponsor decides for one reason or
5 another to change the source of their drug
6 substance, the source of the material, the IND is
7 updated and the IND update is then submitted to the
8 FDA. The IND update would or should, would include
9 information to show that the change in the source
10 has had no impact on the quality of the material
11 and one would provide data demonstrating that
12 source A and source B provide equivalent material.

13 BY MR. JACOBOWITZ:

14 Q Would that be the equivalent of doing the
15 Phase I and Phase II studies over again with the
16 new source?

17 A Well, one would not necessarily repeat the
18 Phase I and II clinical studies over again, but one
19 would do additional chemical studies, stability, an
20 example of one, chemical purity, to show that the
21 quality of material from source A and the quality
22 of material acquired from source B are equivalent.

1 One should not repeat the clinical aspects, but one
2 would repeat the chemical manufacturing control
3 information data.

4 Q Now, if the change in source did produce a
5 change, if the sponsor could not provide such
6 assurance that these matters had not changed, would
7 that be a matter for concern?

8 A Yes.

9 Q If the fingerprint or the marker is
10 different, would that be a cause for concern?

11 A Yes.

12 Q Just a moment, please.

13 [Pause.]

14 BY MR. JACOBOWITZ:

15 Q And if this happens a little further along
16 in the process, after Phase I, Phase II, and Phase
17 III and then the source changes before marketing,
18 when the company does want to market, would they
19 again have to submit to the FDA proof that these
20 matters had not changed?

21 A Yes.

22 Q And if they could not submit such proof,

1 that would be a cause for concern?

2 A Yes.

3 Q If the fingerprint or the marker was
4 different at that stage?

5 A Yes.

6 Q What would they have to do then?

7 A Well, they'd have to do a lot. They would
8 have to go back and consider the secondary source
9 to evaluate whether the purity levels are the same,
10 to ensure that the degradation products, the
11 byproducts are the same. That would be a major
12 exercise to go from source A to B during the
13 advanced clinical trials, in particular where
14 efficacy and safety profiles are being established.
15 It would not be a trivial experience. It would be
16 a major undertaking.

17 MR. JACOBOWITZ: We have nothing more.

18 JUDGE BITTNER: Redirect?

19 MR. BAYLY: Thank you, Judge Bittner.

20 REDIRECT EXAMINATION

21 BY MR. BAYLY:

22 Q Dr. Auslander, you were asked about a Drug

1 Master File. If a Drug Master File is on file with
2 FDA either in a Phase I or Phase II study for a
3 botanical, would it necessarily be the case that
4 all the constituent markers would be known on that
5 Drug Master File?

6 A Well, it depends who's producing the Drug
7 Master File. I mean, very often, Drug Master Files
8 are produced or prepared by companies which are not
9 the sponsor itself but could be companies which
10 have been outsourced or contract facilities. The
11 quality of Drug Master Files varies all over the
12 place. It may very well contain all this
13 information. It should be contained. I mean, it's
14 certainly desirable. It should be contained. But
15 it's not a guarantee that the information will be
16 contained.

17 Q Going back to, it looks like page five of
18 Government 92, the "Guidance for Botanical Drug
19 Products"--

20 A Okay.

21 Q All right. It's the same quote that you
22 were confronted with by Respondent's attorney. It

1 starts out, "In many cases, the active
2 constituent," and it goes down to at the end there,
3 "if feasible." Do you see that, Dr. Auslander?

4 A No, we looked at--direct me to that, to
5 that statement. I'm sorry, where would that be?
6 Oh, yes, I see it now. Yes, I see that. Yes.

7 Q In the context of this quote, how
8 important are the markers for a botanical?

9 A Well, I think probably in context, it's
10 probably quite important. FDA would like,
11 certainly at the advanced clinical stage, Phase
12 III, that these chemical constituents be
13 characterized and quantified. They would like
14 that. But they recognize the complexities and the
15 technological aspects, the resources and so forth,
16 so they do give a certain amount of allowance to
17 markers. It seems to me that in my judgment, this
18 means that in the absence of having well-characterized
19 active constituents, they would
20 certainly have the expectations that markers, which
21 are surrogates for these constituents, be well
22 established.

1 Q If IND is getting a source of botanical
2 from some outdoor source, say, is there still the
3 issue of that botanical not having consistent
4 markers as the researchers or the manufacturers
5 supplied?

6 A The answer to your question is yes.
7 That's a consideration. If the sponsor obtains
8 materials from facilities that are outside their
9 control, even though the control could be by on-site
10 monitoring or by having people present during
11 the cultivation and in the various exercises, that
12 is--I'm not sure I'm answering your question to the
13 extent you wanted me--that you had in mind, but the
14 complexity is there and certainly you would need to
15 have markers or surrogates for the active
16 constituents well established.

17 Q Okay. Thank you, Dr. Auslander. That's
18 all I have on redirect.

19 JUDGE BITTNER: Recross?

20 MR. JACOBOWITZ: I think just a little.

21 RE CROSS EXAMINATION

22 BY MR. JACOBOWITZ:

1 Q Based on what you just testified to, if
2 you were advising a pharmaceutical development
3 company that was seeking to take a botanical to
4 market, would you advise them to obtain control of
5 a reliable and consistent source to avoid these
6 concerns that we've discussed?

7 A Well, I would think it would be important,
8 clearly. Companies should have a consistent
9 source, pipeline. It makes good business judgment
10 and good business sense and good scientific sense,
11 foremost, that the sponsor company should have a
12 source which is pretty well established to avoid
13 the complexities going down the road.

