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ALSO PRESENT:

MATTHEW STRAIT
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RICHARD DOBLIN, Ph.D.
Representative of Respondent

C O N T E N T S

WITNESS	DIRECT	CROSS	REDIRECT	RECROSS
Matthew Strait	1008	1116	- -	- -

- - -

E X H I B I T S

EXHIBIT NOS.	MARKED	RECEIVED
RESPONDENT'S		
12	(previously)	1005

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

2 MS. CARPENTER: Your Honor, before we
3 start with Mr. Strait--

4 JUDGE BITTNER: Yes.

5 MS. CARPENTER: --could I address two
6 quick housekeeping matters?

7 JUDGE BITTNER: Do you want to do it off
8 the record?

9 MS. CARPENTER: Well actually, it probably
10 should be on the record. They're exhibits.

11 JUDGE BITTNER: Okay.

12 MS. CARPENTER: The first thing is to
13 tender to the Court Respondent's Exhibit No. 12. I
14 gave a copy of it to Mr. Bayly yesterday. This is
15 the letter about the orphan drug designation, and
16 it has the signature on it that was missing from
17 the other version.

18 JUDGE BITTNER: Okay.

19 MS. CARPENTER: So perhaps--I don't know
20 if we had marked the other one. I don't know if--

21 JUDGE BITTNER: I think I withheld ruling
22 on it, right?

1 MS. CARPENTER: I think you did, but I
2 don't know whether we had a substitute Exhibit No.
3 12.

4 JUDGE BITTNER: That would probably be a
5 good idea, so actually, first, let me ask, Mr.
6 Bayly, do you have any objection to it?

7 MR. BAYLY: No, no, I looked at it. I did
8 get a--

9 JUDGE BITTNER: Okay; so, substitute
10 Exhibit No. 12, which we will now refer to as
11 Exhibit No. 12, is received.

12 [Respondent Exhibit No. 12 was
13 received in evidence.]

14 MS. CARPENTER: Thank you, Your Honor.
15 And moved into admission? Okay; great.

16 And the other quick question was we had
17 another exhibit which you had withheld ruling on.
18 It was our Respondent's Exhibit No. 26, and it was
19 the protocol from the United Kingdom.

20 JUDGE BITTNER: Yes.

21 MS. CARPENTER: Mr. Hopper can--I just
22 wanted to get this done before the end of the week

1 so we could take care of it before the next session
2 but would propose admitting or attaching an
3 affidavit from Mr. Emanuel Jacobowitz, who was the
4 attorney at Steptoe and Johnson who received the
5 letter to which that was attached, and Mr. Hopper
6 can tell you what the affidavit would say.

7 MR. HOPPER: The affidavit--I got an email
8 from a man at Steptoe. Mr. Jacobowitz' affidavit
9 would state that he received the exhibit from Chief
10 Inspector Alan D. McFarlane of the Drugs Branch of
11 the U.K. Home Office pursuant to a telephone
12 conversation that Mr. Jacobowitz had with Mr.
13 McFarlane, and in a follow-up email, Mr. McFarlane
14 informed Mr. Jacobowitz that it had come--it being
15 the exhibit, the protocol--had come into effect on
16 April 1, 2005. Mr. McFarlane's assistant, Michael
17 Evans, told Mr. Jacobowitz by email that it was an
18 internal protocol. The phrase he used was internal
19 working document in its final form. And Mr.
20 Jacobowitz can produce those emails as well.

21 JUDGE BITTNER: He can.

22 MR. HOPPER: Yes.

1 JUDGE BITTNER: Oh, good.

2 Mr. Bayly?

3 MR. BAYLY: I think we may want to defer
4 this, because number one, we'd like to see the
5 affidavit itself, and secondly, we want to check up
6 on it, and we may have a counter-affidavit. I
7 don't know. We may not.

8 But I think the Government is somewhat
9 prejudiced by submitting the affidavit at this
10 point. We have a break, and we know we're going to
11 be back in September, so if the Respondent team
12 wants to submit that to us at this time, and then,
13 we can revisit this in September.

14 JUDGE BITTNER: Ms. Carpenter.

15 MS. CARPENTER: That would be fine, Your
16 Honor.

17 JUDGE BITTNER: I think that makes a great
18 deal of sense.

19 MS. CARPENTER: That's fine.

20 JUDGE BITTNER: So I think what we're
21 looking at is attaching to Exhibit No. 26 as
22 Exhibit No. 26, who knows what, an affidavit from

1 Mr. Jacobowitz and an exchange of emails.

2 MS. CARPENTER: That's right.

3 JUDGE BITTNER: Okay; all right. So
4 somebody has made a note of that, and we'll look at
5 it the first thing in September.

6 MS. CARPENTER: Okay.

7 Whereupon,

8 MATTHEW STRAIT

9 was recalled as a witness herein and, having being
10 previously duly sworn, was examined and testified
11 further as follows:

12 CROSS-EXAMINATION (Resumed)

13 BY MS. CARPENTER:

14 Q Good morning, Mr. Strait.

15 A Good morning.

16 Q Mr. Strait, I think yesterday, we had just
17 started on Exhibit No. 16, so if you could turn to
18 Government's Exhibit No. 16. And that's the note
19 that you took of the interview in which Dr. Grant
20 gave the answers; is that correct?

21 A Correct.

22 Q Okay; let me direct your attention to page

1 8 of 19. And in the box just below question 18,
2 and look down to the very bottom of that box,
3 there's a little star there. It says private firms
4 generally prefer not to sponsor head to head trials
5 of their product versus smoked marijuana. I know
6 you testified that I think Ms. Bentley added that
7 in; is that correct?

8 A Correct.

9 Q Do you recall that conversation when you
10 were having the interview?

11 A Not specifically, no.

12 Q Did Ms. Bentley or anybody tell you why a
13 private firm would prefer not to sponsor head to
14 head trials of their research versus smoked
15 marijuana?

16 A I don't recall.

17 Q Okay; do you know why?

18 A No.

19 MS. PAREDES: Objection, calls for

20 THE WITNESS: No.

21 MS. CARPENTER: Okay; but you had
22 testified some about that on cross, I mean.

1 JUDGE BITTNER: On direct.

2 MS. CARPENTER: I'm sorry?

3 JUDGE BITTNER: On direct.

4 MS. CARPENTER: On direct; thank you, Your
5 Honor.

6 BY MS. CARPENTER:

7 Q And then, at the top of that box, the
8 third sentence, which starts limitations; the
9 sentence says limitations result from this approach
10 from a scientific view b/c, which I assume means
11 because, and then, there was nothing after that.
12 Was there something missing after that sentence, or
13 do you recall what the reasons were that when this
14 notation--

15 A No, actually, there is a comment after it,
16 which was subsequently stricken by the folks at
17 CMCR who actually had the opportunity to modify
18 this response. So what would have been after
19 because--

20 Q I see.

21 A --is objectives have to match with private
22 firm.

1 Q Oh, okay. And who crossed that out?

2 A That would--I don't know specifically,
3 actually.

4 Q Okay; but there's a little star there, and
5 you think that star refers to the star down below?

6 A Yes.

7 Q Which says private firms generally prefer
8 not to sponsor? Oh, okay; I understand, then. And
9 your notes underneath that say GW expressed concern
10 over consideration of smoked versus sublingual
11 spray. Was there any discussion of that at the
12 meeting?

13 A This would have been the response by Dr.
14 Grant.

15 Q And that was to your question about why
16 objectives would have to match with a private firm.

17 A This would have been in response to
18 question 18 and any follow-up which he may have
19 added.

20 Q Okay; was it expressed in those
21 conversations that GW or other private firms that
22 provided nonsmoked products wouldn't want to

1 compare their product with smoked marijuana because
2 they thought smoked marijuana might be more
3 efficacious?

4 A Perhaps--could you rephrase or--

5 Q Sure.

6 A I don't know if I understand.

7 Q During this discussion with Dr. Grant
8 where he is talking about limitations on the
9 results and private firms not wanting to go head to
10 head with smoked marijuana, was there any comment
11 during that discussion that the reason private
12 firms might not want to be involved in a head to
13 head competition with smoked marijuana versus their
14 own marijuana product was that smoked marijuana
15 might be more efficacious?

16 A I actually don't recall.

17 Q If you turn over to the next page, page
18 19.

19 A I'm sorry? Which page?

20 Q I'm sorry; page 9 of 19; beg your pardon.
21 I'm sorry; let me just turn you back one page;
22 question 19. The question is have you ever had any

1 difficulty obtaining marijuana from NIDA for all
2 strengths of cigarettes to meet research
3 requirements, and Dr. Grant answered yes, he has
4 had difficulty, isn't that right?

5 A Yes.

6 Q And on the next page, he indicates that
7 getting consistencies of six to eight percent have
8 been difficult; is that right?

9 A Yes, that was his response.

10 Q Okay; and then, down below, in answer to
11 the question do you feel that any problems you've
12 experienced could be remedied by the addition of a
13 second supplier, there's quite a bit of discussion
14 about GW and sophisticated farming procedures that
15 lead to a more consistent product, isn't there?

16 A There are some comments that I had noted
17 from his response and then, subsequently had been
18 modified by the CMCR.

19 Q Right; and in those comments, they
20 indicate that GW has a way of guaranteeing with
21 more certainty the concentrations of THC in the
22 product; isn't that right?

1 A Well, we kind of discussed in this, and I
2 guess it was during direct, that there was some
3 confusion as to how this was actually meant to
4 read, so if I'm not mistaken, I think we kind of
5 agreed that it really very clear what was actually
6 said in there.

7 Q Well, you're the one who was there, Mr.
8 Strait. Was it your understanding that Dr. Grant
9 was saying that GW has the ability to provide or
10 predict the concentrations with more certainty?

11 A The only thing I can state for you is what
12 I have written. The comment that or the
13 modification that Ms. Bentley had made, which is
14 the modification below is--

15 Q I'm sorry; go ahead.

16 A --subject, I guess, to the interpretation
17 of the Court, because we agreed it was kind of
18 difficult to hash through.

19 Q Okay; but your language was that GW can
20 guarantee with more certainty; isn't that right?
21 That's what you wrote down during your
22 conversation. Nobody struck that out, right?

1 A Let me read for you what it states.

2 Q Fine.

3 A It says GW has a very sophisticated
4 procedure of genetic engineering. They can
5 adequately predict the concentrations, period.
6 They don't know of U. Miss--I think it should have
7 been if U. Miss--does that, but GW can guarantee
8 with more certainty. If that were possible, it
9 would lessen the degree of uncertainty. Those
10 would have been my handwritten notes that were in
11 response to the comments that were provided by Dr.
12 Grant.

13 Q You were taking the notes of what Dr.
14 Grant said, right?

15 A Absolutely.

16 Q Okay; let me ask you to turn to--

17 JUDGE BITTNER: Oh, I see. I just noticed
18 something. If I may, this is--I was missing a
19 noun. And the noun appears to me, anyway, to be
20 GW, so that the smaller handwriting is Ms.
21 Bentley's; is that correct?

22 THE WITNESS: Yes.

1 JUDGE BITTNER: So I think that the last
2 three lines of that box, the one area we might like
3 to see more reliability on is the strength of the
4 medical marijuana cigarettes. We know this is
5 difficult with plant material, but we were told
6 that, and then, the area goes up to GW.

7 MS. CARPENTER: Right.

8 JUDGE BITTNER: And then goes up to the
9 blank part appeared to be able to predict. Am I
10 correct on that?

11 THE WITNESS: I think you're correct in
12 that. When we tried to recreate the full comment
13 that was made with the cross outs and the
14 additions, I think we had some difficulty agreeing
15 on exactly how it was to read.

