

UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

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In the Matter of: :
: Docket No. 05-16
LYLE E. CRAKER, Ph.D. :
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VOLUME 6
Monday, December 12, 2005
DEA Headquarters
600 Army Navy Drive
Hearing Room E-2103
Arlington, Virginia

The hearing in the above-entitled matter
convened, pursuant to notice, at 9:08 a.m.

BEFORE:

MARY ELLEN BITTNER
Chief Administrative Law Judge

APPEARANCES:

On behalf of the DEA:

BRIAN BAYLY, ESQ.
Office of Chief Counsel
Drug Enforcement Administration
(202) 307-8010

IMELDA L. PAREDES, ESQ.
Senior Attorney
Office of Chief Counsel
(202) 353-9676

On Behalf of the Respondent:

JULIE M. CARPENTER, ESQ.
Jenner & Block LLP
601 13th Street, N.W.
Suite 1200 South
Washington, D.C. 20005
(202) 661-4810

M. ALLEN HOPPER, ESQ.
Senior Staff Attorney
Drug Reform Project
American Civil Liberties Union Foundation
1101 Pacific Avenue, Suite 333
Santa Cruz, California 95060
(831) 471-9000 Ext. 14

ALSO PRESENT:

EMANUEL JACOBOWITZ, ESQ.
Steptoe and Johnson

RICHARD DOBLIN, Ph.D.
Representative of Respondent

C O N T E N T S

WITNESS	DIRECT	CROSS	REDIRECT	RECROSS
Mahmoud El Sohly	1130	1343	--	--

E X H I B I T S

GOVERNMENT'S	MARKED	RECEIVED
No. 5	--	1281
Nos. 6, 7, and 8	--	1330
Nos. 12 and 13	--	1215
No. 15	--	1224
Nos. 65 through 71	1331	1335
Nos. 75, 76 and 77	--	1341
No. 93	--	1135
No. 94	--	1283

RESPONDENT'S

No. 4	--	1365
No. 5	--	1374
No. 6	--	1396
No. 7	--	1409
No. 8	--	1436
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P R O C E E D I N G S

JUDGE BITTNER: On the record.

Mr. Bayly.

MR. BAYLY: Thank you, Judge Bittner.

Brian Bayly DEA Chief Counsel. Before we proceed with our next witness, Dr. Mahmoud El Sohly--and I want to make sure I can be heard by the court reporter and the clerk and everybody. If anybody can't hear me, please let me know.

Just to advise the Court and Respondent's Counsel and the witnesses, I just want to give a very, very brief opening statement of the remaining witnesses and the schedule. The first witness we have, as I indicated before we went on the record, Judge Bittner, is Dr. El Sohly, who is sitting here ready to testify, and he will be testifying today. I anticipate he'll go into tomorrow, and out of an abundance of caution, as I've discussed this, I believe with your clerk and with Ms. Carpenter, we may need to go a little bit late tonight, and perhaps we can discuss starting a little early tomorrow to gauge where we're at, because we know

1 that Dr. El Sohly must catch an afternoon flight, I
2 think about 5:10 from National. So we
3 probably--we're shooting to finish up at 3:30.

4 So just for scheduling purposes, we're
5 going to try to get in as much as we can. I think
6 we can finish, but we'll just have to see.

7 At any rate, of course Dr. El Sohly is the
8 witness who was the head of the University of
9 Mississippi project that grows and provides
10 marijuana to the researchers through NIDA. He's
11 also grows marijuana for his own research purposes,
12 and he will give the overview and, indeed, the
13 details of the operation of the University of
14 Mississippi, go through the contracts, how the
15 contracts are bid upon and how the contracts work
16 with NIDA.

17 Then Wednesday morning, we are going to
18 have Dr. Steve Gust testify. Dr. Gust is the HHS
19 representative who will talk about NIDA from the
20 HHS side and how the system works. We
21 anticipate--he'll be here first thing Wednesday
22 morning, and we anticipate that he will testify all

1 of Wednesday in terms of direct and cross. Worse
2 case scenario--he's local. So he'll be available
3 Thursday morning to finish up if and when we get to
4 that point.

5 Now, the third Government witness--and as
6 we get into Thursday and Friday, we're going to
7 have less and less to do and probably more extra
8 time, because Thursday, the Government plans to
9 call Dr. David Ouslander. He's a pharmaceutical
10 drug expert, and he will be testifying about some
11 of the same issues in rebuttal, maybe in
12 re-enforcing Dr. Irwin Martin, who was the
13 pharmaceutical expert who testified on behalf of
14 Respondent from the University of Massachusetts.

15 Now, Dr. Ouslander's testimony is not
16 lengthy. So we anticipate that it would be
17 certainly less than a half day, and he's coming
18 down Thursday, but he won't be here until late
19 Thursday morning. Now, to fill the gap Thursday
20 morning, the Government has--we actually prepared
21 93, perhaps a few more, documents. We would like
22 some time--and I'm sure there will be extra time on

1 Thursday and Friday--to go through the documents,
2 to list the ones that we voluntarily withdrew, to
3 acknowledge the ones that were excluded by your
4 order, Judge Bittner, and then to admit the rest of
5 the documents. I anticipated that Respondent won't
6 object to most of them, but certainly there may be
7 some objections to some of them, and we would want
8 to reserve time to make sure that those objections
9 are on the record and see if we get those documents
10 into evidence or not.

11 The reason I say that is because quite a
12 few of the documents are not the kind that go in
13 through the witnesses themselves. So there will be
14 a number of documents which we will want to submit
15 in that manner.

16 Then, finally, Friday, we have Dr. Eric
17 Vogue. He's a physician, and also we're going to
18 tender him as an expert witness on various issues
19 pertaining to marijuana, and he'll talk about
20 marijuana in terms of the abuse, treatment. We've
21 heard testimony about a product called Satisfact
22 from Respondent's. Dr. Vogue will testify about

1 that, but in light of the various orders that the
2 parties have obtained from you, Judge Bittner, and
3 in light of the Government itself cutting back his
4 testify, his testimony is, likewise, not going to
5 be that lengthy. So Friday is probably more than
6 enough time to cover Dr. Vogue.

7 So that is in a nutshell the scheduling
8 and a very brief synopsis of what all these
9 witnesses will be testifying about, and I
10 appreciate the Court and Respondent's counsel being
11 flexible and working with us on the witness
12 scheduling.

13 Thank you. That's all I have at this
14 time.

15 JUDGE BITTNER: Thank you, Mr. Bayly.

16 Ms. Carpenter, any comments or questions?

17 MS. CARPENTER: No, Your Honor.

18 JUDGE BITTNER: So we're looking at
19 finishing the Government's case this week, and then
20 we'll see whether Respondent has any rebuttal in
21 January? Is that the plan at the moment?

22 MS. CARPENTER: That's right, Your Honor.

1 JUDGE BITTNER: At the moment--I know when
2 we talked about resuming in January, our preference
3 was for the second week. So far, the case that I
4 had that week hasn't disappeared like I wish it
5 would. So at the moment, we're still scheduled for
6 the first week in January.

7 MR. BAYLY: So are we still, then,
8 tentatively scheduled for January 3rd and 4th if we
9 need it?

10 JUDGE BITTNER: Yes.

11 MR. BAYLY: Okay.

12 MS. CARPENTER: And that's fine with us,
13 Your Honor.

14 JUDGE BITTNER: So let us go ahead, Mr.
15 Bayly.

16 MR. BAYLY: Yes. Thank you, Judge
17 Bittner. We'll call Dr. El Sohly to the stand,
18 please.

19 Whereupon,

20 MAHMOUD EL SOHLY, Ph.D.
21 was called to testify and, having first been duly
22 sworn by the Chief Administrative Law Judge, was

1 examined and testified as follows:

2 DIRECT EXAMINATION

3 BY MR. BAYLY:

4 Q Good morning, Dr. El Sohly.

5 A Good morning, Mr. Bayly.

6 Q Please let me know if you don't understand
7 my questions or if you can't hear me, and I'll ask
8 you to please speak up.

9 And if anyone is not hearing me or Dr. El
10 Sohly, please let us know.

11 And I see you're ready there with water.
12 So we'll commence. Please state your name for the
13 record.

14 A My first name is Mahmoud, M-A-H-M-O-U-D.
15 My last name is El Sohly, E-L, S-O-H-L-Y.

16 Q At this point, Dr. El Sohly, I just want
17 you to answer very briefly generally what is your
18 occupation, profession, or business.

19 A I am research professor at the National
20 Center for Natural Products Research at the
21 Research Institute of Pharmaceutical Sciences,
22 School of Pharmacy, University of Mississippi. I'm

1 also the resident and laboratory director of my own
2 private laboratory, which is an analytical forensic
3 laboratory in Oxford, Mississippi, El Sohly Labs,
4 Incorporated.