14 Q Just a moment, please.

15 [Pause.]

16 BY MR. JACOBOWITZ:

17 Q Just to nail it down now, if the FDA has
18 approved Phase I and Phase II studies based on
19 information that's in a Drug Master File, you would
20 expect that the FDA is satisfied that it has the
21 botanical information that it needs at that stage?

22 A Well, okay, let's recognize that Phase II,

1 Phase I, they're evolving clinical processes, Phase
2 I, Phase II, Phase III. Generally speaking, based
3 upon my experience and interactions with FDA, both
4 as a consultant and as a corporate employee, FDA
5 has concerns, they will get back to the client
6 either by letter or telephone call. Absence of
7 any--you know, usually, FDA will get back to the
8 client, the sponsor, with any questions regarding
9 the data that has been submitted. However, the
10 sponsor--there's a dialogue between FDA and the
11 client and the sponsor. So the sponsor is also
12 providing updated information periodically, as
13 well. It's not done in a vacuum. So at the Phase
14 II level--I mean, keep in mind, there's consistent
15 dialogue between FDA and industry. Certainly at
16 the Phase II level and beyond, FDA meetings,
17 dialogue, memorandum that may go back and forth.
18 So any kind of concerns FDA would have, may have,
19 are usually expressed in some form or another.

20 JUDGE BITTNER: But would it hold up the
21 trials?

22 THE WITNESS: Potentially, it could. Yes,

1 it could. It could hold up, depending on the
2 severity of their concern. The most severe concern
3 would lead to a clinical hold. But depending on
4 the concerns, it could potentially hold up the
5 clinical trial, correct. However, it may not.
6 They may ask for information to be provided. They
7 may ask for information to be provided at a future
8 date and a future time. They may ask the company
9 to provide commitments to provide this data as it
10 goes along. So it really depends upon the severity
11 of their concern, whether it has immediate impact
12 or whether the impact is such that it can be--that
13 the data and program of studies can be conducted
14 concominantly or at a future point. So there's no
15 one answer to that question, but it depends really
16 on the FDA's level of concern. I would say it's
17 common to have FDA-sponsor dialogue of this sort.

18 [Pause.]

19 MR. JACOBOWITZ: I think that's all, then.
20 Thank you.

21 JUDGE BITTNER: Okay. Any re-redirect?

22 MR. BAYLY: Thankfully, no.

1 JUDGE BITTNER: Thank you very much, Dr.
2 Auslander.

3 THE WITNESS: Thank you.

4 [The witness was excused.]

5 JUDGE BITTNER: Mr. Bayly, do you have any
6 further witnesses?

7 MR. BAYLY: We don't. We're done with the
8 testimony. We want to thank Dr. Auslander and wish
9 him a nice trip back.

10 JUDGE BITTNER: I have a note from my
11 secretary that the court reporting company advises
12 you to throw out the transcript for December 13 and
13 14 because they're not numbered consecutively, so
14 we'd have multiple volumes with the same page
15 numbers on them.

16 MS. CARPENTER: Okay.

17 COURT REPORTER: The ones I gave you today
18 are the ones to keep. You have 12, 13, and 14 in
19 there.

20 JUDGE BITTNER: Just make sure that it's
21 consecutively numbered. Are they numbered
22 consecutively from August? I haven't looked at

1 them. Because that's what it should be. So
2 December 12 doesn't start with page one.

3 Excellent. Okay, thank you.

4 Mr. Bayly, you had something else?

5 MR. BAYLY: Well, there's just one
6 housekeeping matter which I don't think--we may
7 want to resolve this post-hearing, but very shortly
8 post-hearing. We did arrive at a stipulation for
9 Ken Davis. He's the RTI witness that was going to
10 be here. So the stipulation has been hammered out.
11 However, it needs to be placed in affidavit form,
12 so we just want a chance to get that in, obviously.
13 We'll get the copy to Respondent's counsel so they
14 can make sure the affidavit is verbatim what the
15 stipulation is.

16 JUDGE BITTNER: Okay. Other than that,
17 you rest?

18 MR. BAYLY: Yes.

19 JUDGE BITTNER: Okay. Ms. Carpenter, what
20 are you doing?

21 MS. CARPENTER: Well, stretching, Your
22 Honor.

1 [Laughter.]

2 MS. CARPENTER: We are--we have some
3 potential rebuttal evidence, and I'd like to
4 discuss with the Court and Mr. Bayly what the best
5 way is to proceed with that.

6 JUDGE BITTNER: Would you like to do that
7 off the record?

8 MS. CARPENTER: I would.

9 JUDGE BITTNER: Okay. Let's go off.

10 [Discussion off the record.]

11 JUDGE BITTNER: First item, Government
12 Exhibit 24, which I received into evidence on
13 Wednesday, December 14, refers to, on page three,
14 to a 1997 NIH workshop. Government Exhibit 25 was
15 withdrawn, but now Respondent believes that it
16 should be in because of material about that
17 workshop. Mr. Bayly, do you object?

18 MR. BAYLY: No.

19 JUDGE BITTNER: Okay. Government 25 is
20 received. I will need a copy, Nicole.

21 [Government's Exhibit No. 25
22 was received into evidence.]

1 JUDGE BITTNER: Now with that, the
2 Government has rested. Respondent seeks to offer
3 certain rebuttal evidence not through testimony,
4 and the first item is that Respondent's Exhibit 54,
5 which I believe we discussed on Wednesday and did
6 not resolve, is testimony given April 1, 2004, by
7 Dr. Robert Meyer, who was at that time Director of
8 the Office of Drug Evaluation II, it says here.
9 And my recollection is that the Government objected
10 on grounds that this should have been offered as
11 part of Respondent's case in chief and wasn't and
12 was in existence at the time, correct?