16 JUDGE BITTNER: Right.

17 THE WITNESS: But it's my understanding
18 that that comment was supposed to be inserted
19 before this statement that I had written in
20 response to Dr. Igor's grant being fielded the
21 question.

22 JUDGE BITTNER: Okay; so, the asterisk

1 before the first reference in darker, bolder ink--

2 MS. CARPENTER: Right.

3 JUDGE BITTNER: --the one area, et cetera,
4 you think was supposed to go before GW several
5 lines up.

6 THE WITNESS: I believe that.

7 JUDGE BITTNER: Okay; and do you remember
8 what color ink was all this in, since I should note
9 that everyone is using a copy, and all of the
10 copies are black.

11 MS. CARPENTER: Yes.

12 THE WITNESS: I think that Ms. Bentley's
13 comments were in blue when they were returned to
14 me.

15 JUDGE BITTNER: Okay.

16 BY MS. CARPENTER:

17 Q Okay; but in any event, it is clear from
18 that comment that in response to the question about
19 whether problems would be remedied by the addition
20 of a second supplier, the response of CMCR was
21 there is somebody else out there who seems to be
22 able to predict or guarantee with more certainty

1 the concentrations of the product; isn't that
2 right? And that somebody is GW.

3 A I can only state what is stated here in
4 the response that they provided, that Dr. Grant
5 provided.

6 Q Do you think something I'm saying is
7 wrong? I just want to be clear about what it--because you
8 see it's a little unclear, obviously,
9 from where the markings are. So I just want to be
10 clear I understand what it says. In response to
11 the question, do you feel that the problems that
12 you have experienced could be remedied by the
13 addition of a second supplier, the CMCR folks
14 responded by saying GW has a more sophisticated
15 procedure, and they can do a better job predicting
16 the accuracy of the concentration; isn't that
17 right?

18 A The only response I can say is that when
19 asked the question, Dr. Grant responded by saying
20 that GW has a very sophisticated procedure of
21 genetic engineering and that they can adequately
22 predict the concentrations. They don't know if U.

1 Miss does that, but GW can guarantee with more
2 certainty.

3 Q Okay; thank you.

4 A I can only offer what was presented by Dr.
5 Grant.

6 Q And then, you said if that were possible,
7 it would lessen the degree of uncertainty.

8 A That is what is written down there.

9 Q Okay; let me ask you to turn to page 12 of
10 Government's Exhibit No. 16.

11 A Yes.

12 Q And in response to the question is the
13 potency of the current product consistent, the
14 answer is no, right?

15 A The answer is no, with a footnote.

16 Q Right; and I just want to clear up, I'm
17 unsure from your testimony yesterday. Did you say
18 yesterday that you added that in later. later?

19 A No.

20 Q That particular--no, that was written down
21 at the time?

22 A No, that would have been written down at

1 the time.

2 Q That was written down at the time?

3 A Absolutely.

4 Q Okay; and then, if you turn over to the
5 next page, page 13 of 19, and the question is
6 number 29, have any patients ever complained about
7 the freshness of marijuana, and the answer is yes,
8 right?

9 A That is correct.

10 Q And then, there are some comments about
11 harshness.

12 A Yes, with a modification made by Ms.
13 Bentley.

14 Q Okay; did you have any discussion with her
15 about that modification?

16 A No, I did not.

17 Q Or any of the modifications?

18 A No, I did not.

19 Q You did not call her up to say what did
20 you mean by this or--

21 A I called her to say thank you for sending
22 the documents.

1 Q Okay; and at that bottom of the page, it
2 says analysis will done in house soon, and then, in
3 separate writing which I guess is Ms. Bentley's, on
4 the content--I'm sorry, on THC content.

5 A Yes.

6 Q Do you know why was that added? Why is
7 that there?

8 A I don't recall what context the comment
9 was offered, but the comment would have been
10 offered by Dr. Grant.

11 Q So Dr. Grant said they were going to start
12 analyzing the marijuana they got from NIDA in house
13 soon?

14 A It appears that that's what he said, yes.

15 Q Was there any discussion about why they
16 would need to analyze the marijuana they got from
17 NIDA in house?

18 A I don't necessarily recall specifically
19 any further discussion.

20 Q Did it have anything to do with the
21 variations in potency that he had been talking
22 about?

1 A I don't know.

2 Q Would CMCR require a special license from
3 the DEA to do their analysis in house on THC
4 content?

5 A No, chemical analysis can be done under a
6 research registration.

7 Q Okay; and if you turn over to page 16,
8 question 35, do you think it would be clinically
9 important to evaluate the efficacy of a higher
10 potency cigarette for your patient population, and
11 the answer was yes, wasn't it?

12 A Yes.

13 Q Okay; and then, there's a little note to
14 the side, and I think you read that on direct.

15 A Yes.

16 Q They arrived at 8 percent based on
17 discussions with NIDA; seemed amenable and
18 appropriate at the time. Do you know who seemed
19 amenable? Was it CMCR, or was it NIDA? Who seemed
20 amenable?

21 A It seems like--I don't recall specifically
22 what it was in reference to, but it appears to be

1 with regard to NIDA since NIDA is prefaced in the
2 sentence.

3 Q So NIDA seemed amenable to giving them 8
4 percent THC; is that what that means?

5 A Well, it appears that my response to this
6 or my additional comment that Dr. Grant provided me
7 is that they had arrived at 8 percent based on
8 discussions with NIDA and that NIDA seemed amenable
9 and appropriate at the time to be able to provide
10 that.

11 Q Okay; was there any discussion about
12 whether CMCR or Dr. Grant in particular had--I
13 guess not Dr. Grant as a researcher, but CMCR had
14 sought higher potencies and sort of came down to 8
15 percent because that's what NIDA could provide?

16 A I don't know.

17 Q And then, question 36, does any
18 information suggest that a higher potency product
19 would have a more beneficial outcome as compared to
20 the current product provided by NIDA? And the
21 answer is yes, isn't it?

22 A Yes.

1 Q Okay; And then, if you turn over to page
2 17, question number 40.

3 A Yes.

4 Q The question is has CMCR made any contact
5 with NIDA to ascertain the feasibility of producing
6 a higher potency product, and the answer is yes,
7 right?

8 A Yes.

9 Q And then, if you turn over to the next
10 page, there are some comments, and is it fair to
11 say that in those comments that Dr. Grant said that
12 NIDA has not addressed that request specifically?

13 A I don't recall specifically if it's NIDA
14 or CMCR.

15 Q Okay; well, he said--the question before
16 said CMCR has made any contact with NIDA to
17 ascertain the feasibility of producing a higher
18 potency product, right?

19 A You're referring to--

20 Q It's sort of clear they had contact with
21 NIDA.

22 A You're referring to question 40?

1 Q Question 40.

2 A Has CMCR made contact with NIDA to
3 ascertain the feasibility of producing a higher
4 potency product; yes.

5 Q And the answer is yes. And then, the
6 document or the explanation of that is has not
7 addressed specifically. That would seem it would
8 have to be NIDA; is that right?

9 A I don't think that's correct.

10 Q And why would CMCR not address it
11 specifically if they've already made contact with
12 NIDA to ascertain the feasibility of getting higher
13 potency?

14 MS. PAREDES: Objection, calls for
15 speculation.

16 JUDGE BITTNER: Did the interviewee answer
17 that question, or did the interviewee advise you?

18 THE WITNESS: I don't recall specifically
19 if Dr. Grant had provided specific information.

20 JUDGE BITTNER: Sustained.

21 BY MS. CARPENTER:

22 Q All right; let's go on. It was Dr.

1 Grant's impression that 8 percent was the highest
2 limit, comma, and then, is that perhaps future?

3 A Yes.

4 Q Do you know what that means?

5 A This is a little bit broken, so I can't
6 say definitively what his exact words were at that
7 point, but I don't know precisely what he was
8 actually saying at that point.

9 Q Well, let me just ask you what that word
10 is. Is that perhaps future?

11 A That is correct.

12 Q And when you took these notes, did you
13 understand what he was saying?

14 A I would say yes, but I don't recall
15 specifically if I understood when I was asking him
16 question 40. I can't recall, you know,
17 definitively.

18 Q You don't recall if you understood the
19 answer when you got it; is that what you're saying?

20 A You're asking me to remember whether I
21 understood a response that I got two years ago.

22 Q Yes, I am.

1 A So I can't tell you definitively if I
2 recall my understanding of his response at that
3 very time.

4 Q Okay; when you read these notes recently
5 preparing for trial, did you understand what you
6 meant by them then?

7 A I don't know if I actually did tread this
8 note before we prepared for trial.

9 Q But as you sit here today, do you
10 understand what you meant what you wrote that?

11 A No, I don't.

12 Q Okay; the next sentence, they do have
13 concerns that NIDA would say they are not into
14 product development. Now, the first they in that
15 sentence, does that refer to CMCR?

16 A Actually, it appears to--oh, I'm sorry;
17 where are you?

18 Q The second sentence in that paragraph,
19 starting with they do have concerns.

20 A Yes.

21 Q Do you understand that they to refer to
22 CMCR?

1 A Yes.

2 Q Because it's they do have concerns that
3 NIDA would say.

4 A Yes.

5 Q And is that second they after NIDA, does
6 that refer to NIDA?

7 A Yes.

8 Q It would say NIDA is not into product
9 development, in other words?

10 A I'm not certain if that was a modification
11 that was added by Heather Bentley or if that was my
12 own notes, but clearly, there is a paren that says
13 after the second they that it's referring to NIDA.

14 Q Well, actually, I'm not to that next
15 sentence there. I'm still on the first sentence.

16 A Oh.

17 Q They do have concerns that NIDA would say
18 they are not into product development.

19 A Ah, that they.

20 Q Yes, there's a lot of theys. Does that
21 mean that NIDA would say NIDA is not into product
22 development given the next sentence?

1 A Give me a second.

2 Q Take your time.

3 A Yes, I would say that's NIDA.

4 Q All right; and then, the last sentence,
5 they, parentheses NIDA, usually leave that to the
6 manufacturing sector.

7 A Yes, there is a paren there that that
8 refers back to NIDA.

9 Q Okay; and this, again, was in response to
10 the question about CMCR making contact with NIDA to
11 figure out whether they could make a higher potency
12 product. is it fair to say that it was CMCR's
13 concern that NIDA would say that they're not into
14 product development and that that should be left to
15 the manufacturers?

16 A I don't know what Dr. Grant's point would
17 have been.

18 Q That wasn't my question. Is it fair to
19 say that the response to the question 40 was we,
20 CMCR, are concerned that NIDA will say if we asked
21 them for a higher potency product that they are not
22 into product development, and they leave that to

1 the manufacturing sector?

2 A I think you would have to leave that up to
3 or ask Dr. Grant.

4 Q Well, you did ask Dr. Grant. Isn't that
5 the answer right here?

6 A The answer that was written down is the
7 answer that's on this question.

8 Q Okay; now, let me ask you just one more
9 question about your note taking. Was it your
10 practice when you were taking notes that if there
11 was something unclear to ask a question to clarify
12 that?

13 A I can't say that that was necessarily the
14 case. There may have been opportunities for
15 follow-up questions, but I also thought there was a
16 need for consistency across respondents.

17 Q So if they said something you didn't
18 understand, you wouldn't ask them to clarify it so
19 that you could write it down properly and correctly
20 and accurately?

21 A Well, I--

22 MS. PAREDES: Objection, asked and

1 answered.