5 Q And, Dr. El Sohly, in this capacity, is
6 there one particular drug or plant that you deal
7 with?

8 A Well, I deal with a lot of different--not
9 deal, but I work with a lot of different drugs,
10 analysis and drug development and so on, but the
11 one particular drug that I have been working with
12 for so many years is marijuana.

13 Q All right. Dr. El Sohly, how long have
14 you been so employed in your present capacity or
15 your occupation at the University of Mississippi?

16 A I have been with a University of
17 Mississippi since 1975. I came to Massachusetts
18 right after I finished my doctorate degree from the
19 University of Pittsburgh and started out as a
20 post-doctoral fellow in 1975. In 1976, I became a
21 research associate at the Research Institute of
22 Pharmaceutical Sciences and started working on the

1 marijuana project with my predecessor, Dr. Carlton
2 Turner. So I have been there for almost 30 years.

3 Q All right. Now, did you have any job or
4 occupation before you worked at the University of
5 Mississippi?

6 A I was a teaching assistant at the School
7 of Pharmacy at the University of Pittsburgh before
8 coming to Mississippi, and before that, I was a
9 teaching assistant at the School of Pharmacy,
10 Department of Pharmacognosy at the School of
11 Pharmacy, University of Cairo, and after--and
12 before that, right after graduation with a pharmacy
13 degree from the University of Cairo, I worked with
14 a pharmaceutical company in Egypt that's a national
15 company for pharmaceutical trading.

16 JUDGE BITTNER: Pharmacognosy?

17 THE WITNESS: What's that?

18 JUDGE BITTNER: You referred to
19 Pharmacognosy.

20 THE WITNESS: Pharmacognosy is the science
21 of the crude drugs, science of natural products,
22 herbal products.

1 JUDGE BITTNER: How do you spell it?

2 THE WITNESS: Pharma, cogosy,
3 C-O-G-N-O-S-Y.

4 JUDGE BITTNER: Thank you.

5 THE WITNESS: Pharmacognosy.

6 MR. BAYLY: Judge Bittner, I'd like to
7 present the witness with Government Exhibit 93,
8 marked for identification, and that's Dr. El
9 Sohly's C.V.

10 JUDGE BITTNER: Okay. As soon as I find
11 it.

12 Okay. Why don't I have it? Did you file
13 it later, Mr. Bayly?

14 MR. BAYLY: It was in a supplemental, the
15 fourth or fifth.

16 MS. CARPENTER: I think it was the fifth,
17 Your Honor.

18 JUDGE BITTNER: Let's make sure I've got
19 it. What was the date of your fifth?

20 MR. BAYLY: We're looking at it now.

21 JUDGE BITTNER: Here we go. I have it.

22 MR. BAYLY: All set?

1 JUDGE BITTNER: Yes.

2 MR. BAYLY: For the record, now I'm
3 handing Dr. El Sohly a copy of Government Exhibit
4 93, the C.V. for Dr. El Sohly.

5 BY MR. BAYLY:

6 Q And, Dr. El Sohly, you're free to look at
7 that. I'm going to ask you a few questions
8 relating to your C.V. as we go through your
9 testimony; however, I promise I won't be going
10 through the entire C.V. or probably not even most
11 of it since it is rather lengthy; but could you
12 identify Government Exhibit 93 for the record?

13 A Yes. This is my curriculum vitae.

14 Q And did you prepare this?

15 A Yes, I did.

16 Q And is this current to the best of your
17 knowledge?

18 A Pretty much so. There might be some
19 publications that haven't made it to this one, but
20 it's pretty close to what the actual current C.V.
21 would be.

22 MR. BAYLY: All right. Your Honor, at

1 this point, I'd like to admit Government Exhibit 93
2 into evidence.

3 MS. CARPENTER: No objection.

4 JUDGE BITTNER: Received.

5 [Government Exhibit No. 93 was
6 received in evidence.]

7 BY MR. BAYLY:

8 Q Just by way of background here, Dr. El
9 Sohly, could you tell us if you obtained an
10 undergraduate degree?

11 A Yes. Maybe I can go through my whole
12 education very briefly.

13 Q Yes.

14 A I have a bachelor's degree in pharmacy and
15 pharmaceutical chemistry from the University of
16 Cairo in 1966 and a master's degree in pharmacy and
17 pharmaceutical sciences, 1971.

18 Q Where was that from?

19 A University of Cairo. Both my
20 undergraduate and master's degree are from the
21 University of Cairo, and a Ph.D. in pharmacy with a
22 a major in pharmacognosy in 1975 from the

1 University of Pittsburgh, and since that time, I
2 moved to Mississippi, and I think I mentioned
3 before that I've been there since that time.

4 Q Now, Dr. El Sohly, there are a number of
5 articles that you have listed as being the author
6 of in your C.V., and, just generally, these
7 articles listed in your C.V., Government Exhibit
8 93, do any of them pertain to research,
9 cultivation, or extraction of marijuana?

10 A Yes, there are. Actually, quite a number
11 of my publications--I have over 200 publications in
12 scientific journals. Many of those publications
13 deal with the subjects of marijuana or
14 cannabinoids, which are the natural products coming
15 out the cannabis plant.

16 Q Now, Dr. El Sohly, we may get into a
17 little more detail on the marijuana or its
18 constituents, but at this point, in terms of
19 background, what areas of research have you
20 accomplished with marijuana?

21 A We've actually targeted so many different
22 aspects of research in that area. My main focus

1 was actually on the chemistry of the plant. We
2 have done quite a number of publications on the
3 extraction of the plant material, isolation of
4 different components, analysis of the plant
5 material, both with the material that we grow and
6 harvest at the university and also we have
7 confiscated material that we receive. We receive
8 materials from DEA's regional labs. We receive
9 materials from other State narcotics agents and so
10 on, and we've published worked along those lines
11 dealing the potency of the materials on the illicit
12 market.

13 We did work with the pharmacology of some
14 of the cannabis constituents. We did some work
15 with developing procedures for extraction and
16 isolation of tetrahydrocannabinol, normally
17 referred to as THC, which is the main component of
18 the plant and has the psychological properties and
19 most of the pharmacological properties ascribed to
20 the plant because of this particular substance. We
21 have a developed a process for extraction of the
22 material in an economic way. We also developed

1 other processes for manufacturing or synthesis of
2 other cannabinoids that might have other biological
3 activities.

4 We have done some product development work
5 that dealt with not directly with
6 tetrahydrocannabinol, or THC, but a product of THC.
7 We have done quite of number of publications on the
8 analysis of biological effects as a result of
9 ingestion of marijuana and ingestion of the
10 cannabinoids. So we've really covered quite a wide
11 range of activities with the plant or with the
12 cannabinoids that are the major components of the
13 plant.

14 JUDGE BITTNER: When you say we, Doctor,
15 to whom do you refer?

16 THE WITNESS: I refer to myself and my
17 coworkers at the University of Mississippi.

18 JUDGE BITTNER: So this is all talking
19 about the University of Mississippi?

20 THE WITNESS: The University of
21 Mississippi and also with my private lab, which we
22 do quite a collaborative work with the university.

1 JUDGE BITTNER: So you're testimony just
2 now was with one or the other entities?

3 THE WITNESS: That's correct, and, Your
4 Honor, as a researcher, you rarely do anything all
5 just by yourself. You always have
6 co-investigators, coworkers, and associates that
7 participate in the research. So I refer to the
8 work, although I'm the singular scientist, as we.

9 JUDGE BITTNER: Okay.

10 BY MR. BAYLY:

11 Q Dr. El Sohly, this may be a good time to
12 ask you, then, to name the major participants that
13 work with you at the University of Mississippi in
14 terms of all of the different things you do with
15 marijuana that you just testified about.

16 A Well, it depends really when you want me
17 to start naming those people, because as I
18 mentioned, I have been there since 1975, starting
19 working with marijuana in 1976.

20 Q Maybe we should just go with the current
21 folks then.

22 A The current folks I have with me, Mr.

1 Zlatko Mehmedic, who is the quality control, you
2 know, person. I have Dr. Samir Ross, who was a
3 co-investigator on a project a few years ago. I
4 have Mr. Don Stanford, who is a quality assurance
5 officer for the project. I have a quite of number
6 of young investigators that are working there.

7 Prior to that, I was collaborating with
8 Dr. Carlton Turner who was my predecessor on the
9 project. So there's quite a number of people that
10 contribute to this work.

11 JUDGE BITTNER: During the break, we're
12 going to have to get some spellings.

13 BY MR. BAYLY:

14 Q Dr. El Sohly, are you the head of all
15 these people; you supervise them?

16 A Yes.

17 Q Now I want to ask you a few specific
18 questions about your testimony that concerns all
19 that you do with marijuana. First of all, you talk
20 about cannabinoids. Can you explain to us what are
21 cannabinoids in terms of marijuana?