13 MR. BAYLY: Yes, that's the initial
14 objection, not the only one, but yes.

15 JUDGE BITTNER: Okay. That was an
16 objection, anyway. Respondent then declined to
17 offer the exhibit, saying that he might offer it as
18 part of Respondent's case on rebuttal.

19 MS. CARPENTER: That's correct.

20 JUDGE BITTNER: Okay. Now, Respondent
21 would like to offer a sentence, really, toward the
22 end--well, two sentences at the end of the document

1 to rebut Dr. Voth's testimony about whether
2 marijuana could meet the FDA's guidelines for
3 botanical drugs, or drugs derived from botanicals.
4 Do I have that straight?

5 MS. CARPENTER: That's correct, Your
6 Honor.

7 JUDGE BITTNER: Okay. Moving right along.
8 And Mr. Bayly has an objection which he is about to
9 tell me.

10 MR. BAYLY: Right. The paragraph that
11 Respondent wants to put in says FDA will continue
12 to be receptive to sound, scientifically-based
13 research into the medicinal uses of botanical
14 marijuana and other cannabinoids. Dr. Voth was
15 talking about a--it was my understanding he was
16 talking about a completed product, not talking
17 about research.

18 Now, if indeed he said that research will
19 be impossible, and we don't remember it that way--I
20 think the word was difficult--but even if he said
21 research is impossible, they've already got their
22 rebuttal because we stipulated research is ongoing.

1 We know that the CMCR doctors are doing research
2 with cannabis. This is such an open-ended, vague
3 statement that it really serves no purpose to
4 rebut. Dr. Voth's testimony certainly, or at least
5 theoretically, may very well be rebutted by our
6 stipulation by the CMCR researchers and what have
7 you. So I'm just not willing to agree that this is
8 proper rebuttal testimony.

9 JUDGE BITTNER: Okay. Ms. Carpenter?

10 MS. CARPENTER: Yes, ma'am. First of all,
11 clearly, the two sentences there, it will be
12 receptive to sound, scientifically-based research
13 and, in the next line, will continue to facilitate
14 the work of manufacturers interested in bringing to
15 the market safe and effective products, so clearly,
16 the FDA is talking about both research and
17 pharmaceutical development.

18 Dr. Voth's testimony, and obviously Your
19 Honor can go back and read the testimony, which may
20 be more helpful, but he was asked many questions
21 about whether marijuana could possibly meet the
22 standards, whether all the cannabinoids and other

1 constituents had been identified, how difficult
2 that would be, and the strong implication from that
3 testimony is there is virtually no way that that
4 material could be approved as a product, and the
5 FDA has said quite the opposite. We are receptive
6 to this as long as it's sound and scientifically
7 based, and that's a fundamental--obviously, DEA is
8 going to argue that one reason the license ought to
9 be denied is because it's not feasible to bring it
10 to market. But the FDA has said, we're receptive
11 to this. It's clearly rebuttal testimony and it's
12 important.

13 JUDGE BITTNER: I will overrule the
14 objection with, of course, the caveat that if Dr.
15 Voth didn't say what you all think he said, that it
16 wouldn't be rebutting anything. So I will receive
17 Respondent's Exhibit 54, limited to the identifying
18 material and the second-to-the-last paragraph on
19 page--I keep losing the page number here--on the
20 last page, anyway. I mean, since it's been quoted
21 to the record, it's all right.

22 MS. CARPENTER: Could I get a copy, Your

1 Honor?

2 JUDGE BITTNER: You should have a copy.

3 No, you didn't--

4 MR. BAYLY: For the record, Judge Bittner,
5 we're going to continue to object, so what we would
6 like to do is brief this issue, because--

7 JUDGE BITTNER: Oh, sure.

8 MR. BAYLY: --I just don't see that this
9 statement rebuts. But once we get the transcript,
10 Your Honor will have a much clearer picture and so
11 we would ask you to please keep an open mind and
12 possibly overturn this ruling, and, of course,
13 we'll ask the Deputy Administrator to do the same.

14 JUDGE BITTNER: Of course.

15 MR. BAYLY: I'm not convinced at all that
16 this is rebuttal.

17 JUDGE BITTNER: Okay. That's understood,
18 and, of course, you can brief anything you want and
19 I'll read it.

20 MR. BAYLY: Okay.

21 JUDGE BITTNER: Although string citations
22 are not my favorite things to read, so I'd rather

1 you limit those. Okay.

2 So for that limited purpose, and actually
3 that limited portion, Respondent's 54 is received.

4 [Respondent's Exhibit No. 54
5 (in part) was received into
6 evidence.]

7 JUDGE BITTNER: Okay. The next item in
8 Respondent's rebuttal is, I guess, a proffer of
9 what should be marked, I imagine, as Respondent's
10 Exhibit 57?

11 MS. CARPENTER: Are we up there? I
12 thought we were--

13 JUDGE BITTNER: No, we have--because I
14 rejected 56.

15 MS. CARPENTER: Okay.

16 JUDGE BITTNER: I think, didn't I? Yes.
17 Respondent's 56, which is an affidavit from a Mr.
18 Al Byrne, and Respondent is offering this document
19 to rebut Dr. Elsohly's testimony with respect to a
20 photograph in Respondent's Exhibit 19, Figure 6,
21 page 50, as to whether the plant material came from
22 a NIDA cigarette, right?