2 JUDGE BITTNER: Overruled.

3 THE WITNESS: I would say that if I did
4 not understand something, I may have made an
5 opportunity to ask follow-up, yes.

6 BY MS. CARPENTER:

7 Q And certainly, because you were trying to
8 be accurate, because you were gathering information
9 that was relevant for the Agency's consideration of
10 the application, you would have made every effort
11 to be complete in your notes, wouldn't you?

12 A Don't forget we did have the opportunity
13 for the respondents, and these respondents took
14 three months to review the comments that were made,
15 they had ample time to ensure accuracy in their
16 responses, which was, you know, prefaced by their
17 modifications to the statements. So if they were
18 comfortable with the statement as it was prepared,
19 then, they wouldn't have made a modification.

20 Q But my question goes to your practice. It
21 was important to you in getting this information to
22 be accurate and consistent and complete in what you

1 wrote down, wasn't it?

2 A Yes, the reason for giving them the
3 opportunity to modify.

4 Q And as you said earlier, the reason that
5 you took the notes was because it was a burden on
6 the interviewers to have to answer questions, and
7 you thought that there was a pretty good chance if
8 you just left a question there, they'd never get to
9 it, right?

10 A Yes, what we felt strongly about was that
11 we would provide them with the questionnaire, and
12 then, we would actually do the writing for them to
13 expedite the process, yes, and to relieve the
14 burden.

15 Q Okay; so, it was also--they probably would
16 have felt a burden to have to go through and
17 explain all of your comments as well, wouldn't
18 they? So it's likely that they might not have done
19 that extraordinarily carefully.

20 A I can't answer that question.

21 Q Okay; all right; let's turn to Exhibit No.
22 19. And if you could turn--this is the notes from

1 the interview with Dr. Israelski; is that right?

2 A That is correct.

3 Q And if you would turn to page 12 of 12.

4 A Yes.

5 Q And your notes there are about the article
6 in the San Mateo County Times, is that right?

7 A Yes.

8 Q And in that article, there was a statement
9 that one of the patients in Dr. Israelski's study
10 had left the study because of bronchitis developed
11 when he was participating in the study using NIDA
12 marijuana; isn't that correct?

13 A Yes, there are comments about Philip
14 Alden. I should also say just for clarification,
15 there were a few issues addressed in this
16 additional comment section, and the one you're
17 referring to is where the arrow leads to; is that
18 correct?

19 Q Right.

20 Now, I think you said on direct that Dr.
21 Israelski said, and you said here he was very
22 careful not to make statements about quality, and I

1 guess you're talking about to the reporter; is that
2 right?

3 A Yes.

4 Q And within that article.

5 A Yes.

6 Q Okay; did you ask him why he would be very
7 careful not to make statements about quality to the
8 reporter?

9 A My question to him was did he make any
10 comments about quality, and his response, which is
11 what I prepared, was the PI was very careful not to
12 make statements about quality.

13 Q And you didn't ask him why he was very
14 careful not to make statements about quality?

15 A No.

16 Q Did he say in this conversation that Phil
17 Alden did not have bronchitis developed during his
18 study?

19 A Based on my notes, no.

20 Q And did he say that he did not recommend
21 that Mr. Alden should leave the study?

22 A Based on my notes, no.

1 Q And did he say that he thought NIDA
2 marijuana had no effect whatsoever on Mr. Alden's
3 respiratory health?

4 A The issues were not addressed.

5 Q Okay; did you ask him whether Mr. Alden
6 had bronchitis or not, as it was reported in the
7 newspaper?

8 A No.

9 Q Okay; and there's a comment there that
10 says Philip Alden made comments, but PI did not
11 prescreen his answers.

12 A Correct.

13 Q And did you ask him why he would want to
14 prescreen the answers of a patient?

15 A No, I did not.

16 Q Just didn't come up?

17 A [Nods in the negative.]

18 Q Was there any other discussion about
19 Philip Alden that's not reported here?

20 A Just what is reported--that would be my
21 responses--whatever is reported here would be
22 consistent with our conversation.

1 Q My question is not was there anything else
2 that was said not consistent with, but was there
3 anything else that was said during this
4 conversation that's not reported here?

5 A Then I would say the answer to.
6 Everything that is listed is what we spoke of.

7 Q I understand that everything that is
8 listed is what you spoke of, but that is not my
9 either. My question was was there anything else
10 said that was not reported?

11 A The answer would be no.

12 Q And if you would turn, then, to
13 Government's Exhibit No. 20, if you'd look, I'm
14 sorry, at page 10 in that exhibit.

15 A Yes.

16 Q And in the answer to question 19, do you
17 feel it would be clinically important to evaluate
18 the efficacy of a higher potency cigarette for your
19 patient population, the answer is not for current
20 study; the highest potency is adequate; is that
21 right?

22 A That is correct.

1 Q Okay; and then below that, there is a
2 discussion about future studies that could be
3 designed to look at higher doses. Is that right,
4 especially in cancer studies?

5 A He said future studies in cancer, future
6 studies and cancer studies could be designed to
7 look at higher doses, especially due to the fact
8 that this patient population usually tolerates high
9 levels of drugs.

10 Q Okay; and was there any discussion at this
11 time that--this was the interview with Dr. Wallace;
12 is that right?

13 A Yes.

14 Q Was there any discussion with Dr. Wallace
15 about designing his protocol around the products
16 that were then available from NIDA?

17 A I don't recall.

18 Q Okay; and then, if you would look down at
19 the next point there, the next little hyphenated
20 point.

21 A Yes.

22 Q Would provide less smoking tar and other

1 components found in smoke.

2 A Yes.

3 Q Does that refer to a higher dose or a
4 higher potency product, which is what you're
5 talking about in question 19?

6 A Yes; the higher doses that he's referring
7 to would be the higher potencies probably.

8 Q Okay; and so, that would be a benefit,
9 that it provides less smoking tar.

10 A Correct.

11 Q And then, below that, he says the risk
12 would be minimal because toxicity/lethality does
13 not appear to be an issue.

14 A Yes.

15 Q This is not the case for other therapeutic
16 classes of drugs, which can be lethal.

17 A Yes.

18 Q Is that opioids, anticonvulsants,
19 antidepressants, et cetera?

20 A Correct.

21 Q So did you all discuss that there was no
22 toxic level of medical marijuana?

1 A No, but I wouldn't have been qualified to
2 speak on that level with him.

3 Q Okay; and then, question number 20, in
4 your professional opinion, do the benefits outweigh
5 the risks, and the answer is yes, isn't it?

6 A It is.

7 Q All right; and if we turn to Exhibit No.
8 21, if you would turn to page 6.

9 A Yes.

10 Q And under the question have you observed
11 any physical deformities in the appearance of the
12 cigarette--well, I'm sorry; let me look at number
13 10 first; is the potency of the current product
14 consistent, and the answer is no, right, see note
15 below?

16 A Correct.

17 Q Let me just ask you again: would you
18 consider that a complaint if the potency of the
19 product was not consistent?

20 A I think similar to what I said yesterday,
21 I don't consider these as complaints. I consider
22 them as responses to questions that were asked.

1 Q Do you consider that is a negative
2 response to the question that was asked?

3 A I think no is a negative response to the
4 question.

5 Q And then, down below, it says originally
6 approved, and I presume this means his protocol was
7 originally approved for 3.9 percent THC content.

8 A Yes, that would have been by the
9 scientific review boards.

10 Q Okay; and then midway through the, quote,
11 short-term effects, close quote, protocols, NIDA
12 informed that the potency had been downgraded to
13 3.5 percent. Everything since is said to be at 3.5
14 percent.

15 A That is correct.

16 Q Okay; was there any discussion about that
17 between you and Dr. Abrams?

18 A No, not between myself and Dr. Abrams, no.

19 Q Was there between somebody else and Dr.
20 Abrams?

21 A Yes.

22 Q Who would that have been?

1 A Dr. El-Sohly.

2 Q So Dr. Abrams talked to Dr. El-Sohly?

3 A No, this would have been during my
4 conversation with Dr. El-Sohly.

5 Q But in terms of what Dr. Abrams was
6 saying, NIDA essentially changed their product from
7 3.9 percent to 3.5 percent in the middle of the
8 protocol; is that right?

9 MS. PAREDES: Objection; calls for
10 speculation.

11 MS. CARPENTER: I don't think that calls
12 for speculation that NIDA changed--

13 JUDGE BITTNER: Overruled.

14 THE WITNESS: Yes.

15 BY MS. CARPENTER:

16 Q Okay; and did Dr. Abrams say that that was
17 a good thing for that protocol to have the drug
18 that had been approved for the protocol to be
19 reduced in potency halfway through?

20 A I don't recall what his comment was.

21 Q And then, if you would look back at
22 question number 11, and this was a question about

1 the physical deformities in the appearance of the
2 cigarettes.

3 A Yes.

4 Q And he says no, nicely rolled, but there
5 is loss of material in the can--is this the can?

6 A Yes.

7 Q From dropping out of the cigarette as a
8 result of the freeze/thaw process; is that right?

9 A That is his statement, yes.

10 Q Okay; and would that be a problem in terms
11 of a medical protocol to have the material left in
12 the can out of a particular cigarette so that one
13 cigarette wouldn't necessarily have the right
14 amount of product in it?

15 MS. PAREDES: Objection; calls for
16 speculation.

17 JUDGE BITTNER: I'm sorry; I missed the
18 question. Could you repeat it?

19 MS. CARPENTER: Sure.

20 BY MS. CARPENTER:

21 Q Did Dr. Abrams indicate that it was a
22 problem with his protocol, with his research, that

1 cigarettes came out of the can without some of the
2 material they had started in the can with?

3 A I don't recall.

4 Q Okay; did you ask any questions about this
5 particular comment when he made it?

6 A I don't specifically recall a follow-up
7 question.

8 Q Okay; I think--and then, just below that,
9 it says rolling the ends would prevent loss; is
10 that right?

11 A Yes, which would have been a follow-up
12 comment that he made.

13 Q And so, from that comment, did you assume
14 him to mean that he would prefer that the
15 cigarettes be rolled on the ends for his protocol?

16 A No, I would not make that assumption.

17 Q You would assume that he would prefer the
18 cigarettes be unrolled at the end so that they
19 would lose material when they came out?

20 A I can't make a judgment as to what he
21 meant by that statement. He said that that as a
22 statement could be one way to resolve the issue.

1 Q So resolving the issue would fix the
2 problem, right?

3 A I don't know if he would prefer it that
4 way.

5 Q You don't know if he would prefer to have
6 the problem resolved?

7 A I don't know if he would prefer to have
8 the cigarettes rolled as opposed to unrolled.

9 Q But rolling the cigarettes would solve the
10 problem, you just said, right? Resolve the issue.

11 A Based on his comment, yes.

12 Q All right; question number 12, what plant
13 parts have you observed in the cigarettes you
14 obtained for research?

15 A Yes.

16 Q And what is the list of plant parts that
17 he has seen listed there?

18 A Seeds, leaf, and some stems.

19 Q And page 7, question number 13.

20 A Yes.

21 Q In your professional opinion, do any of
22 the plant parts make the cigarettes unacceptable

1 for your research, and the answer is yes, isn't it?

2 A It is.

3 Q Would you consider that a complaint?

4 A It's again a response to the question.

5 Q And then, his comment there, the second
6 sentence, also, trying to minimize those components
7 resulting from smoke that are harmful while at the
8 same time--and there's a little arrow there. Does
9 that mean increasing? This is the second sentence
10 in that box, in number 13.