22 A Cannabinoids, Your Honor, are the natural

1 components that only exist in the cannabis plant.
2 This is a group of chemical compounds that have not
3 be identified in any other plant besides the
4 cannabis plant or the marijuana plant. They are
5 defined as a C-21 compound, C-21 meaning they
6 contain 21 carbons. The chemistry, the chemicals,
7 contain 21 carbons that exist in the cannabis plant
8 and only in the cannabis plant.

9 Also, they are derivatives, and they're
10 synthetic analogs. Any compounds that were made to
11 mimic those compounds that exist in the plant
12 material are referred to as cannabinoids. So it's
13 just a general classification of chemical compounds
14 that exist in the plant material.

15 Q Dr. El Sohly, would the cannabinoids be
16 considered active or inactive ingredients or both?

17 A Some of the cannabinoids--of course, the
18 major cannabinoid that exists in the plant material
19 is the THC, and even THC actually does not exist in
20 the plant material as the free THC. It exists as a
21 precursor that has to be heated in order to produce
22 the THC; but nonetheless, it's the THC that

1 actually exerts most of the pharmacological
2 activities of the plant.

3 Now, there are many, many other
4 cannabinoids that actually do not have the
5 psychological activities that are associated with
6 the drug, but the major cannabinoid is the THC and
7 its precursor.

8 Q These other cannabinoids, then, that you
9 mentioned, are they considered active or inactive
10 ingredients or unknown?

11 A Well, they might have activities, but
12 those activities are necessarily psychological
13 activities as the THC has. So they will be active,
14 but not necessarily in the same psychological
15 activity and not necessarily in the same spectrum
16 of activity as THC. Some just have no known
17 pharmacological activities per se.

18 Q How many cannabinoids are there known in
19 marijuana?

20 A Well, at the last count, I believe there
21 is a total of 66 different cannabinoids.

22 Q Are there any other active ingredients in

1 the marijuana plant other than cannabinoids?

2 A Again, it depends on what the definitions
3 of active are, but in terms of the--as far as I
4 personally know, most, if not all, the
5 pharmacological activities ascribed to the cannabis
6 plant could be accounted for by that activity of
7 THC. So although some of those other components
8 might contribute to the overall activity of the
9 plant, the net result of the activity of the plant
10 is because of the THC.

11 Q Dr. El Sohly, you also mentioned the term
12 "extraction", which I think intuitively, perhaps,
13 we can figure out what that is, but maybe out of an
14 abundance of caution, it would be best to get some
15 testimony from you about what extraction is in
16 terms of the marijuana plant.

17 A Well, extracting the plant material is
18 just like, really, when you make coffee, you're
19 extracting the coffee grinds. When you make tea,
20 you're extracting the tea leaves. So when
21 you're--and it just happens for these two examples,
22 you use water to do that, or hot water in

1 particular, but with the cannabis plant, because
2 the components in the cannabis that have biological
3 or pharmacological activity are not water soluble
4 or water immersible, then the extraction is usually
5 carried out with an organic solvent. The solvent
6 of preference in most of those extractions is
7 ethanol, simply because if you have some left over
8 solvent in the extract, then it's not something
9 that would be, you know, terrible to have; but
10 other organic solvents have been used to extract
11 the plant material, such as petroleum distillates,
12 such as chloroform, such as methyl acetate,
13 acetone, just to name a few.

14 Q Dr. El Sohly, in terms of your work with
15 the marijuana plant, are you familiar with the term
16 "fingerprinting"?

17 A Yes.

18 Q Can you tell us what that means to you?

19 A Fingerprinting, we have actually carried
20 out--and I failed to say that when referring to
21 some of the works that we did with the cannabis
22 plant. Fingerprinting is when you try to define

1 the characteristics of a given group of plants
2 whether based on the country of origin or source or
3 something like that, and you define--you'd say, for
4 example, that Mexican samples have a certain
5 fingerprint, a chemical fingerprint. Colombian
6 samples would have possibly a different
7 fingerprint. Jamaican samples would have a third
8 fingerprint. Domestic samples would have a
9 different fingerprint.

10 So when you refer to fingerprinting,
11 you're chemically defining the components of the
12 plant material that would be characteristic for a
13 given region, and we have done this work back in
14 1992 or so and, you know, determined that you can
15 actually tell the country of origin or the source
16 of the plant material by doing an exhaustive
17 chemical analysis, which we have done, and we have
18 shown that you can actually tell the different
19 between Mexican marijuana versus Colombian versus
20 Jamaican versus Thai material versus domestic, is
21 it grown indoors or outdoors, and all these
22 difference represents--for each one of those

1 classes, there is a fingerprint, and the
2 fingerprint is like an I.D., like a person having a
3 fingerprint that would be characteristic only for
4 that person.

5 Chemically speaking, Your Honor, it could
6 be analyzed exhaustively. We have analyzed over
7 170 different components in the plant material that
8 make up the fingerprint for the different types of
9 marijuana.

10 Q Now, you also mentioned the term "THC"; is
11 that correct?

12 A Yes.

13 Q Can you tell us what THC stands for?

14 A THC stands for tetrahydrocannabinol, and
15 there are several THCs, actually.

16 Q Several THCs as what? Components of--

17 A No. There are several THCs because
18 tetrahydrocannabinol by definition, there is one
19 double bond in the molecule, and that
20 tetrahydrocannabinol could be a delta-9, could be a
21 delta-8, could be a delta-7, and could also be
22 delta-6-18-A. And so there are several THCs, but

1 the one that we refer to when we speak about
2 marijuana and we speak about THC, it's delta-9-THC,
3 which would be delta-9-tetrahydrocannabinol.

4 Q Dr. El Sohly, now I'd like to ask you if
5 you have ever testified as an expert on marijuana
6 prior to this hearing?

7 A Yes, I have.

8 Q Was that in the State or Federal Courts or
9 both?

10 A Both.

11 Q Was it in criminal or civil proceedings or
12 both?

13 A I believe in both, but mostly in criminal
14 cases, but there might have been some analytical
15 testimony in civil cases.

16 Q In terms of criminal, as testifying as an
17 expert in marijuana, did you generally stick to one
18 type of expert testimony, or did it vary?

19 A Actually, I have no choice of
20 who--basically who calls me. I get some calls from
21 the government sometimes. I get some calls from
22 the defense sometimes in those criminal cases, and

1 I'm basically presented with the case and give an
2 opinion, and if whoever is calling me thinks that I
3 could help their case, they put me on the stand.
4 If they don't, they say thank you, nice talking to
5 you, and they don't call me back.

6 Q As an expert testifying about marijuana in
7 these court proceedings, did you testify about the
8 identification of materials of marijuana, marijuana
9 extracts?

10 A Yes, I have, both.

11 Q Did your expert testimony concern the
12 potency of marijuana?

13 A It concerned the potency, the yield, the
14 analysis, all three aspects.

15 Q Now, Dr. El Sohly, based on your education
16 and experience, when you talk about potency of
17 marijuana, can you explain to us what potency means
18 in the context of marijuana?

19 A Usually when you talk about the potency of
20 marijuana, you're talking about it in terms of the
21 concentration of THC in the plant material. So the
22 potency of the plant is directly proportional to

1 the amount of THC in the plant on a
2 weight-by-weight basis, which is concentration.
3 The higher the THC content, the more potent the
4 drug is. The lower the THC content, the less
5 potent the drug is.

6 Q Dr. El Sohly, when you say THC content,
7 what specific THC are you referring to?

8 A As I indicated before, when I say just
9 THC, it's the delta-9-THC.

10 Q And you also indicated that you testified
11 about the yield of marijuana as an expert in some
12 of these court proceedings. Can you tell what
13 yield means in this context?

14 A The yield--the testimony regarding the
15 yield, it was--you know, first of all, let me
16 answer your question directly, and that is the
17 yield refers to the amount of usable material that
18 one can get or would get from cultivated plants,
19 and of course the cultivation depends on the
20 conditions--useful cultivations depends on whether
21 it's indoors or outdoors, what the growth cycle is,
22 what part of the country, what kind of plant

1 material, and so on. So when I refer to the yield,
2 I'm referring to the amount of usable plant
3 material that could be obtained, let's say, per
4 plant or per unit earlier or something like that.
5 I would have to be given the specifics of the case,
6 where the material is grown, and based on my
7 experience, I can say how much material you can
8 get. If you have some plants, I can say how much
9 material you can get out of that plant. If you
10 just cut a plant from the base and you just weigh
11 it, a green plant, and I can tell you how much
12 usable material you can get out that plant. If you
13 tell me the weight of the plant, I can tell you
14 roughly how much material you can get. Usable
15 material means smokeable material, not seeds, not
16 stocks, not roots, but actual leaves and buds.

17 Q Dr. El Sohly, can you tell us how long
18 have you been involved in cultivating marijuana
19 plants at the University of Mississippi?

20 A I would say about 29 years. Actually, I
21 didn't start working with marijuana until 1976. So
22 29 years.

1 Q With this marijuana, do you provide some
2 of this marijuana, or does some of this marijuana
3 get provided to researchers that use the marijuana?