1 MS. CARPENTER: That's correct.

2 JUDGE BITTNER: And you are now offering
3 Respondent's Exhibit 57, and Mr. Bayly, I
4 understand you object?

5 MR. BAYLY: Yes, and I'd like to go down
6 paragraph by paragraph, if I may, Your Honor.

7 JUDGE BITTNER: Sure.

8 MR. BAYLY: On number one and number two,
9 these are things that we can stipulate to.
10 However, they don't rebut anything that Dr. Elshohly
11 said.

12 As to case number three, he was there at
13 the time that the photographs were depicted on 49
14 and 50 of the article. Well, that's fine, but
15 that's not rebuttal.

16 Number four, actually, but for the last
17 sentence, paragraph number four actually offers
18 brand new evidence that is not rebuttal. He states
19 in this affidavit, "I'm a long-term cohort of five
20 of the federally-supplied cannabis patients," and
21 he just goes on and on about his participation, I
22 guess, in the Compassionate Use Program, whatever

1 it is. Then he says, "when smoke stems were harsh
2 and the seeds often exploded, as well as having a
3 negative therapeutic value, I have personally
4 observed this with several of the patients," that's
5 not rebuttal. That's certainly new evidence. So
6 that clearly should be stricken.

7 Then the last sentence says, "To document
8 this, I and others decided to photograph the
9 cannabis supplied in order to demonstrate the
10 quality of the medicine received," well, yes,
11 that's self-evident in the pictures, so that we can
12 stipulate to, but it's certainly not rebuttal.

13 Then number five is clearly new evidence
14 and it doesn't rebut anything Dr. Elsohly could
15 have possibly said. Dr. Elsohly was not there when
16 these pictures were taken, nor was he present to
17 know who was there or what they did or how this was
18 completed. So paragraph number five is clearly not
19 rebuttal and it is new evidence.

20 Number six says, quote, "In my presence,
21 Dr. Russo then photographed the marijuana that had
22 been rolled in the cigarettes." Well, there are

1 photographs of marijuana in there and if that's
2 what the intent of the article was, to show that,
3 this number six doesn't add anything, either.

4 Number seven, this affidavit says, "I have
5 observed the seeds and stems in the marijuana. I
6 also observed seeds and stems on the ends of some
7 cigarettes remaining in the open can." Well,
8 that's new evidence, as well. That should not be
9 in.

10 Number eight--the problem with number
11 eight is that the statement here doesn't say
12 anything about the pictures being either blown up
13 with, I guess, a telephotic lens or being made
14 smaller with a wide-angle lens or what have you,
15 and I think there may have been testimony by Dr.
16 Elsohly that he didn't think the pictures were
17 representative of the size. But the problem with
18 number eight is that the affidavit--the affiant
19 claims that the stems and seeds--seeds, stems, and
20 the size of the leaves, stems, and seeds relative
21 to each other as they existed were unrolled. Well,
22 Dr. Elsohly never said that the seeds and the stems

1 were relative to each other in error. So that is
2 offering new evidence and it's certainly not
3 rebuttal.

4 Then the last paragraph in this statement
5 by Al Byrne says the captions in the photographs,
6 including the photo labeled six, accurately
7 describe these photographs. There's no typo or
8 other error. Yes, I think Dr. Elsohly said maybe
9 there's a typo or error. Well, this is not
10 rebutting that because he just said maybe. But if
11 this does come in as, number nine as rebuttal, that
12 he's saying, no, there were no typo or other errors
13 in the captions, then so be that.

14 Then I also need to let you know, Judge
15 Bittner, that he's a co-author of this article, and
16 that certainly we can affirm, but this is a person
17 that has not given an address. Where is he? If
18 the parts of this that are admitted that we object
19 to, because we just got this today, we would want
20 the opportunity to perhaps call him and cross-examine him,
21 or at least put in some kind of
22 rebuttal evidence to this.

1 So I really don't want to have to drag
2 this on, but I just don't think that this measures
3 up to proper rebuttal.

4 JUDGE BITTNER: Okay. Ms. Carpenter?

5 MS. CARPENTER: Yes, Your Honor.

6 JUDGE BITTNER: Thank you, Mr. Bayly.

7 MS. CARPENTER: First of all, to go
8 paragraph by paragraph, I think is a little
9 misleading. If someone were sitting on the stand,
10 they wouldn't just say the pictures are accurate.
11 Obviously, the background is necessary to indicate
12 why he was in a position to know that what he says
13 is true. So all of those first paragraphs are
14 specifically related to that.

15 The affidavit then goes on to examine
16 exactly what happened when the photographs were
17 taken. Your Honor, I took pretty careful notes
18 when Dr. Elsohly was talking and this is what he
19 said about those pictures. There is--this is a
20 quote--"there is no way this was the material in
21 these cigarettes." Then he talked about how the
22 stems would puncture the paper, and then he says

1 this might be materials from bulk material, from
2 bulk material from RTI, but I have to challenge
3 that this material is from those cigarettes.

4 So this is clearly rebuttal because it
5 indicates that, in fact, the material is directly
6 from those cigarettes. I don't think it can get
7 much more rebuttal than that.

8 JUDGE BITTNER: I will overrule the
9 objection because I think the initial paragraphs
10 are background, and I do remember Dr. Elsohly's
11 testimony that he was--and I believe that he said
12 something about referring to the dimensions of the
13 items in the photograph and making certain
14 assumptions, which I don't remember, about what
15 size they would have to be in order to comport with
16 the usual size of a marijuana seed, with which
17 again I am not familiar, and that that's why he
18 felt that these items were too large to be in a
19 cigarette. So there's a clear conflict here.