11 A Oh, in the first box?

12 Q Yes.

13 A The last line?

14 Q The last sentence.

15 A Yes, that's an up arrow for increasing.

16 Q So increasing the medicinal value of THC,
17 right?

18 A That is what it says, yes.

19 Q Okay; then, if you go down to number 15,
20 have any of the issues discussed regarding quality,
21 visual differences, deformities, plant parts,
22 freshness of research grade marijuana adversely

1 impacted your research, and the answer is yes,
2 isn't it?

3 A It is.

4 Q And then, on the next page, it says if
5 yes, please explain. A few patients have
6 terminated early due to harshness; isn't that
7 right?

8 A That is what it says.

9 Q So out of a group of 20 or 21, two or
10 three have dropped?

11 A Yes.

12 Q Okay; and then, yesterday, I think you
13 said with regard to these notes, you said you think
14 the exclusion criteria had changed, and as a
15 result, he had had less people drop out; do you
16 recall saying that yesterday?

17 A Actually, I do recall saying that, but I
18 don't recall that is what I said. I said that it
19 may have increased the number of people that had
20 dropped, not decreased the number that would have
21 dropped out.

22 Q The exclusion criteria would change, and

1 it would increase the number of people dropping
2 out?

3 A If, in fact, the exclusion criteria were
4 changed to make it more restrictive, then, more
5 people may have had to have dropped out. If the
6 exclusion criteria was changed to allow more people
7 in, then, it probably would have resulted in more
8 people not dropping out.

9 Q Yesterday, when you were explaining the
10 next comment, less have dropped, you said, and I'm
11 quoting, I believe, exclusion criteria have
12 changed, and as a result, he's had less people
13 dropping out. Do you remember that testimony?

14 A I recall the line of questioning, but I
15 don't recall specifically my answer.

16 Q Okay; but in any event, there's nothing in
17 these notes about exclusion criteria changing, is
18 there?

19 A You are correct.

20 Q Okay; so, do you recall today that he
21 actually said that or not?

22 A I couldn't state unequivocally that that's

1 what in fact he said during this conversation, and
2 I would say probably not.

3 Q Okay; and in fact, the first line there
4 says a few patients have terminated early due to
5 the harshness; isn't that right?

6 A That is what it says, yes.

7 Q And in fact, Dr. Abrams was pretty precise
8 about his corrections, wasn't he, when he had a
9 chance to go back through and correct?

10 A Dr. Abrams, if I am not mistaken, I think,
11 made two or three modifications to my comments,
12 yes.

13 Q And he took out, for example, the plus
14 between the Marinol and the placebo?

15 A That is correct, yes.

16 Q Let me ask you to turn to page 9 of 12.
17 And in the box under 17, there is a comment to the
18 side, MAPS data.

19 A Yes.

20 Q And that says 14 to 19 percent prescribed.

21 A Yes.

22 Q Do you know if Dr. Abrams said prescribed?

1 A I believe that he would have, because I
2 don't know why I would have written it that way if
3 he did not.

4 Q Okay; and you testified yesterday that you
5 said you did not think it was legal for marijuana
6 to be prescribed in the Netherlands.

7 A That is my understanding.

8 Q But Dr. Abrams said it was prescribed,
9 didn't he?

10 A Yes.

11 Q If you just turn, I'm sorry, to page 10,
12 and Dr. Abrams answered yes to the question of
13 whether he had ever sought a higher potency
14 product, right?

15 A Which question; I'm sorry?

16 Q I'm sorry; 18, question number 18.

17 A Yes.

18 Q And he also answered yes, it would be
19 clinically important to evaluate the efficacy of
20 higher potency cigarette for his patient
21 population, right?

22 A Yes.

1 Q And he also answered yes, the benefits
2 would outweigh the risks in his professional
3 opinion, right? On question number 20.

4 A Yes.

5 Q Okay; and in the answers, in the box to
6 question number 19.

7 A Yes.

8 Q Dr. Abrams said one of the benefits of
9 evaluating a higher potency would be that you would
10 consume less to achieve a pharmacological--and
11 then, what is the last word there in that sentence?

12 A Dose.

13 Q Okay; pharmacologic dose; okay. All
14 right; and then, on the last--sorry, page 12.

15 A Yes.

16 Q In the comments there again, is he saying
17 this is about the patients who have dropped out of
18 his studies due to the harshness of the cigarettes?

19 A Yes, his statement says few have dropped
20 out due to harshness.

21 Q All right; can I ask you to turn to
22 Exhibit No. 22? And these are the notes of your

1 interview with Dr. Polich, is that correct?

2 A I need to get a copy of that. I'm sorry;
3 what was the question?

4 Q Are these the notes of your interview with
5 Dr. Polich?

6 A Yes.

7 Q And if you would turn to page 7 out of 12,
8 in answer to the question have any patients ever
9 complained about the freshness of the marijuana, he
10 answered yes, didn't he?

11 A Yes.

12 Q And he said more than three may have
13 commented that the product was harsh; is that
14 correct?

15 A Correct.

16 Q Can I ask you to turn back to Exhibit No.
17 19, and then, we'll be hopefully done with that
18 series; page 12. This is again questions with
19 regard to the newspaper article in the San Mateo
20 County Times.

21 A Yes.

22 Q Why did you take that out there to show

1 Dr. Israelski or send it to him and talked to him
2 about it?

3 A Because it was brought up in Dr. Craker's
4 June 3, 2003, letter. It was attached to the
5 letter he provided to us.

6 Q And the article referred to some problems
7 with NIDA marijuana; is that right?

8 A The article was prompted by the San Mateo
9 Times and hadn't--was used by Dr. Craker as
10 evidence that researchers were unhappy with the
11 marijuana they received from NIDA.

12 Q Because that's what the article said;
13 that's why it was evidence of that fact, right?

14 A That's actually what the title said.

15 Q So you don't think that there was anything
16 in the article that indicated there were any issues
17 among researchers with NIDA marijuana.

18 A That's what we wanted to ask Dr. Israelski
19 were his comments about that article.

20 Q And so, what did you ask Dr. Israelski
21 about that article?

22 A Actually I don't recall what--how I

1 brought it up. I don't have it written down as to
2 what exactly was the question I asked him.

3 Q Do you recall if you asked him if the
4 article was accurate?

5 A I don't recall specifically what I said to
6 him.

7 Q Do you recall whether he ever said that
8 the article was accurate?

9 A I don't recall that specifically, no.

10 Q Okay; so, Mr. Strait, we've just been
11 through a number of the exhibits of the interview
12 notes that you took, and I'll just represent to you
13 that I went back through these last night, and if
14 you want to look through them all again and make
15 sure I'm right, that's fine, but would you agree
16 that Dr. Ellis, Dr. Abrams and Dr. Grant all
17 answered no to the question as to whether the NIDA
18 product was consistent?

19 A I would have to look back at all of them
20 to confirm that.

21 Q Do you want to do that?

22 A Which Government Exhibits?

1 Q Those would be--Grant would be 16. It
2 would be 16, 21, and 17.

3 A And which question was that?

4 Q This was with regard to consistency.

5 A Do you have a number by any chance?

6 Q The number of the question of Dr. Grant
7 was a little different, because it was the NIDA
8 one. You know, this is probably more time than
9 it's worth to go through all of this. We'll just--

10 JUDGE BITTNER: I think it's going to show
11 for itself, and again, I'm going to read all this
12 again.

13 MS. CARPENTER: I appreciate that, Your
14 Honor.

15 BY MS. CARPENTER:

16 Q Now, you said in your testimony yesterday
17 that you and Ms. Kaupang were exquisitely
18 sensitive, I think were your words, to the possible
19 problems that researchers might have with talking
20 with DEA. Do you remember that testimony?

21 A Yes.

22 Q Okay; but you didn't make these

1 questionnaires anonymous, did you?

2 A No.

3 Q That might have allowed them to speak with
4 a little bit more freedom were you worried about
5 their candid responses, wouldn't it?

6 A We didn't seem to have any concerns about
7 making these anonymous.

8 Q But you were concerned about--you were
9 exquisitely sensitive, you said, to the possible
10 fears of researchers talking to DEA about
11 marijuana.

12 A We had received from Dr. Craker and then
13 subsequently from Dr. Doblin letters that had
14 mentioned that these doctors were fearful to talk
15 to DEA. So my comment was within that context that
16 we were sensitive to that because we had been
17 informed of that.

18 Q But my question is you didn't make them
19 anonymous, did you?

20 A No.

21 Q And you also had--well, how many DEA
22 employees were involved in most of these

1 conversations? Wasn't it at least three or four?
2 There were you and Ms. Kaupang and two agents from
3 the local field office.

4 A At any given time, there were probably two
5 people, at least there was always more than one; I
6 can say that. Most of these were over the phone.
7 And two, I think, were in person or three.

8 Q Now, let me turn your attention to the
9 meeting that you--

10 JUDGE BITTNER: Could I just ask, though,
11 because I think there's sort of a hanging issue
12 here that--

13 MS. CARPENTER: Okay.

14 JUDGE BITTNER: --may not be intentional.
15 Were any of the DEA personnel who either sat in on
16 the live interviews or were in the room or in
17 communication during the telephonic interviews
18 special agents?

19 THE WITNESS: No.

20 JUDGE BITTNER: Okay.

21 BY MS. CARPENTER:

22 Q Were they agents from the local field

1 office?

2 A No.

3 Q There were no agents from local field
4 office.

5 JUDGE BITTNER: I think we need to
6 define--

7 MS. CARPENTER: Oh.

8 JUDGE BITTNER: Because there's agent, and
9 there's special agent.

10 MS. CARPENTER: Okay.

11 JUDGE BITTNER: And I'm using the term
12 special agent as a term of art, meaning a DEA
13 employee who has a badge and law enforcement
14 authority.

15 THE WITNESS: Yes.

16 JUDGE BITTNER: A law enforcement
17 personnel as opposed to diversion investigators or
18 intelligence specialists or--

19 THE WITNESS: Correct.

20 JUDGE BITTNER: --science officers who--

21 THE WITNESS: So I can qualify it by
22 saying that there were no special agents that were

1 available or involved in these interviews.

2 MS. CARPENTER: Okay.

3 BY MS. CARPENTER:

4 Q When you say not available, did you seek
5 to have some?

6 A No.

7 Q Okay; and maybe I misunderstood your
8 testimony yesterday, but I had understood that at
9 the CMCR meeting, there were two agents from the
10 local field office.

11 A There were two diversion investigators
12 from the local field office.

13 Q And diversion investigators investigate
14 diversion, I would think?

15 A Yes, their title--it's one of the core
16 series of employees here at DEA, and they're the
17 ones that handle all issues related to the
18 diversion program.

19 Q Okay; and would they handle licensing
20 issues, for example, for hospitals.

21 A Yes.

22 Q And they would handle problems that might

1 arise in a hospital if something went awry with a
2 controlled substance.

3 A Yes, I imagine they may be involved.

4 MS. CARPENTER: Okay.

5 JUDGE BITTNER: Do diversion investigators
6 have arrest authority?

7 THE WITNESS: I don't know.

8 JUDGE BITTNER: But they do not carry
9 guns.

10 THE WITNESS: No, they don't.

11 JUDGE BITTNER: Are they permitted to
12 participate in undercover operations?

13 THE WITNESS: I don't know for sure.

14 JUDGE BITTNER: Okay.

15 BY MS. CARPENTER:

16 Q But in any event, these would be--how many
17 diversion agents would there be in the DEA office
18 in San Diego, for instance?