4 A Actually, all the material that we produce
5 under the NIDA contract is used for research.

6 Q Is that clinical, nonclinical, or both?

7 A Well, all of the above.

8 Q And have you and the University of
9 Mississippi personnel also done some research and
10 analysis on marijuana?

11 A Yes, sir, we have.

12 MR. BAYLY: Your Honor, at this time, I
13 would like to tender Dr. El Sohly as an expert in
14 the cultivation and research of marijuana.

15 JUDGE BITTNER: Ms. Carpenter?

16 MS. CARPENTER: No, objection, Your Honor.

17 JUDGE BITTNER: You're an expert, Doctor.

18 THE WITNESS: Thank you, Your Honor.

19 By MR. BAYLY:

20 Q Dr. El Sohly, I'd just like to briefly get
21 into a little bit of historical background on the
22 University of Mississippi's project with marijuana.

1 Are you aware of the University of Mississippi's
2 work with marijuana before you started working
3 there?

4 A Yes, I am.

5 Q When was the University of Mississippi's
6 initial registration with DEA, to your knowledge?

7 A I would say around 1968.

8 Q And back in '68, did the University of
9 Mississippi have a registration with DEA?

10 A Yes, it did. You must have a registration
11 with the DEA to be able to do any work with the
12 controlled substance. So the university was
13 registered with the DEA at that time. I believe
14 the first registration was to my predecessor, Dr.
15 Waller, W-A-L-L-E-R, who actually was the first
16 investigator that worked at the university back in
17 1968. So then after that came Dr. Carlton Turner,
18 who took over in 1971 as director of the project,
19 and so the registration to his name, and then it
20 changed to my name in 1980.

21 Q Dr. El Sohly, up until--during this period
22 up until you started working at the University of

1 Mississippi, were you aware of what kind of DEA
2 registration the university had in order to
3 cultivate and work with marijuana?

4 A The registration at the university has
5 always been an analytical laboratory registration
6 that allowed the university to do the cultivation,
7 you know, the production of this material for
8 government use and research activities and also to
9 do the analytical work, receiving samples from
10 different parts of the country for analysis, and
11 also allowed the distribution under the NIDA
12 program to other investigators. So it's an
13 analytical laboratory license that really that
14 license is a broad license that allows you to do
15 research, manufacturing, and distribution.

16 Q All right. Dr. El Sohly, this would be a
17 good time to get into this area concerning your
18 contract with NIDA. First of all, are you aware of
19 a component of the U.S. Department of Health and
20 Human Services known as NIDA, N-I-D-A?

21 A Yes, I am, very much so.

22 Q And do you know what NIDA stands for?

1 A NIDA is the National Institute on Drug
2 Abuse.

3 Q And while you have been at the University
4 of Mississippi, did the University of Mississippi
5 in relation to its marijuana program contract with
6 NIDA to supply marijuana to researchers?

7 A Yes, it does. The work at the University
8 of Mississippi is the result of a contract with the
9 National Institute on Drug Abuse that actually is a
10 competitively-renewed contract, a cost
11 reimbursement contract. The advertisement for the
12 contract was on the Federal Register at this
13 particular point in time with giving investigators
14 a chance to submit a proposal, a response to that
15 request for proposal or RFP. You know, there was a
16 special deadline for that when you submit your
17 proposal, and the proposal usually has two
18 components, a technical component and a business
19 component. And those proposals from the University
20 of Mississippi and any other organization that
21 could perform this type of work would submit a bid,
22 would submit a response.

1 The technical proposal is reviewed, and
2 the respondents to the RFP would be classified by
3 priorities, you know, this gets so many points,
4 this gets so many points, and so on. They pick the
5 top one or two. I don't know exactly that they
6 pick, depending on the number of the participants
7 or respondents, and then they look at the business
8 proposal of the price as a secondary qualification,
9 and then they pick the organization that most fits
10 not only in terms of the technical merit, but in
11 price merit. After that, there are some
12 negotiations as far as the price goes with the top
13 organization that they pick.

14 This goes into a three-year cycle. Every
15 three years, the contract is re-advertised, and
16 they get a new request for proposal. It might add
17 new items. It might delete some items, but the
18 basic structure of the contract is the same, but
19 with different change from one contract cycle to
20 the other. And the contracts, usually they have
21 options in them. The government has options to
22 grow or not to grow. There is a basic clause in

1 the contract for having the contract in place for
2 doing all of the peripheral work that is done
3 besides the production of the plant material.

4 In 1999, for the first time, the
5 government decided to make it a five-year cycle.
6 So the contract that started in November of 1999
7 was actually a five-year contract.

8 Q All right. Dr. El Sohly, let's back up a
9 little here. Prior to the '99 contract, I think
10 you indicated the contract between U. Miss. and
11 NIDA was three years?

12 A That's correct.

13 Q Now, how long have you worked at
14 the--these contract between U. Miss. and NIDA, when
15 did you first start working with these contracts?

16 A Well, I started as an associate to or as a
17 co-principal investigator. The principal
18 investigator Dr. Carlton who moved to the White
19 House in 1980 as President Reagan's drug abuse
20 policy advisor. I then took over as the project
21 director at that time, but before that, I was the
22 co-project director from 1976 to 1980, four years.

1 Q Now, as of 1980, were you, in essence, the
2 person in charge of the U. Miss. project?

3 A I was the one who actually submitted the
4 response to the request for proposal.

5 Q And what is your current job title in
6 relation to the NIDA project at U. Miss.?

7 A I am the project director.

8 Q You talked about these contracts. Let me
9 ask you this, Dr. El Sohly: Were these contracts
10 that were submitted--or bids that were submitted
11 for the contracts, were these bids open or secret
12 bids?

13 A These are secret bids. Nobody knows who
14 submitted them. As a matter of fact, to this date,
15 as long as I've been working with this contract, I
16 never knew who else applied for the contract. So
17 they are secret bids, and then once you are chosen,
18 whoever it is, it becomes public knowledge, but the
19 whole review process, the whole selection process,
20 and all of that is confidential.

21 Q Dr. El Sohly, can you please just
22 generally describe the job functions in relation to

1 being the director of the NIDA project at the
2 University of Mississippi?

3 A Well, I basically oversee all of the
4 different activities that go on with the contract.
5 Of course the registration is in my name. So I am
6 one responsible for getting the registration in
7 place and following the rules and regulations rule
8 for dealing with the controlled substance. I
9 direct all of the activities on the contract. I
10 communicate with the National Institute on Drug
11 Abuse and the Drug Enforcement Administration
12 regarding all of the different aspects, scientific
13 and legal aspects of the project. I supervise all
14 of the activities that go with the contract, the
15 growing, the harvesting, the potency monitoring,
16 the analysis, the extraction of the plant material,
17 the isolation of different components. All of the
18 different aspects of the project, I oversee all of
19 those activities.

20 Q Now, Dr. El Sohly, was there a specific
21 written contract that you have with NIDA in 1999?

22 A Yes, there is. Every contract cycle,

1 there is a contract. I might add that even though
2 the contract is a three-year or a five-year
3 contract, it's actually an incrementally funded
4 contract, which means that you don't get all the
5 money for all five years or three years at the same
6 time. You get one year at a time, and, you know, I
7 assume the government will have an option to not
8 necessarily do the whole entire three years or five
9 years. So every year, the contract, if everything
10 is going well, they fund another year and another
11 year and another year, but they don't have to
12 re-advertise between those years, but at the end of
13 the cycle, three- or five-year cycle, then there is
14 new advertisement and a new contract will be in
15 place.

16 Q Dr. El Sohly, how long did the '99
17 contract between you and NIDA exist, for what
18 period of time?

19 A The contract was put in place November 8th
20 or 7th or 9th, around that time. Let's say 8th,
21 November of '99, and was supposed to end in
22 November of 2004, but the contract was actually,

1 for some variety of reasons, extended until the new
2 contract was put in place in March of 2005. So
3 that contract actually extended just a few months
4 beyond the five years.

5 Q Did you as the director of the University
6 of Mississippi bid on the NIDA project contract in
7 2005?

8 A Yes, I have.

9 Q Were you awarded that contract?

10 A Yes.

11 Q And how long would that contract go for?

12 A Which one? The 1999 or the 2005?

13 Q The current one.

14 A The current one, yes. This one is also
15 for five years. So it will be for March 2005 to
16 March 2009, I guess.

17 JUDGE BITTNER: 2009 or 2010?

18 THE WITNESS: 2010. I'm sorry. It's five
19 years.

20 MR. BAYLY: Your Honor, if I may ask that
21 the witness be presented with Government Exhibits
22 12 and 13.

1 [Pause.]

2 MR. BAYLY: For the record, I'm now
3 presenting the witness, Dr. El Sohly, with
4 Government Exhibits, marked for identification, 12
5 and 13, and before I commence questioning, I want
6 to make sure everybody is on the same page here.