20 So I'll overrule the objection, but I have
21 two points. One is if the Government wishes to
22 have the hearing remain open in order to call him,

1 I think that that would be certainly acceptable.

2 MS. CARPENTER: Absolutely.

3 JUDGE BITTNER: There is an address for
4 him, but it's three years old, on the article
5 itself--

6 MS. CARPENTER: We're happy to provide an
7 address--

8 JUDGE BITTNER: But you would be able to
9 supply an accurate address?

10 MS. CARPENTER: Actually, it's the same
11 one.

12 JUDGE BITTNER: Okay. I'd also like to
13 note, and this should just be in the record, that
14 there seems to be something rather glitchy with the
15 fax machine because the date stamp on the top of
16 the document is January 1, 2002.

17 MS. CARPENTER: Oh, that's right. I will
18 represent that's my fax machine, so--

19 JUDGE BITTNER: Is it? Okay. I thought
20 that was--

21 MR. BAYLY: There's a fax on the bottom,
22 thought.

1 JUDGE BITTNER: No, I'm talking about--I
2 looked at this and thought that it was three years
3 old--four years old.

4 MS. CARPENTER: No, Your Honor. We just
5 received it today. I don't know what--

6 JUDGE BITTNER: Okay. So the date January
7 1, 2002, is wrong?

8 MS. CARPENTER: We will actually get the
9 original and submit that. It's just that we just--because
10 the testimony was just on Monday, we were
11 able to track him down, but we've not been able to
12 get the original yet. That should be coming
13 tonight.

14 JUDGE BITTNER: All right. So I will
15 receive Respondent's 57 without the fax
16 information--

17 MS. CARPENTER: Okay.

18 JUDGE BITTNER: --on the receiving machine
19 and keep the record open for some unidentified
20 period of time at the moment so that the Government
21 may have an opportunity to decide whether or not
22 you want to call him for cross.

1 MR. BAYLY: Well, one, to call him and/or--

2 JUDGE BITTNER: Or--

3 MR. BAYLY: --surrebuttal, right?

4 JUDGE BITTNER: Yes. I'm sorry. I didn't
5 mean to limit you. Okay. So Respondent's 57 is
6 received.

7 [Respondent's Exhibit No. 57
8 was received into evidence.]

9 JUDGE BITTNER: Now, item number three.

10 MS. CARPENTER: Number three. That was an
11 as yet unidentified affidavit.

12 JUDGE BITTNER: Right, that the reference
13 in Government Exhibit 40 on whether passage of a
14 State referendum on medical marijuana would make it
15 easier to obtain illegal marijuana, and Respondent
16 wishes to offer an affidavit from--

17 MS. CARPENTER: From Dr. Rodney Skager.

18 JUDGE BITTNER: Who has done research on
19 this subject.

20 MS. CARPENTER: Particularly with regard
21 to teenagers.

22 JUDGE BITTNER: Right. So I think that

1 you would just need to file a motion to do, and Mr.
2 Bayly is on notice that you're planning to do so
3 and you're on notice that Mr. Bayly plans to object
4 to it, right?

5 MR. BAYLY: On notice on--

6 JUDGE BITTNER: On the issue of having
7 some kind of an affidavit from Dr. Skager rebutting
8 the comments in Government Exhibit 40 about a State
9 referendum making it easier for teenagers to get
10 illegal marijuana.

11 MR. BAYLY: If I could put an objection on
12 right now, I'd be glad to object to any motion or
13 supplemental that's put into the record, but--

14 MS. CARPENTER: Well, let me just say it's
15 not a supplemental because it's in the pre-hearing
16 statement. So it's simply affidavit form of
17 testimony. If you'd rather have us bring him here,
18 I suppose we could do that, too.

19 MR. BAYLY: Yes. I think it would be
20 better if they did the motion and then we can--

21 JUDGE BITTNER: Okay.

22 MR. BAYLY: --see exactly what's going on

1 on this.

2 JUDGE BITTNER: All right. So that's on
3 hold, as far as I'm concerned, anyway.

4 MS. CARPENTER: That's fine.

5 JUDGE BITTNER: And then item four was
6 Respondent's intention to offer into evidence--which you
7 don't have at the moment, I assume--

8 MS. CARPENTER: No, it just came out
9 today.

10 JUDGE BITTNER: --a catalog indicating at
11 least some of the Schedule I substances that are
12 available commercially to researchers to rebut Dr.
13 Gust's testimony that there are only a handful of
14 such substances available. So we have to wait on
15 that, too, and you'll have an opportunity to
16 respond, Mr. Bayly.

17 MR. BAYLY: Okay. I have, I guess amongst
18 other possible objections is one I can think of
19 right off the top of my head is the materiality of
20 this and the cross-examination and rebuttal gets
21 kind of minutiae here, but--

22 JUDGE BITTNER: Actually, I think that was

1 on direct. I'm not sure, though, on direct
2 examination of Dr. Gust, but I'd have to look at--

3 MS. CARPENTER: Yes. It was clearly on
4 direct examination.

5 JUDGE BITTNER: Okay. And I'm hoping that
6 you all will agree on some of these one way or the
7 other.

8 MS. CARPENTER: I'm certainly happy to,
9 Your Honor.

10 JUDGE BITTNER: I am sure.

11 [Laughter.]

12 JUDGE BITTNER: And then the last item
13 was--and this was the one where I said I didn't
14 remember the testimony, which doesn't help--Respondent would
15 like to put in the third chapter
16 of what had been excluded as Respondent's Exhibit
17 21, what I excluded back in August, to rebut Dr.
18 Voth's testimony about the harm of using marijuana
19 at all and of consequences of using various
20 concentrations.