19 JUDGE BITTNER: Diversion investigators.

20 MS. CARPENTER: I'm sorry; diversion
21 investigators.

22 JUDGE BITTNER: You can't look at anybody

1 else, Mr. Strait.

2 THE WITNESS: I don't know. No, I just
3 don't know the answer.

4 JUDGE BITTNER: I was just trying to
5 distinguish between agent in the normal sense of an
6 agent of another person or of an organization--

7 MS. CARPENTER: I understand.

8 JUDGE BITTNER: As opposed to a law
9 enforcement officer.

10 MS. CARPENTER: Yes, I understand, and my
11 questions were about whether the diversion
12 investigators would have, had they had authority
13 over the regulated entities, the hospitals that you
14 were talking to, right, or the CMCR.

15 THE WITNESS: Well, the DEA does and
16 obviously--

17 BY MS. CARPENTER:

18 Q And they were the ones who enforced
19 locally the DEA policies and objectives.

20 A Yes.

21 Q Okay; now, I think you also indicated that
22 in your being careful with the witnesses so that

1 they would feel free to talk with you, you assured
2 them that the results would be only internal DEA
3 results. Do you recall that testimony?

4 A Yes.

5 Q And were these results ever shared with
6 any other agency?

7 A These results?

8 Q Yes.

9 A No.

10 Q The reports that you generated here.

11 A No.

12 Q Or the trip report that Ms. Kaupang
13 generated.

14 A No.

15 Q That would not have gone to NIDA, for
16 example?

17 A No.

18 Q Or Dr. El-Sohly?

19 A No.

20 Q So the doctors' comments about potency and
21 quality, those were never shared with Dr. El-Sohly
22 or NIDA?

1 A No, actually, I did say that the comment
2 was something that was with us when we participated
3 in the trip down to the University of Mississippi
4 and would have been asked within the context of
5 what the program is for analyzing samples and how
6 that works.

7 Q I don't understand your answer. You said
8 the comment. What comment?

9 A When you had asked me about Dr. Abrams'
10 comment that he put in his questionnaire about his
11 material being downgraded.

12 Q I see.

13 A And it was that piece of information that
14 we would have tried to ask Dr. El-Sohly about how
15 their sampling process and their analysis process
16 works.

17 Q But other than that, there was never any
18 communication to NIDA or to Dr. El-Sohly about any
19 comments, negative or positive that were developed
20 in these interviews with regard to the quality of
21 NIDA's marijuana?

22 A No, these questionnaires were used for

1 purposes of evaluating the application.

2 Q I understand that, but the information in
3 the questionnaires, was that given out?

4 A No.

5 Q Okay; now, let me actually turn your
6 attention to the meeting in January 2004 that you
7 had, I think it was--was that the one with NIDA, or
8 was that with NIH?

9 A I believe the NIDA meeting was in January
10 '04.

11 Q Okay; and was that meeting to talk about
12 the will of NIDA marijuana?

13 A Not specifically quality. It was more to
14 learn about the contract process.

15 Q Okay; but you said earlier that you had
16 had comments, and that's what sent you out to CMCR
17 was to find out information about the quality of
18 NIDA marijuana. So you didn't have any discussions
19 with NIDA about their own quality concerns?

20 A No.

21 Q Okay; do you know of any previous
22 investigations by NIDA or by DEA into the quality

1 of NIDA's marijuana?

2 MS. PAREDES: Objection; outside the scope
3 of direct.

4 JUDGE BITTNER: I don't know.

5 MS. CARPENTER: Well, Your Honor, he
6 testified that he was the one who was tasked to
7 gather this quality information, so I think if
8 there were previous studies that he looked at or
9 knew about, that would be relevant to the question.

10 JUDGE BITTNER: All right; I think it's
11 relevant. The question is whether it's outside the
12 scope.

13 MS. CARPENTER: No, I understand that.
14 But he testified that he was tasked to gather
15 information. So perhaps I--

16 JUDGE BITTNER: Why don't you rephrase the
17 question, then?

18 BY MS. CARPENTER:

19 Q During your gathering of information
20 related to the quality of NIDA marijuana, did you
21 find out that there had been any previous
22 investigation of the quality of NIDA's marijuana?

1 A No.

2 Q And again, the reason that this
3 investigation of the quality of NIDA's marijuana
4 started was because of Dr. Craker's application; is
5 that right?

6 A Yes.

7 Q And I think I asked you yesterday, but I
8 think I may have asked you specifically, and I
9 guess my question is do you know as you coordinated
10 the response to Dr. Craker's application whether
11 there was anybody at DEA who investigated whether
12 the current system was adequately competitive?

13 A Can you repeat that?

14 Q Sure. You testified yesterday that you
15 were coordinating the response to the application.

16 A I was one of.

17 Q One of; okay. And in your meetings with
18 other people at DEA about the application, did you
19 understand or did anybody bring to the meeting any
20 information about any DEA investigation into
21 whether the current system was adequately
22 competitive?

1 A I don't recall specifically.

2 Q And who decided who would be at this
3 meeting in 2004?

4 JUDGE BITTNER: I'm sorry; which one?

5 MS. CARPENTER: I'm sorry; the January
6 2004 meeting.

7 JUDGE BITTNER: With NIDA personnel.

8 MS. CARPENTER: With the NIDA personnel.

9 THE WITNESS: Probably the section--my
10 section chief, who at that point had changed,
11 because there was a retirement.

12 BY MS. CARPENTER:

13 Q And who would that have been?

14 A Christine Santerrud.

15 JUDGE BITTNER: And who had retired?

16 THE WITNESS: Frank Sapienza.

17 JUDGE BITTNER: And when did he retire?

18 THE WITNESS: I think it was December 1,
19 2003.

20 BY MS. CARPENTER:

21 Q And then, turning your attention back to
22 the CMCR meetings in September of 2003--

1 A Three.

2 Q Thank you; I've got to get my time lines
3 straight. I think you said yesterday that you
4 didn't category or you didn't interview anybody at
5 CMCR other than the folks whose interview notes
6 have appeared here; is that correct?

7 A That is correct.

8 Q And who gave you the names of who to
9 contact with CMCR?

10 A We actually worked with the CMCR on that
11 list.

12 Q Okay; how did that work? Did they send
13 you a list?

14 A We received and continue to receive
15 quarterly information from the CMCR.

16 Q And how did this particular one work? Did
17 they send you a list of people that you could
18 contact?

19 A No; I believe we actually pulled one of
20 their reports and used that as a basis.

21 Q And so on those quarterly reports, there's
22 a listing of all the investigators?

1 A There's actually a listing of all of the
2 protocols.

3 Q All of the protocols.

4 A Yes.

5 Q And does it also identify the
6 investigators? And so, did you call all the
7 investigators that were listed on that quarterly
8 report?

9 A No.

10 Q Okay; how did you decide who to call and
11 who not to call?

12 A We worked through the CMCR administrative
13 folks, specifically Heather Bentley.

14 Q Okay; so you pulled the quarterly report;
15 you had the list of the names; then, you called Ms.
16 Bentley.

17 A It was not me.

18 Q Who did that?

19 A Frank Sapienza.

20 Q And what happened after that? Did Ms.
21 Bentley send you a list of names of people to call?

22 A I don't recall specifically. I don't know

1 if she sent us a list of names or whether it was
2 something negotiated verbally on the telephone. I
3 don't know.

4 Q Okay; was it your intent to talk to
5 everybody at CMCR who had been an investigator
6 using NIDA marijuana?

7 A This was coordinated by Frank, so it was
8 not necessarily my intent to do anything.

9 Q Did you understand it was Mr. Sapienza's
10 intent to contact everybody? Or was it cut down is
11 my point. I was just trying to get to the point of
12 whether there were--you contacted less than a whole
13 group of all of the investigators or not.

14 A I don't know what Mr. Sapienza's intent
15 was.

16 Q Do you know how many investigators are
17 engaged or were engaged at the time in CMCR
18 research?

19 JUDGE BITTNER: Principal investigators?

20 MS. CARPENTER: Yes, principal
21 investigators.

22 THE WITNESS: I couldn't name all of them

1 for you, but I do know that there are a number of
2 investigators that are either principal
3 investigators or coinvestigators.

4 BY MS. CARPENTER:

5 Q Okay; but do you know ball park what that
6 number is?

7 A No.

8 Q Do you think it's more than five?

9 A It may be.

10 Q Okay; did you ever talk with Dr. Mark
11 Agius, A-G-I-U-S?

12 A No.

13 Q Okay; did you ever talk with Suzanne
14 Dibble?

15 A No.

16 Q Did you ever talk with Ann Meang, M-E-A-N-G?

17 A No.

18 Q Did you ever talk with Danielle Piomelli,
19 P-I-O-M-E-L-L-I?

20 A No.

21 Q Would it surprise you to know that they're

1 all investigators doing research with medical
2 marijuana under the CMCR research grant?

3 A As part of a qualification, at the time
4 when the interviews were conducted?

5 A It's not surprising to me that there may
6 be other people that had sub-studies or preclinical
7 studies that were going on.

8 Q Would it surprise you to know that these
9 people were doing clinical research?

10 A Not necessarily, no.

11 Q Did you have a set number of people that
12 you wanted to talk to?

13 A No.

14 Q Did CMCR say there were some people who
15 wouldn't talk to you?

16 A No.

17 Q Do you know how you ended up with only
18 five investigators out of the principal
19 investigators that were available?

20 A It was the result of discussions between
21 the CMCR and Frank Sapienza.

22 Q Let me ask you: were you the only person

1 taking notes at these meetings?

2 A I don't know. I would imagine there were
3 other people taking notes.

4 Q What other people would have been taking
5 notes?

6 A Anyone else who was around the table.

7 Q Would people from the local DEA office out
8 in San Diego be taking notes?

9 A They could have.

10 Q Do you think the doctors were taking
11 notes?

12 A They could have?

13 Q Do you remember any of them taking notes?

14 A I don't remember, no.

15 Q And of the notes that appear here, are
16 these your only notes from the interviews?

17 A Yes.

18 Q And were there any other notes that you
19 took, or this is the whole universe?

20 A As stated, those were the notes I took
21 during the meeting.

22 Q You referred yesterday to a trip report

1 that Helen Kaupang wrote up after the interviews
2 were over, the whole series of interviews.

3 A No, I don't think that's correct.

4 Q Was there any sort of a report that Helen
5 Kaupang wrote up to which she attached some of
6 these documents?

7 A Yes.

8 Q In the discussion we had, it was like
9 attachment one?

10 A Yes, that was a separate interview that
11 was conducted on a different date.

12 Q Oh, okay, okay. Was there any report that
13 was written up about the CMCR investigators'
14 interviews?

15 A Yes.

16 Q What report would that have been.

17 A Trip report.

18 Q And did you write that up or somebody
19 else?

20 A I did.

21 Q And who would that have gone to?

22 A That actually was prepared for the

1 section's file, so it wasn't to anyone. It was to
2 our files.

3 Q And what did the report cover?

4 A A summary of the trip.

5 Q Did it also include comments about what
6 people had said in terms of the interviews, or was
7 it more to we went to San Diego on this day,
8 interviewed five people and came home?

9 A Actually, they do include a lot of that
10 type of information, simply put, the, you know,
11 kind of administrative aspects of the trip.

12 Q And what's the purpose of the trip report.

13 A To document the trip that was taken?

14 Q For travel purposes or for Dr. Craker's
15 application file purposes?

16 A It was probably for both.

17 Q So a copy of this trip report would be in
18 Dr. Craker's application file?

19 A Not necessarily, no.

20 Q So where would it be, then?

21 A You probably recall that I said there was
22 no file. I mean, multiple people who were involved

1 had different files. I'm not sure where these
2 files, these reports would have been specifically
3 located. I can't say that it was in--assuming that
4 there was a Dr. Craker application file. I can't
5 say that it made it into that file.