7 BY MR. BAYLY:

8 Q Okay. Dr. El Sohly, first I'm just going
9 to direct your attention to Government Exhibit 12,
10 and just tell us very briefly, generally, what that
11 exhibit is.

12 A This is the award document for the
13 contract that started in 1999. It says effective
14 date November 9, 1999.

15 Q And who are the parties to this contract?

16 A The National Institute on Drug Abuse and
17 the University of Mississippi.

18 Q Is there any other party that's involved
19 in this contract, either as a major contracting
20 party or a subcontracting party?

21 A We usually in this contract would have
22 actually two subcontractors, one major

1 subcontractors, the Research Target Institute of
2 North Carolina, that manufactures the cigarettes,
3 and then we would have--in the years we grow, we
4 would have a subcontractor for security, but that's
5 not a technical contributor to the contract. The
6 Research Target Institute, RTI, is a technical
7 subcontractor?

8 Q Well, let's call them RTI. Can you what
9 part they do in the contract, how they operate
10 under this contract?

11 A RTI is our subcontractor. When we
12 submitted the contract in '99, this contract named
13 the University of Mississippi as the contractor,
14 and then we have the Research Target Institute as
15 the subcontractor. Their major function is the
16 manufacturer of the cigarettes that are required
17 under the contract. One item in the contract
18 requires that we manufacturer cigarettes, and they
19 carry out all the activities that are related to
20 that manufacturing process, the analysis, the
21 certification, the distribution, and all of the
22 different aspects of getting those materials, those

1 cigarettes, to the researchers. But all the
2 paperwork and everything goes from NIDA to the
3 University of Mississippi as the contractor. We
4 will make sure all the paperwork from our part is
5 completed, and then only then we have ask--we
6 release the material from RTI. We give them the
7 release to ship the materials and ship directly
8 from RTI to the investigator.

9 Q Dr. El Sohly, I believe you previously
10 testified that you bid to obtain the award of this
11 contract in '99; is that correct?

12 A That's correct.

13 Q And was this bid published in the Federal
14 Register?

15 A Yes. Yes, it has.

16 Q Now, just generally speaking, you
17 previously testified that the contracts prior to
18 this were for what period of time?

19 A 1999 to 2004.

20 Q I'm sorry. The contracts previously in
21 '99 were for how long?

22 A For three years.

1 Q Were those contracts substantially similar
2 to the '99 and the current contract?

3 A Yes, they were. There were, you know, a
4 number of differences between the contracts and the
5 ones prior to 1999, but the basic function of the
6 contract requires the growing of the plant
7 material, the harvesting, the manufacturing of the
8 cigarettes, and all of this as basically the same
9 analysis of the confiscated materials. There are
10 some other additional aspects that were added to
11 the 1999 and the 2005 contracts.

12 Prior to 1999, there was actually two
13 separate contracts. There was--the University of
14 Mississippi has a contract to grow and do the
15 analysis and all the aspects and RTI had a totally
16 separate contract for the manufacture of the
17 cigarettes. So there were two separate contracts.
18 In 1999, the government decided that this should be
19 just one contract that involved the whole activity,
20 and we elected to subcontract that portion of the
21 manufacturing of the cigarettes to RTI since
22 they've been doing that for many years and they

1 have the expertise to do that. We figure they
2 would do a better job than we can. So together we
3 submitted one contract with RTI being our
4 subcontractor.

5 Q Dr. El Sohly, I'm going to now refer you
6 to the '99 contract as well as the current contract
7 and just ask you in general under both of these
8 contracts, are there requirements for growing
9 marijuana?

10 A Yes, sir.

11 Q And can you then give a little bit of
12 specifics on the growing of marijuana requirements,
13 what you do to grow the marijuana?

14 A Well, the growing of the plant material,
15 the government actually has several options
16 depending on the demand for materials. They have
17 an option for us to grow only one, one and a half
18 acres or six acres or twelve acres, basically the
19 whole garden. We have a 12-acre plot that is
20 secure and so on for production, and the government
21 has three different types of options depending on
22 how much they want us to grow.

1 So the first thing that has to happen is
2 the government will exercise that option, which
3 means they're going to have to put more money into
4 the contract just to do that activity. Once we get
5 the request to start the process, then we start the
6 production. We start the production from seed into
7 seedling. It goes to the field for growing them,
8 nourishing them, fertilizing them and so on,
9 cultivating them, until such time as the plants
10 mature, and then we start the harvesting process.
11 And there are some different types of ways that you
12 can cultivate the plant material to get the
13 different potencies as you are harvesting since the
14 contract really requires that you have the plant
15 material with different potencies. So we have to
16 be able to do that.

17 In the 1999 and the current contract,
18 there's the requirement for having high-potency
19 material, and when I say high potency, it means
20 more than three or four percent, and we have done
21 that in the contract, in the 1999 contract. We
22 have been able to harvest and have the stock and

1 supply of materials as high as 14 percent in bulk,
2 not just by selecting the harvesting of buds and
3 sensimilla and so on, but just in the general
4 production, we have materials ranging all the way
5 from one and a half percent to maybe 14 percent.

6 So this is the production process.

7 Q Now, Dr. El Sohly, I want to shift kind of
8 into the contractual, slash, registration process
9 in terms of the requirements for distributing
10 marijuana. So when the University of Mississippi
11 either in the '99 or current contract wants to
12 supply marijuana for researchers through NIDA, how
13 does that work?

14 A First, the researcher here, the University
15 of Mississippi, cannot ship materials to anyone
16 without going through NIDA. So sometimes some
17 investigator would send their full DEA-222, they
18 send it to us directly, which is really not the
19 way to do it. We then transfer that to NIDA and
20 get NIDA to approve it before we process it, but
21 the correct procedure is for the investigator to
22 send the DEA-222 to the National Institute on Drug

1 Abuse which then determines, yes, this investigator
2 should get the material. They sign the full--they
3 sign the back of the form and send it to us for
4 processing, and with approval, then we take it from
5 there. If it's for bulk material, then the
6 material is shipped from our inventory. If it's
7 for cigarettes, then they're shipped from the
8 inventory at RTI.

9 Q Then what does RTI do?

10 A Under the current and previous contract
11 from 1999 on, there are certain forms that have to
12 be filled out by the investigator, and those forms,
13 we have to receive those forms, and when we have
14 all the proper documentation, then we release the
15 shipment from RTI, which is shipped directly to the
16 investigators, and they have a certain procedure
17 that they follow to do that, including giving the
18 investigator some directions on how to handle the
19 material once they receive it and where to store it
20 and how to humidify it and all of the procedures.

21 Q Now, who actually makes the cigarettes to
22 supply to the researchers?

1 A RTI makes the cigarettes. We ship bulk
2 material in multiple kilos. So we ship to RTI.
3 RTI takes that material, processes it into the
4 manufacturing process all the way to making the
5 cigarettes, analyzes the cigarettes, certifies the
6 content of the cigarettes for the THC content and
7 moisture content and all of these aspects, and they
8 are stored at RTI in a freezer, and once they get
9 the order to ship, then they ship that material.

10 Q Dr. El Sohly, does the University of
11 Mississippi under your NIDA contract have occasion
12 to sometimes make its own cigarettes?

13 A We've only made really one batch of
14 cigarettes. I don't recall the date, but it was
15 certainly past '99, maybe 2002. To be honest, I'm
16 not sure when we made them, but we made that batch
17 because there was a request from CMCR, the Center
18 for Medical Research in California, in San Diego.
19 They had a request for eight percent cigarettes and
20 really needed it fast. We got the approval from
21 NIDA, you know, to do that. The conditions were
22 that RTI might need sometime to make this material.

1 So we made a small batch. I believe it was 500
2 cigarettes at that time. We made them in
3 Mississippi and then shipped them to RTI where they
4 could be distributed from there.

5 The reason that RTI did not make those in
6 a timely manner and we had to do this was that the
7 higher the potency is, the more difficult it is for
8 that plant material to go through the cigarette
9 manufacturing machine that RTI has. The cannabis
10 plant, as you might or might not know, is a very
11 resinous plant, and the higher potency, that means
12 you have more THC, more terpenes. The plant
13 material is very sticky, and it gums the machine
14 the higher the THC content. It makes the plant
15 material actually gum the machine and stop it. So
16 it's very difficult to do it with this
17 manufacturing.

18 So it has to hand done, and that what we
19 did at the time we made the eight percent batch.

20 Q Thank you, Dr. El Sohly. Now I'd like to
21 ask you what type or kind of researchers obtain
22 marijuana through the University of Mississippi,

1 either through you directly or indirectly through
2 RTI?