21 MS. CARPENTER: Right.

22 JUDGE BITTNER: Mr. Bayly?

1 MR. BAYLY: May I have a moment, Your
2 Honor?

3 JUDGE BITTNER: Sure. You want to go off
4 the record?

5 MR. BAYLY: I think it will be quick.

6 JUDGE BITTNER: Okay.

7 [Pause.]

8 JUDGE BITTNER: Yes, Mr. Bayly. We're on.

9 MR. BAYLY: All right. I think we can
10 address this on the merits. If they feel it should
11 go in for rebuttal, it's been in the record since
12 during--

13 JUDGE BITTNER: Well, it's been available,
14 but it's not been offered because I said you
15 objected to it and I said they couldn't offer it.

16 MR. BAYLY: Right. It's a document that's
17 been around a long time that we're aware of, so we
18 won't object to that. It's these brand-new
19 documents that we get on the day of the hearing
20 that we have more problems with.

21 JUDGE BITTNER: Okay. So--I don't think

1 I've ever had so much trouble finding exhibits.
2 Respondent 21, pages, what, 137 to where, Ms.
3 Carpenter?

4 MS. CARPENTER: I'm sorry, Your Honor. I
5 don't have it in front of me now.

6 JUDGE BITTNER: The chapter is from pages
7 137 to 154.

8 MS. CARPENTER: That's what it is, then.
9 It's just that chapter.

10 JUDGE BITTNER: Okay. So, Mr. Bayly,
11 you're not objecting?

12 MR. BAYLY: Correct.

13 JUDGE BITTNER: Okay. So Respondent--and
14 again, the identifying information obviously needs
15 to be in, too, but I'm not going to read the rest
16 of it.

17 MS. CARPENTER: That's fine.

18 JUDGE BITTNER: Respondent--so now the
19 rest of it stands as rejected and you still want
20 the whole thing to go to the Deputy Administrator?

21 MS. CARPENTER: Yes, Your Honor.

22 JUDGE BITTNER: Okay.

1 MS. CARPENTER: Yes.

2 JUDGE BITTNER: Respondent 21, Chapter 3,
3 pages 137 to 154, plus identifying pages, are
4 received.

5 MS. CARPENTER: Thank you, Your Honor.

6 [Respondent's Exhibit No. 41
7 (in part) was received into
8 evidence.]

9 JUDGE BITTNER: Okay. And that was it?

10 MS. CARPENTER: That's it.

11 JUDGE BITTNER: Okay. Now, since we have
12 rebuttal and virtual rebuttal, Mr. Bayly, do you
13 have any virtual or real surrebuttal?

14 MR. BAYLY: Not now.

15 JUDGE BITTNER: Okay. I can see this is
16 going to be an interesting year. Let's go off the
17 record.

18 [Discussion off the record.]

19 JUDGE BITTNER: Pursuant to earlier
20 rulings, Respondent's Exhibit 23, 24, 25, and 27
21 were in limbo because I had excluded them and then
22 Respondent had, notwithstanding that exclusion,

1 Respondent was considering whether or not to offer
2 them and decided not to offer them until the
3 rebuttal portion of Respondent's case in case they
4 became rebuttal. So at this point, having excluded
5 them and not having new reasons to not exclude
6 them, Respondent's 23, 24, 25, and 27 are rejected,
7 but they will be forwarded to the Deputy
8 Administrator eventually.

9 MS. CARPENTER: Thank you.

10 JUDGE BITTNER: Okay. Was there more?

11 Okay. There's more.

12 [Pause.]

13 JUDGE BITTNER: This way, I don't have to
14 go to the hearing clerk later and say, did I-- And
15 there were also Respondent Exhibit 44--

16 MS. CARPENTER: Yes. We have finally
17 located the signed copy of that, which apparently
18 is a very bad fax, which is why that's not the one
19 that we have. I will obtain a copy of that and
20 send it to the Court, if that's acceptable.

21 JUDGE BITTNER: Mr. Bayly, is that okay
22 with you?

1 MR. BAYLY: Yes.

2 JUDGE BITTNER: Okay, so--

3 MS. CARPENTER: It's a bad copy--

4 JUDGE BITTNER: So Respondent--or could
5 you just show it to Mr. Bayly, the signed copy?

6 MS. CARPENTER: I don't have it with me,
7 but I'd be happy to send it to him. We have just
8 sort of located it--

9 JUDGE BITTNER: Okay. Could you all enter
10 into a stipulation at some point that there was a
11 signed copy so I can receive this exhibit, and I'll
12 do it then?

13 MR. BAYLY: I do.

14 JUDGE BITTNER: Okay. Respondent Exhibit
15 44, the difficulty with it, I believe, was that
16 there were no signatures on it. It's a letter from
17 Senators Kerry and Kennedy.

18 MS. CARPENTER: And I think the date at
19 the top was also confusing, so--

20 JUDGE BITTNER: Oh, yes, because it shows
21 at the top as if a header, Senator Kennedy and
22 Kerry letter to the DEA, October 20, 2004, and then

1 just below "United States Senate," it says, October
2 20, 2003.