6 Q So there's not one place where Dr.
7 Craker's application exists, and information
8 relevant to it comes into that file.

9 A That's as I stated yesterday.

10 Q Now, let me ask you a question about
11 researchers other than CMCR. You, I think,
12 contacted Dr. Polich at Scripps and the animal
13 doctor, whose name I have forgotten.

14 A Dr. Lichtman.

15 Q Dr. Billy Martin--

16 A Yes.

17 Q --or Aaron Lichtman.

18 A Yes.

19 Q Did you contact any other researchers
20 other than--

21 A No.

22 Q Okay; why not?

1 A Time and expense.

2 Q Okay; do you know if there are other
3 researchers that were using medical marijuana in
4 research?

5 A Medical marijuana?

6 Q Yes.

7 A Actually, I would say no.

8 Q Okay; DEA has a database with all the
9 people who are licensed to do research with medical
10 marijuana, right?

11 A I think we're disagreeing over the term
12 medical marijuana.

13 Q Marijuana use for medical research.

14 A I would say no.

15 Q Let me start again. DEA has a database of
16 licenses that it issues to researchers, doesn't it?

17 A Yes.

18 Q And included in that database, would there
19 not be licenses issued to researchers who were
20 doing research with the medical effects of
21 marijuana?

22 A Yes, they are located in this database.

1 Q Okay; and I thought you said yesterday
2 that you had that file, and so, you looked at it,
3 or you had that database, access to it, so you
4 looked at it to determine who else was doing
5 research with regard to medical marijuana; did I
6 misunderstand that?

7 A I think we're disagreeing on terms.

8 JUDGE BITTNER: Okay; would you explain
9 what the disagreement is?

10 THE WITNESS: There are a number of
11 manufacturers that are doing research with
12 marijuana, some of which may be looking at the
13 potential therapeutic benefits of marijuana; others
14 may be simply looking at other aspects of it,
15 specifically abuse type information or its effects
16 on, you know, driving ability or things that aren't
17 really looking at the potential therapeutic value
18 of the plant.

19 JUDGE BITTNER: Okay; you just said there
20 are a number of manufacturers.

21 THE WITNESS: Did I say manufacturers?

22 JUDGE BITTNER: Right.

1 THE WITNESS: If I did, I meant to say
2 researchers, because this is in the context of
3 Schedule 1 researchers, and I apologize if I said
4 manufacturers.

5 BY MS. CARPENTER:

6 Q All right; well, then, let's take your
7 definition, then, of just straight marijuana. Did
8 you look at the DEA database to see whether there
9 were other researchers using marijuana?

10 A Yes.

11 Q And of those, do you know roughly how many
12 of those there are?

13 A I couldn't give you an exact number.

14 Q More than 10?

15 A Yes.

16 Q more than 20?

17 A Yes.

18 Q More than 50?

19 A I don't know.

20 Q Somewhere between 10 and 50?

21 A [Nods in the affirmative.]

22 Q Okay; and of those, you contacted two; is

1 that right?

2 A Yes.

3 Q And how did you pick those two?

4 A Proximity.

5 Q Whoever was close by?

6 A Yes.

7 Q Okay; did you talk with NIDA to determine
8 who received their marijuana as a way of figuring
9 out who to talk to about quality?

10 A I'm not sure I understand your question.

11 Q Did you ever call up NIDA and say can you
12 give me a list of the people who receive your
13 marijuana so I can go talk to them about the
14 quality of it?

15 A There was some thought of doing that, but
16 no, we did not.

17 Q Okay; now, did you talk to any sponsors
18 rather than direct researchers but sponsors of
19 marijuana research, that is the companies who are
20 looking to develop a particular product?

21 A I don't think we know of anyone or at the
22 time we knew of anyone, no.

1 Q I guess a sponsor would be somebody who
2 would sponsor the research, so CMCR would be a
3 sponsor, I guess. You talked to them, right?

4 A And we did speak to CMCR, sure.

5 Q And you don't know of any others?

6 A I don't know of any others.

7 Q So other than CMCR, which is, of course, a
8 nonprofit organization involved in research and
9 MAPS--

10 A Are they a nonprofit organization?

11 Q CMCR? I believe they are.

12 A I think they're a state funded
13 institution.

14 JUDGE BITTNER: I don't know what their
15 corporate structure is.

16 MS. CARPENTER: I do know it is a not for
17 profit.

18 JUDGE BITTNER: Correct.

19 MS. CARPENTER: It's a subset of the State
20 of California system, noncommercial development.

21 BY MS. CARPENTER:

22 Q So other than that, MAPS is the only

1 organization that is funding research into medical
2 marijuana; is that right?

3 A I don't know that specifically.

4 Q Well, you certainly knew that MAPS,
5 through the letters from Dr. Craker, that MAPS had
6 problems with the current supplier, right?

7 MS. PAREDES: Objection.

8 JUDGE BITTNER: Ground?

9 MS. PAREDES: Calls for speculation.

10 JUDGE BITTNER: Overruled.

11 THE WITNESS: Can you repeat your
12 question?

13 MS. CARPENTER: Sure.

14 BY MS. CARPENTER:

15 Q You certainly knew that MAPS, because you
16 knew MAPS was involved with Dr. Craker's
17 application, you certainly knew that they had a
18 problem with the current supplier, right?

19 A Well, they weren't a Schedule 1
20 researcher.

21 Q Well, neither is CMCR as an entity.

22 A No.

1 Q So I was talking about the sponsors who
2 were sponsoring the research done by the
3 researchers, and you talked to CMCR.

4 A Right.

5 Q To determine their level of satisfaction
6 with the product, and you knew MAPS was not happy
7 with the product offered by Dr. Craker; is that not
8 right?

9 MS. PAREDES: Objection.

10 JUDGE BITTNER: That's not what you meant
11 to say.

12 MS. CARPENTER: I do beg your pardon.

13 BY MS. CARPENTER:

14 Q Not happy with the product offered by Dr.
15 El-Sohly, right?

16 MS. PAREDES: Objection to the
17 characterization of MAPS not being happy. The
18 witness hasn't stated that he had that knowledge.

19 JUDGE BITTNER: Well, that's the question;
20 overruled. I think the problem is you just shifted
21 gears.

22 MS. CARPENTER: Okay.

1 JUDGE BITTNER: And the witness was stuck
2 with the other gear.

3 THE WITNESS: I think I'm still back in
4 the other gear.

5 JUDGE BITTNER: Okay; first question is, I
6 think, in mid-2003, you knew that both CM--I keep
7 getting this wrong CMCR was sponsoring research
8 into medical marijuana.

9 THE WITNESS: Yes.

10 JUDGE BITTNER: And did you know that MAPS
11 was also sponsoring research into medical
12 marijuana?

13 THE WITNESS: Not at that point, no.

14 JUDGE BITTNER: Okay.

15 BY MS. CARPENTER:

16 Q When you were doing the investigation into
17 NIDA's marijuana, you did not know that MAPS was
18 interested in sponsoring research?

19 JUDGE BITTNER: That's not what was asked.

20 MS. CARPENTER: I'm sorry?

21 JUDGE BITTNER: I asked if MAPS was
22 sponsoring research.

1 MS. CARPENTER: Okay.

2 JUDGE BITTNER: Not what it was interested
3 in doing.

4 MS. CARPENTER: Okay.

5 BY MS. CARPENTER:

6 Q Well, let me ask you that, then. You were
7 unaware at the time, then, despite all of your
8 investigation into MAPS' background that MAPS had
9 sponsored research that was DEA approved through
10 the American Health Foundation as to whether water
11 pipes could be used as an alternative delivery
12 system for marijuana to smoked marijuana?

13 A I was not familiar with that, no.

14 Q You were not aware of that despite all of
15 your research into MAPS' background?

16 A I think that's a mischaracterization of
17 what I was involved with.

18 Q But you were not aware of that at the
19 time.

20 A No, I was not.

21 Q And were you aware, then, that MAPS had
22 sponsored research that was FDA and DEA approved

1 into the medical benefits of psilocybin?

2 A I was not aware of that, no.

3 Q But you knew, certainly, from Dr. Craker's
4 application that MAPS was the one interesting in
5 sponsoring marijuana research at this time, right?

6 A He had noted, Dr. Craker's response to the
7 bulk manufacturing question had noted MAPS.

8 Q Right.

9 A That is correct.

10 Q And that the marijuana that he would be
11 growing, were he allowed to do so by the DEA, would
12 be used for MAPS-funded research; is that correct?

13 A Correct.

14 Q And so it was clear to you that there was
15 another at least interested sponsor in marijuana
16 research out there who did not think that the
17 current supply was adequate; is that not right?

18 A We did know that MAPS, yes, was interested
19 in sponsoring research.

20 Q And that you also believed that they
21 couldn't get a supply under the current system;
22 isn't that right?

1 A I'm not sure that we knew that they were
2 unable to obtain a supply.

3 Q But you knew they were interested in
4 getting another supplier.

5 A We knew that by Dr. Craker's application,
6 they were interested in themselves having a source
7 of supply other than U. Miss.

8 Q Okay; so basically one sponsor of medical
9 marijuana research, you talked to, and the other
10 sponsor who was interested in getting medical
11 marijuana research done, you didn't talk to; is
12 that right?

13 A We did not interview Dr. Doblin or MAPS,
14 no.

15 Q Now, in the two years since you spoke with
16 the investigators at CMCR, have you done any
17 follow-up work with them? Or have you contacted
18 them again to ask them any more questions?

19 A No.

20 Q Okay; have you contacted any other
21 investigators who have used NIDA marijuana in the
22 past?

1 A No.

2 Q Did you contact any of the compassionate
3 use--are you familiar with the Compassionate Use
4 IND program?

5 A Generally.

6 Q Did you contact any of the patients who
7 are under that program to see what their views are
8 on the quality of NIDA's marijuana?

9 A No.

10 Q Did you think about that?

11 A No. They're not--just they're not
12 researchers.

13 Q No, but they use the product; isn't that
14 right?

15 A That is correct.

16 Q So they could speak to the quality issue,
17 which is what you were looking at, right?

18 A Yes.

19 Q Okay; now, you testified yesterday that
20 you learned when you spoke to either NIDA or Dr.
21 El-Sohly that the NIDA contract was open for
22 competition, yes?

1 A Yes.

2 Q That it was open for bid and that people
3 could freely compete for it.

4 A Yes.

5 Q But that contract requires substantially
6 more than manufacturing bulk marijuana, doesn't it?

7 MS. PAREDES: Objection, foundation.

8 JUDGE BITTNER: If he knows. Could you
9 rephrase it?

10 MS. CARPENTER: Sure; why don't we just
11 get a copy of the contract.

12 JUDGE BITTNER: Okay.

13 BY MS. CARPENTER:

14 Q I think--didn't you testify yesterday that
15 you saw the contract?

16 A Yes.

17 Q Let me just, so we can hopefully cut this
18 a little bit shorter without going through the
19 exhibit, although we will if necessary; are you
20 aware that the contract requires whoever gets it to
21 test, to test samples of marijuana that are
22 delivered to the contractee?

1 A Yes.

2 Q And are you aware that they are required
3 to grow a particular type of marijuana at
4 particular levels of THC?

5 A Yes.

6 Q Okay; and are you aware that to comply
7 with their contract, they couldn't grow other types
8 of marijuana, that is, under that contract, they
9 couldn't grow a higher level of potency, for
10 example?