3 A Well, that marijuana that we ship to
4 investigators is used for a variety of reasons.
5 It's used for either animal work, preclinical
6 toxicology in doing animal research. It's used for
7 clinical work like all the materials that are
8 shipped CMCR and other investigators around the
9 country, using the clinical researchers. It's used
10 in chemical research. We use quite a bit at the
11 University of Mississippi and other people at
12 around the country that want to investigate the
13 chemistry or any aspects of the plant material. We
14 do that. We ship materials to them. Also, we use
15 it in some of the canine training facilities around
16 the country. They request materials from NIDA, and
17 so we ship materials to them for that purpose.

18 So all different types of research. Any
19 research that deals with marijuana, that comes from
20 our project. If in bulk, it comes from us.
21 Cigarettes come from RTI.

22 Q Dr. El Sohly, I would like to ask you, and

1 I'll ask the Court and the Respondent's counsel to
2 look at the Government Exhibit 12, which you've
3 identified as the '99 contract with NIDA, and
4 please turn to page 2. First of all, I'd like to
5 refer you to Section B(2)(a), and for purposes of
6 identification, it says there Article B(2), quote,
7 estimated cost, end quote, and then it gives some
8 figures under Subsection Small A. Do you see where
9 I'm at?

10 A Yes.

11 Q Can you tell us what this section relates
12 to?

13 A It just gives the final price of the
14 contract for--that was actually approved or awarded
15 for year one, year two, year three, year four, and
16 year five. There are some other marks underneath
17 which are not my marks, but I can say that the
18 first year means 1999 to 2000 and so on. Year two
19 would be 2000-2001 and so on and so forth.

20 So these are the prices, how much money
21 the contract bids, the basic contract, which is
22 non-grown. Now, if the government exercises the

1 option to grow in any of one of those years, they
2 have to add more funds to that amount to make up
3 for the cost incurred in the growing. Remember
4 that this is a cost reimbursement contract.

5 JUDGE BITTNER: So does the non-growing
6 mean everything except as you're cultivating the
7 marijuana?

8 THE WITNESS: That's correct.

9 JUDGE BITTNER: So that you would include
10 the testing, analysis, the providing materials?

11 THE WITNESS: Providing the materials,
12 research, the isolation of the components, the
13 paraquat analysis, all kinds of different
14 activities that are actually outlined in the
15 statement of work.

16 JUDGE BITTNER: So this was the
17 non-growing. That first part in Article B(2),
18 paragraph A, would also include providing
19 materials?

20 THE WITNESS: That's correct and also
21 re-analysis of the current stock, the inventory
22 that you have of the plant material, reanalysis of

1 each barrel that we have, which we have in excess
2 of a hundred barrels of different material that
3 have to be analyzed. We do all of this, every
4 study on the plant material and extracts, all this
5 is covered under the basic cost of the contract.

6 BY MR. BAYLY:

7 Q Now, Dr. El Sohly, I'd like you to refer
8 to the same page and drop down to Article B(2)(b)
9 where the subsection in all caps says growing. Do
10 you to see that?

11 A Yes.

12 Q Can you explain what this section means?

13 A This is now the growing. You have three
14 options. Option 1(a) grows one and a half acres.
15 Option 1(b) grows six and a half acres. And Option
16 1(c) grows 12 acres. So these are the different
17 options that the government has, and then the
18 table, Year 1, 2, 3, 4, and 5, for any point in
19 time that the government exercises any one of those
20 options, then that's the amount of money they'll
21 have to add to the contract to exercise that
22 option.

1 Q Now, Dr. El Sohly, I want you to jump down
2 to the next section under B(2)(b) where it says in
3 all caps, quote, manufacturing, end quote, and can
4 you explain to us what this section means?

5 A That's the second part. Remember we have
6 two parts as far as the plant material goes. We
7 have the growing, storing the plant material, and
8 then manufacturing of the cigarettes as a separate
9 item. The manufacturing, first, we have a lot of
10 cigarettes already are already manufactured. In
11 order for the government--if the government decides
12 to manufacturer new batches of cigarettes, they
13 have to exercise one of those options, 2(a), 2(b),
14 or 2(c). 2(a) is for exercising an option of
15 50,000--making a batch of 50,000 cigarettes of
16 placebo, and then Option B is 50,000 cigarettes of
17 low THC cigarette, and then Option 2(c) is for 50,
18 000 cigarettes of high potency materials.

19 So, again, the rest of the table shows the
20 amount of money that must be added to the contract
21 for the government exercise any of those options.

22 Q Dr. El Sohly, we see this term "THC" in

1 the contract, and that term appears throughout the
2 current contract as well.

3 A That's correct.

4 Q When we're using the term "THC", can you
5 specifically say what that stands for?

6 A That would be
7 delta-9-tetrahydrocannabinol, delta-9-THC.

8 Q Thank you. Now, we'll stick with same
9 page, but I want you to go back up to Article B(1),
10 towards the top of the page. Look at the second
11 paragraph. It starts, quote, in addition to
12 analysis of grown material, quote, analyses shall
13 be performed on approximately a hundred samples of
14 confiscated marijuana each month provided by the
15 Drug Enforcement Administration. Can you briefly
16 explain what this contract requirement requires you
17 as the director of U. Miss. to accomplish with
18 marijuana?

19 A This is the part of the contract that
20 requires the analysis of confiscated materials.
21 Most of the confiscated materials that come to
22 project for analysis comes from the DEA regional

1 laboratory. When there is a seizure made by the
2 DEA, part of the seizure, which is referred to as
3 the evidence, part of the evidence goes to the
4 regional lab for the area where the material was
5 seized for identification, to know that this is
6 marijuana, and the court case will go through.

7 Part of that material, the sample, that
8 goes to the lab for analysis of the evidence is
9 shipped to us, to the University of Mississippi, so
10 that we can the potency analysis. The DEA labs do
11 the identification, but they don't get involved in
12 actually determining the potency of the plant
13 material. This is done at the University of
14 Mississippi, and the contract requires that we
15 analyze a hundred samples of this confiscated
16 materials every month.

17 In addition--

18 Q Excuse me. Dr. El Sohly, did the
19 University of Mississippi under the '99 contract
20 actually make the analysis of samples?

21 A Yes.

22 Q Roughly, ballpark figure, how many under

1 the '99 contract?

2 A Well, the contract actually requires a
3 hundred samples per month, but it is really very
4 difficult to--when the number of samples exceeds
5 that, you know, we talk to NIDA about adding more
6 money to the amount of material if it becomes more
7 than that, but they basically said, well, the
8 contract requires a hundred samples, so if you make
9 a selection and just do a hundred samples, that's a
10 representative sample of what is confiscated. The
11 purpose of that is to have some idea of the level
12 of THC in the material that is being distributed in
13 the illicit market, but I personally felt the
14 obligation that we should analyze every sample that
15 comes through regardless of the number of samples.

16 Over the years, we have done--I don't
17 think there was any research in the recent past
18 that I remember that only did a hundred samples a
19 month. I think the average was probably somewhere
20 between 2,000 to 4,000 samples a year, in that
21 range. So not only we get the samples from the DEA
22 labs, but we also get samples from the State

1 narcotic agents. About 30, 33 percent of the
2 samples that we receive actually come from the
3 different States, and I felt that if we are going
4 to have a good estimate of what the potency of the
5 material on the illicit is, that we would analyze
6 as many samples as we can, and all the samples of
7 THC, and that's exactly what we do. So the number
8 of samples we do is roughly around two to four
9 thousand per year.

10 Q Well, Dr. El Sohly, you said you've, made
11 this number of analyses in the recent past. Can
12 you estimate what you mean by that? How many years
13 do you go back?

14 A I'd say at least 10 years.

15 Q All right. And is this requirement that
16 we're talking about, to analyze samples of
17 confiscated marijuana, is that in the current
18 contract as well?

19 A Yes, sir, it is, the same number.

20 Q All right. Do you, in fact, make as many
21 sample analyses under the current contract as you
22 did in the '99 contract?

1 A Well, of course, the new contract just
2 started in March. So the samples for 2005 are not
3 totally in yet. It will probably be April of 2006
4 or May 2006 before we get all the 2005 samples in.
5 So it's premature to tell, but just looking at the
6 history and what we have done before, I don't see
7 why we shouldn't be getting about the same as we
8 had before, in that range.

9 Q All right. Dr. El Sohly, now I want to
10 move on to a slightly different topic here and ask
11 you, first of all, in the context of your work with
12 the University of Mississippi and the marijuana,
13 what is a placebo?

14 A A placebo is--when you say a placebo, this
15 will be a placebo tablet, and you're supposed to
16 have--you know, if you're testing morphine, say for
17 the activity of morphine, but you want to know
18 whether the activity that you're seeing, you know,
19 with this tablet is because of the morphine or
20 because the subject thinks that they're getting
21 morphine, so they feel better, that's called a
22 placebo effect, meaning there's no drug actually in

1 it. The placebo for marijuana is plant material
2 that has no THC, so that when you're doing a study,
3 then you're comparing the effect of just smoking
4 something that really doesn't have any THC in it
5 versus plant material that actually has THC, and if
6 you see a difference, then the difference is not
7 because of the psychological thing, that the person
8 thinks they're getting, you know, so they report
9 certain effects, but actually because of the drug.
10 So the placebo for marijuana is marijuana that has
11 no THC.