3 MS. CARPENTER: Right.

4 JUDGE BITTNER: So there's a faxed copy,
5 which is a bad copy, but it clarifies those two
6 points.

7 MS. CARPENTER: --the actual date, and
8 I'll be happy to get a copy of that.

9 JUDGE BITTNER: Okay. So if you all would
10 either stipulate or Respondent send to me, however
11 you want to work it out--

12 MS. CARPENTER: Okay.

13 JUDGE BITTNER: So then at that point--

14 MR. BAYLY: I'll stipulate.

15 JUDGE BITTNER: --I could receive the
16 exhibit.

17 MS. CARPENTER: Great.

18 JUDGE BITTNER: But I won't yet. Okay.
19 Respondent's 44 on hold pending--okay.

20 Then the next item, thanks to Nicole's
21 excellent notes, was the curriculum vitae of Dr.
22 Skager.

1 MS. CARPENTER: Well, there was 46, Your
2 Honor, Respondent's Exhibit 46, which I think you
3 indicated we would just hold until you had read. I
4 don't know whether you want--

5 JUDGE BITTNER: And I haven't read it.

6 MS. CARPENTER: Okay. So we'll just hold
7 off for now.

8 JUDGE BITTNER: So that, though--

9 MS. CARPENTER: That's fine.

10 JUDGE BITTNER: --the argument's in the--

11 MS. CARPENTER: Right.

12 JUDGE BITTNER: I'll just deal with it.

13 MS. CARPENTER: Right.

14 JUDGE BITTNER: Okay.

15 MS. CARPENTER: And then 47 and 48, I
16 guess we would offer those when we tender the
17 affidavit of Dr. Skager.

18 JUDGE BITTNER: Okay.

19 MS. CARPENTER: Does that make sense?

20 JUDGE BITTNER: Okay.

21 MS. CARPENTER: I mean, I guess we could
22 offer them now and then they would be in the

1 record, if we just want to have everything in the
2 binder accounted for.

3 JUDGE BITTNER: Okay. Why don't you do
4 that. So Respondent is offering Respondent's 47
5 and 48?

6 MS. CARPENTER: Right.

7 JUDGE BITTNER: And ruling is withheld
8 pending a ruling on the virtual affidavit of Dr.
9 Skager. Okay.

10 MS. CARPENTER: That's all I have.

11 JUDGE BITTNER: Okay. Thank you, Nicole.
12 You helped a lot.

13 All right. Obviously, there are some
14 submissions to be made. Do you wish to keep open
15 the January hearing dates?

16 MR. BAYLY: That's--I think the Respondent
17 has to file at least one motion. We have to file a
18 response. We've got to perhaps either issue an
19 admin--not an admin, an ALJ subpoena to perhaps
20 cross-examine Al Byrne and/or bring up some other
21 witnesses for surrebuttal. And given that we're
22 now heading into the Christmas-New Year's season,

1 gee, those dates don't look real promising at this
2 point.

3 JUDGE BITTNER: Ms. Carpenter, what's your
4 feeling?

5 MS. CARPENTER: We can certainly bring Mr.
6 Byrne here easily if that would ease things. I
7 mean, if you don't want to have to issue a
8 subpoena, we could--

9 JUDGE BITTNER: Well, no, I mean, issuing
10 a subpoena is no big deal.

11 MS. CARPENTER: All right. I guess it's
12 our view we could have the affidavit filed within a
13 day or two and the Government could respond. It is
14 getting tight. I guess I'm worried about putting
15 off because I know Your Honor's schedule is fairly
16 busy, and if we don't get those days, I'm worried
17 about the days we will get.

18 JUDGE BITTNER: Okay. Let's go off the
19 record and look at dates.

20 [Discussion off the record.]

21 JUDGE BITTNER: At this point, we are
22 canceling the previously scheduled hearing dates of

1 January 3 and 4. I am erasing them from the
2 calendar. This is a very high-tech way of dealing
3 with this. Am I correct about that?

4 MR. BAYLY: Yes.

5 MS. CARPENTER: Yes.

6 JUDGE BITTNER: Okay. And we are
7 reserving here the dates of January 17 and 30 in
8 case we need them, 2006.

9 MR. BAYLY: Yes. The Government is in
10 agreement.

11 JUDGE BITTNER: Okay. And, Ms. Carpenter,
12 you are, too?

13 MS. CARPENTER: Yes.

14 JUDGE BITTNER: Thank you very much, both
15 of you.

16 Now, does either of you wish to make a
17 closing statement, even though we don't have all
18 the evidence yet?

19 MR. BAYLY: Waive it. We'll waive it.

20 JUDGE BITTNER: You're going to waive it
21 altogether?

22 MR. BAYLY: Yes.

1 JUDGE BITTNER: Okay. Ms. Carpenter?

2 MS. CARPENTER: Based on your discussion
3 earlier, we will waive it, as well, Your Honor.

4 JUDGE BITTNER: Okay. Is it--I hesitate.
5 I don't want to set dates for transcripts and so on
6 because I don't know when the hearing's going to
7 end. Other than that, it would be easy. Do you
8 think it might be possible, if I give you some of
9 the sort of usual guidelines, that you two could
10 agree on a date for corrections and briefs?

11 MS. CARPENTER: For corrections, Your
12 Honor, to the transcripts? Is that what you--

13 JUDGE BITTNER: Okay. Let me just go
14 through what happens.

15 MS. CARPENTER: Great.

16 JUDGE BITTNER: Okay. When the hearing
17 finally closes, whenever that may be, normally what
18 I do is at the end of the hearing, I set a date for
19 corrections to the transcript and for the proposed
20 findings of law, conclusions of fact, and argument--findings
21 of fact, conclusions of law, and
22 argument. You can tell it's 4:30 on the Friday

1 before Christmas.