11 A No, I don't know if that's the case.

12 Q Okay; but it certainly wouldn't be
13 consistent with the contract to grow a higher level
14 of potency if you're required by contract to grow a
15 lower level of potency; isn't that right?

16 A I don't know what the terms are of the
17 contract.

18 MS. PAREDES: Objection.

19 BY MS. CARPENTER:

20 Q So in any event, would you agree, then,
21 that there are substantial obligations in addition
22 to simply growing the marijuana under the contract,

1 given the testing requirements?

2 MS. PAREDES: Objection to the
3 characterization of substantial. This witness
4 doesn't have any knowledge or expertise in terms of
5 interpreting the terms of the contract, whether or
6 not something is substantial, which I think is a
7 legal term of art in contracting.

8 JUDGE BITTNER: I don't know if it is or
9 not.

10 MS. CARPENTER: I'll change it to
11 significant.

12 JUDGE BITTNER: Okay.

13 MS. PAREDES: Still, objection as to
14 foundation, and this witness has no knowledge.

15 JUDGE BITTNER: Why don't you ask the
16 witness what he knows about the contract?

17 BY MS. CARPENTER:

18 Q What do you know about the contract?

19 A Very little. I am not a contracting
20 officer or a COTR on any contract in the Federal
21 Government. I know very little about contracts.

22 JUDGE BITTNER: And what's a COTR?

1 THE WITNESS: Contracting officer's
2 technical representative.

3 BY MS. CARPENTER:

4 Q Have you ever read the contract?

5 A No.

6 Q Just to tie the loop on that, but you are
7 aware it has testing requirements?

8 A Yes.

9 Q Okay; so anyone who wanted to simply grow
10 marijuana to provide it as a bulk manufacturer, if
11 they wanted to grow at all under the one contract
12 that makes it available in the United States, they
13 would also have to do the testing requirements;
14 isn't that right?

15 MS. PAREDES: Objection, calls for the
16 witness to interpret the terms of the contract.
17 The witness has said he hasn't read the contract.

18 JUDGE BITTNER: But he knows it has a
19 requirement in it. Overruled.

20 MS. CARPENTER: Thank you.

21 JUDGE BITTNER: So can you answer that?

22 THE WITNESS: I actually can't. I can

1 only speculate, and I don't think that's why I'm
2 here.

3 JUDGE BITTNER: Okay.

4 MS. CARPENTER: Okay.

5 BY MS. CARPENTER:

6 Q And you also testified about the
7 procedures out at the hospital in San Diego. You
8 mentioned two locations; I'm not sure which one it
9 was or maybe both, the procedure for handling
10 orders to get marijuana cigarettes from NIDA to a
11 manufacturer, isn't that right? Do you recall that
12 testimony yesterday?

13 A To a manufacturer?

14 Q I'm sorry; to a researcher.

15 A Yes.

16 Q And I think that you said the order goes
17 into NIDA; NIDA then tells Dr. El-Sohly to send the
18 cigarettes to the hospital.

19 A I believe that's correct.

20 Q Okay; or perhaps they tell RTI; do you
21 know--

22 A No, I believe they tell the University of

1 Mississippi.

2 Q The University of Mississippi. And then,
3 the University of Mississippi ships them to the
4 hospital, isn't that right?

5 A No.

6 Q Where does it go?

7 A To the Research Triangle Institute.

8 Q So Dr. El-Sohly notifies the Research
9 Triangle Institute?

10 A Yes.

11 Q And then, it goes from the Research
12 Triangle Institute directly to the hospital?

13 A Yes.

14 Q So the folks at NIDA never actually have
15 the marijuana, do they?

16 A I don't know if they do or not. I don't
17 know if they have material.

18 Q Well, certainly, in the context of getting
19 an order from a hospital, the order goes to NIDA,
20 you said; then, from NIDA, the order goes to Dr.
21 El_Sohly. Then, from there, the order goes to RTI,
22 and the cigarettes, you said, go directly from RTI

1 to the hospital, right?

2 A Correct.

3 Q So at no point in that process would NIDA,
4 the party who actually paid for the marijuana to be
5 grown, they don't have those cigarettes; isn't that
6 correct?

7 A Correct.

8 MS. CARPENTER: Okay; Your Honor, if we
9 could take about a 10-minute break.

10 JUDGE BITTNER: Okay.

11 MS. CARPENTER: And then, I think we will
12 very shortly be done after that.

13 JUDGE BITTNER: Okay; 10 minutes. Off the
14 record.

15 [Recess.]

16 MS. CARPENTER: Thank you, Your Honor.

17 BY MS. CARPENTER:

18 Q Mr. Strait, just a few more questions.
19 Famous last words, I know.

20 JUDGE BITTNER: That's what they all say,
21 Mr. Strait.

22 BY MS. CARPENTER:

1 Q Let me turn your attention back to the
2 beginning of your testimony yesterday. I think you
3 testified that you are the head of the office
4 that's responsible for dealing with treaty
5 obligations: is that right?

6 A No.

7 Q Oh; okay, I'm sorry. What did you say?

8 A The unit I work for is the quota and UN
9 reporting unit.

10 Q And so, it's just that part of the treaty
11 that you deal with?

12 A It has nothing to do with implementation
13 of the treaty, only following through with the
14 reporting of statistical information, which is an
15 obligation that the DEA has under the treaty.

16 Q Okay; let me turn your attention to
17 Government's Exhibit No. 29, which I think was
18 shown to you yesterday. Did you help draft that
19 letter, Mr. Strait?

20 A I was responsible for coordinating this
21 response.

22 Q And did you help draft the letter?

1 A Actually, yes, but it was really prepared
2 by Frank Sapienza.

3 Q Okay; in the third paragraph, first line,
4 the DEA continues to have international treaty and
5 legal concerns regarding your application. Do you
6 know what that refers to, international treaty and
7 legal concerns?

8 A No.

9 Q So you weren't aware of any treaty issues
10 regarding this particular application?

11 A In this case, no.

12 Q Let me read you a statement and see
13 whether you agree with this. As a registration
14 matter, a Schedule 1 researcher using marijuana
15 could be allowed under current DEA law and policy
16 to obtain marijuana either through NIDA or by
17 import for research. Under these circumstances, a
18 researcher might be permitted to grow various
19 strains of marijuana based upon the marijuana
20 obtained through NIDA or imported if such
21 cultivation were limited to legitimate research
22 purposes.

1 MS. PAREDES: Objection; outside the scope
2 of direct.

3 MS. CARPENTER: Your Honor, I guess I
4 would offer in response that he testified briefly
5 about the Covington and Burling letter, which I
6 think raised issues about that according to what he
7 said.

8 JUDGE BITTNER: Overruled. I think it's
9 close enough.

10 MS. CARPENTER: Okay.

11 BY MS. CARPENTER:

12 Q So do you agree with that statement? Is
13 it accurate?

14 A Can I see it?

15 Q Sure.

16 A I don't know where it comes from.

17 MS. PAREDES: Can we ask what you're
18 showing the witness?

19 JUDGE BITTNER: Oh, sure. I mean, I would
20 assume you're going to show it to counsel first.

21 MS. CARPENTER: This is from the
22 Government's third supplemental prehearing

1 statement under Matthew Strait's testimony.

2 JUDGE BITTNER: Okay.

3 MS. CARPENTER: Can I just show him to
4 refresh his recollection?

5 JUDGE BITTNER: Yes.

6 BY MS. CARPENTER:

7 Q Is that an accurate statement?

8 A It appears to be a statement that was
9 submitted on my behalf, yes.

10 Q But is it an accurate statement?

11 A Yes.

12 MS. PAREDES: May I just ask a point of
13 clarification? Are you referring to the first or
14 second paragraph or both or--

15 MS. CARPENTER: I'm referring to the
16 paragraph that I read into the record, beginning as
17 a registration matter and ending with legitimate
18 research purposes. It's one, two, sentences, okay?

19 BY MS. CARPENTER:

20 Q Are you done reading it? Now, in some of
21 the early meetings that you talked about where
22 there were--I think you were talking about some

1 problems with the application--

2 A I don't know if I agreed with the term
3 problem.

4 Q Okay; in the early meetings where you were
5 coordinating a response to the application.

6 A What context? Which coordination?

7 Q Well, I'm not sure how many you
8 coordinated, so--I think you testified yesterday
9 that you or at least one of the ones you
10 coordinated a response to the application; is that
11 right?

12 A If you're referring to the March 4 letter?

13 Q March 4 letter, and then, after that when
14 you did research to help the Agency determine
15 whether or not to grant the application, right?
16 When you went out and gathered information.

17 A We subsequently went out and gathered
18 information, yes.

19 Q And did you have meetings with other
20 people to discuss the application after you had
21 gathered all this information?

22 A Yes.

1 Q Who did you have meetings with?

2 A The same individuals or I should say the
3 same position titles that were available at the
4 June 2003 meeting that I had mentioned in my
5 testimony.

6 Q Okay; and when was the first such meeting
7 after you had gathered all the information, and I
8 guess were you sort of reporting back--

9 A Yes.

10 Q --to the group? Okay.

11 A When?

12 Q Yes.

13 A I can't give you a definitive date.

14 Q Ball park. Spring, summer?

15 A Fall 2004.

16 JUDGE BITTNER: 2004?

17 THE WITNESS: Yes.

18 JUDGE BITTNER: When did you go to the
19 University of Mississippi?

20 THE WITNESS: December.

21 JUDGE BITTNER: Of?

22 THE WITNESS: 2003.

1 JUDGE BITTNER: Okay.

2 BY MS. CARPENTER:

3 Q And then, you met with NIDA in January
4 2004?

5 A Yes.

6 Q And then, did you meet later with anybody
7 else?

8 A No, I believe that that was it.

9 Q So in between your meeting with NIDA in
10 roughly January of 2004 and fall 2004, do you know
11 what else was happening on the application, Dr.
12 Craker's application?

13 A I know our local field office was still
14 conducting its investigation.

15 Q During that time frame? January 2004 to
16 fall 2004?

17 A Yes.

18 Q Do you know how many times they visited?

19 A No.

20 Q Do you know anything else that was going
21 on during that time?

22 A Not particularly, no.

1 Q So in fall 2004, you had a meeting, you
2 attended a meeting.

3 A Yes.

4 Q And who was there?

5 A The same individuals who were available at
6 the June 2003 meeting.

7 Q And if you could just tell me who those
8 were.

9 A That would have been the Office of
10 Diversion Control Deputy Director.

11 JUDGE BITTNER: Was that still--

12 THE WITNESS: It was not Terry. Terry had
13 retired, so at that time, it was Denise Curry. It
14 would have been the head of the Office of Diversion
15 Control, which had also changed, which was a
16 gentleman, William J. Walker. There would have
17 been Christine Santerrud, who was Frank Sapienza's
18 replacement, because Frank had retired; myself; I
19 believe Ms. Kaupang, who had since been transferred
20 out to another location; and then various
21 representatives from our Office of Chief Counsel,
22 whom I don't necessarily recall whom specifically.

1 BY MS. CARPENTER:

2 Q Okay; and do you recall who called that
3 meeting?

4 A No, I don't recall specifically who called
5 it.

6 Q And do you recall the discussion at that
7 meeting? Let me ask you this first: what was the
8 purpose of this meeting?