12 Q Now, under the '99 contract as well as the
13 current contract, Dr. El Sohly, as director of U.
14 Miss., are you involved in producing material for
15 placebo marijuana?

16 A Yes, we are.

17 Q And can you tell us, first of all, if
18 those are made into cigarettes or provided in bulk,
19 or how does that work?

20 A I believe all the placebo at this point is
21 actually in the form of cigarettes.

22 Q I'm sorry?

1 A In cigarettes, placebo cigarettes. So
2 they're cigarettes rolled, the same kind of paper,
3 the same length, same weight, same everything
4 except that the plant material inside those
5 cigarettes has no cannabinoids.

6 Q And who actual makes the placebo
7 cigarettes themselves? Is that you?

8 A That's RTI. They're part of the--if you
9 remember back to Article B(2) under manufacturing,
10 that manufacturing part is the subcontractor, RTI,
11 and the placebo is part of that. So all the
12 placebo cigarettes are made at RTI.

13 Q Dr. El Sohly, are you aware of how the
14 placebo cigarettes are used by the researchers?

15 A The placebo cigarettes are used in a
16 randomize design that investigators would have to
17 make sure that the activities that they see is
18 because of the active drug, not because of the
19 placebo effect, so that the subjects would never
20 know what they're getting, only the investigators.
21 The study would be designed in such a way that one
22 time the person would be getting the placebo,

1 another time getting the low THC material, and
2 another time getting the high THC cigarette, and
3 they rotate so they never know what they're getting
4 at any point in time. It's only at the end of the
5 study when they break the code that they know when
6 the person reported such and such activity that
7 they were actually getting this material or that
8 material and so on.

9 So that's the way that the study design
10 is, is such that you can really tell that the high
11 effects were caused by the high potency or the low
12 effect was because of the placebo, or if you get a
13 high effect because of the placebo, then there is
14 no difference between the placebo and the drug,
15 and, therefore, you're saying, well, that drug
16 doesn't seem to be doing anything because it's just
17 getting the same thing as the placebo. So that's
18 how the placebo is used.

19 MS. CARPENTER: Your Honor, just a point
20 of clarification here. I think Dr. El Sohly has
21 been tendered as an expert in cultivation and
22 research. It just occurs to me that I want to be

1 clear that it's analytical research and not medical
2 research, and I think we're getting into some
3 medical testimony. If they plan to go much
4 further, I'd like to voir dire him on his expertise
5 in terms of medical research; but if that is as far
6 as we're going, that's fine.

7 JUDGE BITTNER: Mr. Bayly?

8 MR. BAYLY: The line between medical and
9 analytical is pretty fuzzy to me or pretty fine,
10 but I think at this point, we should be okay.

11 JUDGE BITTNER: I think we're okay so far.
12 So I think--

13 MS. CARPENTER: I just want to be clear
14 for the record. Has he been tendered as a expert
15 in medical research or is he tendered as an expert
16 in analytical research?

17 MR. BAYLY: Well, the record just--I
18 tendered him, I believe, in research. The witness
19 has testified that the marijuana through the
20 University of Mississippi has been provided both
21 to--well, a variety of researchers, both clinicians
22 and non-clinicians. So to that extent, I think

1 that the witness is certainly well qualified to
2 testify about the marijuana in terms of placebo,
3 for that matter, in terms of how they're used by
4 researchers, whether they're clinical or
5 nonclinical.

6 That being said, I would agree that the
7 witness shouldn't be talking about whether certain
8 marijuana research tests are going to result or not
9 result in a medical product. I don't think that
10 Dr. El Sohly has even implied or insinuated such
11 testimony. I don't anticipate that he will.

12 JUDGE BITTNER: Okay. I think, though,
13 the question from Ms. Carpenter is in terms of Dr.
14 El Sohly testifying as an expert. He's testifying
15 as an expert with respect to research on analytical
16 research, i.e., what is in a marijuana plant and
17 how you ascertain what's in it and so on.

18 Is that correct, Mr. Bayly?

19 MR. BAYLY: Well, yes, with the caveat
20 that it's analytical research. It's analytical
21 research that can lead to the researchers
22 developing a medical product or perhaps showing the

1 harm of the marijuana or any number or variety of
2 results.

3 THE WITNESS: Your Honor, may I say
4 something?

5 JUDGE BITTNER: Not yet.

6 MS. CARPENTER: But that expertise is not
7 Dr. El Sohly's, how those medical researchers use
8 it and what results it can lead to. I just want to
9 make it clear that with regard to the fact that he
10 provided the marijuana to researchers, he does not,
11 as I understand it at least, have expertise in that
12 medical research that is done with the marijuana
13 after it leaves his facility.

14 JUDGE BITTNER: At least so far, I'm not
15 considering him an expert on those subjects. Now,
16 if we get into it, then we'll have to ascertain.

17 MS. CARPENTER: Okay.

18 MR. BAYLY: We're not advocating that Dr.
19 El Sohly is going to be an expert on medical
20 research that can result from any experiments or
21 use of marijuana.

22 JUDGE BITTNER: Okay.

1 MS. CARPENTER: Thank you.

2 JUDGE BITTNER: Go ahead, Mr. Bayly.

3 BY MR. BAYLY:

4 Q Dr. El Sohly, do both the '99 contract and
5 the current contract call for the extraction of
6 marijuana?

7 A Yes, they do.

8 Q I believe you've already previously
9 explained what extraction entails.

10 A Yes, I have.

11 Q Now, do both contracts--well, I think it's
12 going to be a little bit easier for me to ask you
13 this question in the context of Government Exhibit
14 12 here, and now I want you to turn, please, to
15 page 6, and I want to refer you, Dr. El Sohly, to
16 the very bottom, the last couple lines of that page
17 which indicates, quote, develop new methods for
18 growing marijuana that contain very low
19 concentrations of delta-9-THC, making placebo
20 cigarettes. Is that provision in the current
21 contract as well?

22 A Yes.

1 Q And can you explain a little bit what it
2 means by developing a variety of very low
3 concentrations?

4 A As I mentioned before when we talked about
5 placebo, placebo is plant material that has no THC.
6 The current way of preparing placebo is to take
7 active marijuana and then extract the THC and all
8 other cannabinoids out of the plant material. So
9 only leave the plant parts, but no cannabinoids, no
10 other components of the plant. This material
11 usually because of the extraction process is pretty
12 dry, doesn't really have the smell of the cannabis
13 plant and so on, and, therefore, experienced
14 marijuana smokers could probably tell that they're
15 getting the placebo. Even though they don't know
16 for sure that it's a placebo, they know that this
17 thing really doesn't taste like marijuana, so maybe
18 this is placebo.

19 Therefore, the idea here is to develop a
20 variety of the cannabis plant that has almost no
21 cannabiniol, but has all the other components, the
22 terpenes, all the hydrocarbons, all the other

1 things in there, but not the THC, and that's the
2 reason for this particular part of the contract,
3 and we have actually done that. It hasn't gotten
4 into full production, but we have the varieties
5 that we can grow to do this as soon as we have the
6 government exercise that option.

7 Q Now, Dr. El Sohly, I'm going to turn to a
8 slightly different topic and ask you if you are
9 aware or know of what is sensimilla marijuana, and
10 I think I'll ask you, please, to first spell that
11 term for the record.

12 A Sensimilla is S-E-N-S-I-M-I-L-L-A,
13 sensimilla. It's a word that means, a Spanish word
14 that means no seeds. It means plant material that
15 has no seeds.

16 The cannabis plant is what we call a
17 dioceous plant. It means that it has male and
18 female plants separate from other one another,
19 although there are plants that we have seen over
20 the years that are what we call hermaphrodites
21 where they have both male flowers and female
22 flowers on the same plant, but the majority and the

1 common cannabis plants are dioceous.

2 JUDGE BITTNER: How do you spell dioceous.

3 THE WITNESS: D-I-O-C-E-O-U-S.

4 So when you grow from seeds, you put the
5 seeds in the ground and those seeds come up, half,
6 approximately half, of those seeds will produce
7 male plants, and the other half will produce female
8 plants, and there is really no way to tell from the
9 beginning which seed will produce a male and which
10 seed will produce a female. Generally speaking,
11 it's approximately 50-50 in terms of the population
12 of the plants.

13 The female plants are the ones that are
14 actually defined in the old pharmacopeia as being
15 the plants that are used to make marijuana as the
16 medical plant that was in the pharmacopeia used
17 before 1937. In any case, those, the female
18 plants, the female flowers, will have the part of
19 the female flower, the ovary, and then the stiles
20 and the stigmas, and these have to be fertilized.
21 For the seeds to produce, they have to be
22 fertilized by the pollen that is generated by the

1 male plants. Once that flower is fertilized, then
2 it goes through the development process, and that
3 female flower now will have a seed inside. That
4 component becomes the seed.