2 Now, in this case, you will all have the
3 transcripts very soon. I usually say three weeks
4 after receipt of the transcript, of the last
5 transcript, for corrections. Corrections are
6 precisely that. The purpose of filing corrections
7 is to correct a mistake between what the transcript
8 says and what was said in the room. It is not an
9 order to have the transcript reflect what a party
10 wishes had been said. We are not Congress.

11 [Laughter.]

12 JUDGE BITTNER: And then I usually set a
13 date obviously after that for the filing of the
14 proposed findings of fact, conclusions of law, and
15 argument, which we fondly call briefs for reasons
16 that are not clear to me.

17 MS. CARPENTER: Well, it's briefer than
18 the title.

19 JUDGE BITTNER: Yes.

20 [Laughter.]

21 JUDGE BITTNER: After the briefs come in
22 and I've had a chance to read everything--and I do

1 read everything, which is why I don't like you to
2 string cite cases--I will eventually issue a
3 written decision. After I issue my decision, both
4 parties have the opportunity to file exceptions to
5 it, which are filed with our office.

6 After the period for filing exceptions has
7 expired, I eventually send--and we discussed this a
8 little bit, I think, on Wednesday--my decision,
9 your proposed findings of fact, et cetera, your
10 briefs, the transcript, the exhibits, and various
11 other items that have been filed or issued in the
12 case to the Deputy Administrator. At the time I do
13 that, I will send you a copy of the letter that I
14 send to the Deputy Administrator and a copy of the
15 list that I sent her, so you'll know what she got.

16 Then the Deputy Administrator, as I'm sure
17 you all know, issues a final order and that is the
18 final agency action in the matter and that order is
19 published in the Federal Register and I think a
20 courtesy copy is served on Respondent before that.

21 Then the Respondent, if he, she, or it
22 feels aggrieved, has the opportunity to file a

1 petition for review in the appropriate court of
2 appeals.

3 Now, are there any questions about that
4 process? Mr. Bayly?

5 MR. BAYLY: No, Your Honor.

6 JUDGE BITTNER: Ms. Carpenter?

7 MS. CARPENTER: No, Your Honor.

8 JUDGE BITTNER: Actually, I should have
9 gone to Ms. Carpenter first. I forgot, you have
10 the burden of proof.

11 [Laughter.]

12 JUDGE BITTNER: So what I was asking is,
13 do you think that counsel, since we don't know when
14 the hearing is going to close, do you want me to
15 just set a date for filing corrections and briefs,
16 or do you think you could work out a stipulation as
17 to when you would like to do it and send it to me?

18 MS. CARPENTER: I'm sure we could work out
19 a stipulation.

20 MR. BAYLY: Yes, I believe that would
21 work--

22 JUDGE BITTNER: I mean, that would just be

1 easier than my picking a date and then you all
2 requesting different dates. It's just easier if
3 you'd decide in the first instance.

4 MR. BAYLY: Yes. I'm sure we'll both be
5 very amenable to--

6 JUDGE BITTNER: Ameliorative, yes.

7 MS. CARPENTER: Absolutely.

8 JUDGE BITTNER: Okay.

9 MS. CARPENTER: Could I ask one question,
10 Your Honor, about the process? After the briefs
11 are filed, is there an opportunity to respond to
12 the Government's brief, or we just file one brief,
13 you decide, and then exceptions?

14 JUDGE BITTNER: I've had motions to file
15 reply briefs. I've sometimes had the parties agree
16 that they all want an opportunity to file reply
17 briefs. Do you think you're going to want to?

18 MR. BAYLY: Judge Bittner, my preference
19 would be if you feel that you need a reply brief, I
20 know you've issued orders in the past to do that
21 because that's an exceptional procedure not
22 provided for in our regulations and I don't think

1 it's certainly required by the APA, but certainly
2 if you issue an order saying each party can file a
3 reply brief, and I know you've done that in some of
4 the more complex--

5 JUDGE BITTNER: I've never done it by my
6 own motion, though. In other words, I've--especially when
7 the parties asked--if all parties.

8 Usually, these are in multi-party cases. If all
9 parties say, we want to file reply briefs, I
10 generally let them because I'm a masochist, but--

11 MS. CARPENTER: Okay.

12 JUDGE BITTNER: --it's not usual. I--I
13 think I'll let you two decide whether you want to
14 do that, and if one of you does and the other one
15 doesn't, I'll have to rule on it, okay?

16 MS. CARPENTER: That's fine.

17 JUDGE BITTNER: And also, please note that
18 there is a provision in the regulations about
19 exceptions, that a party may file exceptions or
20 cross-exceptions, but not both, as I recall, so you
21 may want to be aware of that.

22 MR. BAYLY: Right, and the exceptions can

1 be used to attack not only the recommendation, but
2 to attack the other party's positions, too, I would
3 think.

4 JUDGE BITTNER: I guess. See, I don't
5 worry about those. They get filed with me, but
6 then they go elsewhere. They're not my problem.

7 Okay. Any other questions, comments,
8 concerns?

9 [No response.]

10 JUDGE BITTNER: All right. I look forward
11 to hearing from you. I won't close the record. I
12 would like to thank you all. I know this is a
13 rather difficult sort of proceeding and I
14 appreciate all the courtesy that you have shown to
15 each other and to my staff and to me, and I would
16 like to thank my staff, because as you've all
17 noticed, it's rather difficult having a hearing in
18 this building, given the security concerns.

19 So I wish you well. Have a joyous holiday
20 season, and with that, we are adjourned, at least
21 for the time being. Off the record.

22 [Hearing concluded at 4:34 p.m.]