9 A To discuss some of the outcomes of our
10 trip.

11 Q Okay; and was there discussion--I presume
12 you made a presentation about the outcome of your
13 trip?

14 A No.

15 Q No?

16 A No formal presentation.

17 Q Did you answer questions?

18 A Yes.

19 Q Okay; and these were the trips that you
20 had taken, the interview trips that we have already
21 talked about today.

22 A Yes, and others.

1 Q Others?

2 A Yes, those that were also mentioned today.

3 JUDGE BITTNER: Okay; I'm getting
4 confused.

5 MS. CARPENTER: Yes.

6 JUDGE BITTNER: I'm sorry, Mr. Strait; you
7 answered me, and I forgot the answer. When did you
8 go to the University of Mississippi?

9 THE WITNESS: December 2003.

10 JUDGE BITTNER: And then, did you go to
11 Richmond on the way home?

12 THE WITNESS: We went to the Research
13 Triangle Institute and stopped through Richmond on
14 the way home, which is--

15 JUDGE BITTNER: So you went to Mississippi
16 and then a separate trip to Research Triangle.

17 THE WITNESS: Yes.

18 JUDGE BITTNER: And then, Richmond was on
19 the way back from that one.

20 THE WITNESS: Yes.

21 JUDGE BITTNER: Okay.

22 THE WITNESS: Yes; there were multiple

1 meetings that had occurred throughout this whole
2 evaluation process.

3 JUDGE BITTNER: And when was the Research
4 Triangle trip?

5 THE WITNESS: I believe that was in maybe
6 October of 2003.

7 JUDGE BITTNER: Okay; and Mississippi
8 was--

9 THE WITNESS: December.

10 JUDGE BITTNER: Okay.

11 BY MS. CARPENTER:

12 Q Okay; so what was discussed at the
13 meeting?

14 A The results of the various trips that had
15 been taken and course of action.

16 Q Okay; and when you reported on your trips
17 out to CMCR, did you report that the CMCR
18 researchers were satisfied with the quality of NIDA
19 marijuana or that there were comments about the
20 quality of marijuana that might be negative?

21 A No, I think I provided copies of the
22 questionnaires.

1 Q So they had all that information in front
2 of them.

3 A Sure.

4 Q And at that meeting, was there any
5 discussion about whether the quality of NIDA
6 marijuana was sufficient, so as to--well, let me
7 just ask you that: was there discussion about
8 whether the quality of NIDA marijuana was
9 sufficient?

10 A I don't recall that specifically.

11 Q Do you recall any conclusions about
12 whether the quality of NIDA marijuana meant that
13 there was no necessity for another supplier?

14 A I don't recall specifically.

15 Q Do you not recall whether there were
16 conclusions, or you just don't recall what they
17 were?

18 A Neither.

19 Q Okay; so you don't recall whether at that
20 meeting any conclusions were reached.

21 A With regard to quality.

22 Q With regard to quality.

1 A Right.

2 Q Were there conclusions reached with regard
3 to other aspects of the application?

4 A Yes.

5 Q And what were those conclusions?

6 A Course of action.

7 Q And what was the course of action?

8 A The course of action was to have the field
9 finish their investigation.

10 Q And let me just stop you there. What
11 remained to be done in terms of a field
12 investigation?

13 A I don't know.

14 Q And what do you mean by have the field
15 finish their investigation?

16 A Whenever the field conducts a
17 preregistrant investigation, they prepare a report
18 on a DEA form. So we had not received that report.

19 Q You're talking about the people who went
20 up to Dr. Craker's--

21 A Yes.

22 Q --facility.

1 A Yes.

2 Q And you had not received that yet.

3 A No.

4 Q Okay; and what was--anything else in the
5 course of action?

6 A Yes.

7 Q What was that?

8 A It was decided that a position paper
9 should be or decision paper should be written for
10 the deputy administrator.

11 Q A decision paper?

12 A Yes.

13 Q And who decided that?

14 A The head of our office.

15 Q And that was Ms. Santerrud?

16 A No, that was Mr. Walker.

17 Q And was there discussion about what would
18 go into that decision paper?

19 A No.

20 Q And who was tasked to write the decision
21 paper?

22 A The Drug and Chemical Evaluation Section

1 in coordination with the Drug Operation Section.

2 Q Okay; lots of sections, but who was
3 actually going to do it? What person?

4 A Well, it was a shared responsibility
5 between myself and Ms. Kaupang.

6 Q Okay; and did you write that paper?

7 A I had a hand in writing that paper.

8 Q You wrote it with Ms. Kaupang.

9 A Yes.

10 Q And what did that paper say?

11 A I should say first of all that the paper
12 was not authored or not signed by myself or Ms.
13 Kaupang. It was instead signed by the deputy
14 assistant administrator of our office.

15 JUDGE BITTNER: Mr. Walker?

16 THE WITNESS: Mr. Walker.

17 It gave background information.

18 BY MS. CARPENTER:

19 Q Background information on what?

20 A On the application and facts gathered
21 during our subsequent trip reports.

22 Q Okay; and was there any discussion in that

1 decision paper about the quality or availability of
2 NIDA marijuana?

3 A I believe there were some summaries that
4 were prepared of the responses that we received.
5 We did not attach the questionnaires to this paper.

6 Q And were there any conclusions in that
7 decision paper about the sufficiency or--I'm sorry,
8 the quality or availability of NIDA marijuana?

9 A No.

10 Q There were no conclusions?

11 A No.

12 Q What was the purpose of the decision
13 paper?

14 A The purpose of the decision paper was just
15 what the decision paper is. It was an opportunity
16 for the deputy administrator to provide guidance on
17 how to proceed with the application.

18 Q Okay; guidance to the administrator?

19 A To our office head, Mr. Walker.

20 JUDGE BITTNER: There was a disconnect
21 there. You referred to the deputy administrator,
22 and Ms. Carpenter referred to the administrator.

1 MS. CARPENTER: I said was it for the
2 administrator, and he responded for their office
3 head.

4 THE WITNESS: For the office head.

5 JUDGE BITTNER: Who was the paper for?

6 THE WITNESS: The paper was for the deputy
7 administrator.

8 MS. CARPENTER: I see.

9 THE WITNESS: It was not for our
10 administrator.

11 JUDGE BITTNER: That's why I thought there
12 was a disconnect.

13 MS. CARPENTER: Okay.

14 JUDGE BITTNER: So the paper was signed by
15 Mr. Walker.

16 THE WITNESS: Yes.

17 JUDGE BITTNER: Who was the division head.

18 THE WITNESS: Who was the office head.

19 JUDGE BITTNER: Office head.

20 MS. CARPENTER: I'm sorry.

21 JUDGE BITTNER: And it was addressed to
22 the deputy administrator.

1 THE WITNESS: Yes.

2 BY MS. CARPENTER:

3 Q I see; so it went from your office to the
4 deputy administrator so the deputy administrator
5 could make a decision.

6 A From the Office of Diversion Control, yes.

7 Q And is that who makes the final decision
8 on whether or not the application is granted, the
9 deputy administrator for the Office of Diversion
10 Control?

11 A Yes.

12 JUDGE BITTNER: When you say grant, what
13 do you mean, Ms. Carpenter? Because I know it's
14 been used in various ways, grant and deny.

15 MS. CARPENTER: I guess the decision to
16 grant the registration that was applied for or to
17 deny the--it was denied here so I guess--

18 JUDGE BITTNER: That's my problem. I know
19 that various times in this proceeding, there has
20 been references to denying the application, but
21 that's not actually correct.

22 MS. CARPENTER: That's right; all right;

1 that is correct.

2 THE WITNESS: Let me qualify, because I
3 think I went a step further than what she may have
4 been asking in her question.

5 JUDGE BITTNER: Would you like the witness
6 to clarify?

7 MS. CARPENTER: Surely.

8 THE WITNESS: The issue as to what to do
9 with the application, which is deny the application
10 or approve the application, is not the decision of
11 the deputy administrator, no.

12 BY MS. CARPENTER:

13 Q Okay; what does the deputy administrator
14 decide?

15 A In what regard?

16 Q With regard to the decision paper. What
17 decision would he or she make based on that
18 decision paper?

19 A She was asked to concur or nonconcur with
20 a recommendation made by Mr. Walker as to how he
21 would have liked to proceed with the application.

22 Q Okay; so the decision paper did have a

1 recommendation as to how to proceed.

2 A Made by Mr. Walker.

3 Q Made by Mr. Walker. And did you write
4 that or not?

5 A No.

6 Q Did Ms. Kaupang write that?

7 A No.

8 Q Mr. Walker wrote that?

9 A Yes, that was his guidance.

10 Q And do you know what that recommendation
11 was?

12 A Yes.

13 Q What was it?

14 A To issue an order to show cause.

15 Q And do you know what the reasons were for
16 that?

17 A I don't think they were summarized. I
18 think it was just based on the background
19 information provided.

20 Q It was based on the background information
21 provided?

22 A What was provided in the decision paper

1 itself.

2 Q Okay; in your meeting in the fall of 2004,
3 was there discussion about MAPS?

4 A I believe--I won't say specifically that I
5 recall a specific conversation.

6 Q Okay; and did anybody at that meeting
7 discuss the fact that MAPS has sponsored FDA and
8 DEA approved clinical research into the medical
9 benefits of MDMA?

10 A I don't believe that was relevant to our
11 discussion.

12 Q And my question is did anybody bring it
13 up?

14 A I don't believe so.

15 Q Okay; did anybody bring up the fact that
16 MAPS has sponsored research that is FDA and DEA
17 approved into the medical benefits of psilocybin?

18 A No.

19 Q Did anybody bring up that MAPS has
20 sponsored research that was DEA-approved into
21 whether water pipes could be useful as delivery
22 systems for marijuana?

1 A No.

2 Q And did anybody bring up that NIDA had
3 provided marijuana for use in that MAPS sponsored
4 study?

5 A No, if it wasn't brought up.

6 MS. CARPENTER: If I may just have one
7 more minute, Your Honor.

8 [Pause.]

9 MS. CARPENTER: Your Honor, we have no
10 further questions.

11 JUDGE BITTNER: Okay; redirect.

12 MS. PAREDES: Do you mind if we just take
13 two minutes, maybe?

14 JUDGE BITTNER: Sure; off the record.

15 [Recess.]

16 JUDGE BITTNER: Okay; we are on redirect,
17 am I correct?

18 MS. PAREDES: Yes, Your Honor.

19 REDIRECT EXAMINATION

20 BY MS. PAREDES:

21 Q Mr. Strait, why did you focus only on CMCR
22 investigators to interview?

1 MR. BAYLY: Please.

2 JUDGE BITTNER: Okay; how about--and we
3 are still--I think this may as well be on the
4 record. We are still planning to go September 26th
5 through 30th.

6 MS. CARPENTER: That is correct, Your
7 Honor.

8 JUDGE BITTNER: Monday through Friday.
9 And at this point, anyway, December 12th through
10 16th.

11 MR. BAYLY: If needed.

12 MS. CARPENTER: Only if absolutely
13 necessary, Your Honor.

14 JUDGE BITTNER: Right, but at least you've
15 all got those dates on your calendars.

16 MS. CARPENTER: Yes.

17 JUDGE BITTNER: Blocked off.

18 Would you like to start at 9:00 in the
19 morning on September 26th?

20 MS. CARPENTER: That would be fine with
21 us, Your Honor.

22 MR. BAYLY: Yes, that would be good.

1 JUDGE BITTNER: Okay; that is what we'll
2 do, then.

3 We are in recess until then. Thank you,
4 Don. Off the record.

5 [Whereupon, at 11:27 a.m., the hearing was
6 recessed, to reconvene at 9:00 a.m. on September
7 26, 2005.]