5 Now, if you can remove all the male plants
6 so that there is no chance for those female flowers
7 to be fertilized, then the plant keeps producing
8 just the male flowers, but really no seeds are
9 produced. This is a variety that's called
10 sensimilla. It's a way of cultivating the plant.

11 Of course, another way of doing that is
12 not just to grow and remove all the male plants,
13 which is very difficult to do, as we have
14 experienced in our own garden, is to do it, to grow
15 it through the vegetative propagation process where
16 you have a female plant and you take that female
17 plant and you cut from that and you root those
18 cuttings and produce new plants, and new plants
19 become all female plants with the same genetic
20 material as the mother plant.

21 So answer your question in a short way,
22 sensimilla just means a female flower, plants that

1 have female flowers that those flowers have not
2 been fertilized.

3 Q Dr. El Sohly, under the NIDA contracts
4 both for the '99 and the current, are you allowed
5 to produce the sensimilla marijuana?

6 A Yes. If the government needs it, there is
7 a need for it, we certainly can do that.

8 Q Have you actually done so?

9 A Yeah. We have done quite a bit in that
10 area. Yes, we have.

11 Q I'd like you to take Government Exhibit
12 13--I think it's underneath 12 up there.

13 JUDGE BITTNER: Could I ask before we go
14 there what's the purpose of producing--do you refer
15 to sensimilla as a plant, or is it the product from
16 the plant, first of all?

17 THE WITNESS: Well, the product
18 is--marijuana is classified as, you know, so many
19 different types. You have loose marijuana, which
20 is just everything loose. You have buds when you
21 actually take the flowering buds of the female
22 plants that have seeds that are fertilized and so

1 on, and then you have buds that have not been
2 fertilized, and these are called the sensimilla.

3 JUDGE BITTNER: Okay. But not the plant;
4 you don't refer to a sensimilla plant; you refer to
5 a sensimilla bud?

6 THE WITNESS: Right. It's really not a
7 product until it's harvested. When it's growing,
8 you don't know at some point in time it will be
9 fertilized.

10 JUDGE BITTNER: So why would you want
11 sensimilla?

12 THE WITNESS: Your Honor, the female
13 flowers, they come into an inflorescence, almost
14 more or less like a grape bunch. Each one of those
15 grapes in there, it used to be a flower that
16 produced that grape. It's the exact same thing
17 with the marijuana plant. The inflorescence that
18 has all those different complex flowering system
19 that makes the inflorescence, each one of those
20 flowers there in there, in the cannabis plant, has
21 the ovaries protected by a little leafy structure
22 called the brach. That brach has the highest THC

1 content in the plant. As you take the cannabis
2 plant from the outside going in, the THC content is
3 higher and higher and higher and higher. The end
4 of that brach is the highest THC.

5 JUDGE BITTNER: So if you have a brach
6 with no seeds, it's a higher THC content?

7 THE WITNESS: A higher THC content. So
8 you produce sensimilla to increase the potency of
9 the product. So you can get the sensimilla if you
10 remove all of the large leaves around that
11 sensimilla bud, if you will. If you remove all the
12 leave and only leave those brachs in there, you
13 have the plant material for a product that is, you
14 know, depending on the variety and the cultivar and
15 so on, you can have material that is 15, 18, 20, 24
16 percent or more THC.

17 JUDGE BITTNER: Thank you.

18 BY MR. BAYLY:

19 Q Dr. El Sohly, first of all, I ask you to
20 look at Government Exhibit 13, and just please
21 identify what this is, the exhibit is generally.

22 A This is, again, the contract award that

1 was effective March 16th of 2005.

2 Q Between? Who are the parties now?

3 A Between the National Institute on Drug
4 Abuse and the University of Mississippi.

5 Q And is this contract awarded in the same
6 way and method as the 1999 contract was awarded to
7 the University of Mississippi?

8 A That's correct.

9 Q Now I'd like to ask you to please turn to
10 page 6 of this exhibit, and we're at Section
11 B(1)(b). It starts perform triplicate analysis of
12 the sampling. Do you see that?

13 A Yes.

14 Q Would you please explain to us, Dr. El
15 Sohly, what is meant by triplicate analysis of a
16 sampling of each harvest?

17 A This is the--triplicate analysis means
18 that you analyze three different samples from the
19 same material so that you can get an average of the
20 analytical data. In this case, if the THC is the
21 one that we are focusing on, then doing three
22 different analyses on the same plant material would

1 just give you a more firm figure as to what the
2 potency of this plant material is. So triplicate
3 means you do it three times.

4 Q Then I would ask you, please, to turn to
5 page 7 of this same exhibit, and this would be
6 under subparagraph four on page 7. It starts out,
7 quote, develop and produce standardized marijuana
8 cigarettes with a range of specified THC content.
9 Do see where I am?

10 A Yes.

11 Q Can you give us a little more detail and
12 explain what the function is in this provision?

13 A Our function--of course, everything here
14 is our function, but we subcontract a portion of
15 that function. We prepare the raw material that is
16 used for manufacturing the cigarettes at the
17 University of Mississippi. We ship that raw
18 material to Research Target Institute in North
19 Carolina where they actually manufacture the
20 cigarettes. So the requirement here is to have
21 plant material with different THC contents so that
22 they can prepare cigarettes of different potencies.

1 The preparation of the cigarettes is, again,
2 carried out at RTI.

3 JUDGE BITTNER: Doctor, do you to achieve
4 a certain potency in the finished cigarette?

5 THE WITNESS: Yes, Your Honor.

6 JUDGE BITTNER: Do you mix various potency
7 levels of marijuana, or do you--I'm showing my
8 ignorance here, I'm afraid.

9 THE WITNESS: I understand. I understand
10 your question. The answer is yes. We have--as I
11 indicated, for the same plant, take just one plant,
12 and depending what part of the plant you have to
13 harvest, the large leaves, the small leaves, the
14 medium leaves and so on, or just the buds, you're
15 going to get a different potency even with the same
16 plant, and if you harvest that plant material
17 before it's fully matured, even if you have the
18 buds, it's still not going to be high potency. To
19 get the high potency, you have to really wait until
20 you get to the final end result of the maturation
21 process of the female flowers before you get the
22 highest THC content that that plant is capable of

1 producing.

2 So you can different potencies either by
3 harvesting early to get a lower potency, waiting
4 until it is fully matured and harvest only the buds
5 to get the real high potencies, or somewhere in
6 between. You have the whole entire plant, leaves
7 and buds and all of everything together. When you
8 mix it together, the one and a half percent of the
9 leaves, ten percent of the buds, all this mixed
10 together will maybe give you something like six
11 percent or five percent of seven percent. It just
12 depends.

13 Now, the harvest comes out in different
14 batches. Each batch is approximately 20 kilos. If
15 you analyze that batch, one batch might be two
16 percent. One batch might be four percent. One
17 might be six percent. One might be twelve percent.
18 One might be fourteen percent. In the
19 manufacturing process at RTI, if the buyer decides
20 they want to have cigarettes, a batch of
21 cigarettes, let's say at six percent, we know from
22 experience that the manufacturing process loses

1 some potency simply because the THC is contained in
2 very fine structures in the plant material known as
3 the granular hairs. These are just hairs, and
4 those hairs are very fine and very small. During
5 the processing and so on and so forth in making the
6 cigarettes, some of this material actually gets
7 sifted away so that the final product that goes
8 through would have a lower potency than the plant
9 material that we analyzed to start with.

10 So if you want the six percent cigarettes,
11 we need to provide plant material of approximately
12 maybe seven percent or seven and a half percent so
13 that when they go through the process of the
14 cigarettes, it will come out at approximately six
15 percent.

16 Now, if we don't have material exactly at
17 seven, seven and a half percent, we will have some
18 material from five percent, some from ten percent,
19 some from eleven percent, some from nine percent to
20 make a big batch and then combine this, and then
21 when it goes through the manufacturing process,
22 there is a mixing process that will modulate the

1 plant material so that all is the same that goes
2 into the cigarette-making machine.

3 JUDGE BITTNER: So there's two different
4 ways to achieve a potency?

5 THE WITNESS: That's correct.

6 JUDGE BITTNER: One is to provide material
7 that is all the same, and the other is to mix up
8 material?

9 THE WITNESS: That is right.

10 JUDGE BITTNER: And do you do that or does
11 RTI?

12 THE WITNESS: The mixing happens before
13 the manufacturing.

14 JUDGE BITTNER: Okay.

15 THE WITNESS: When we send them the
16 material, we know what the analysis is. They get
17 it. They analyze it again to make sure. Also, we
18 have to accommodate for--the plant material when we
19 harvest it is dried and so on to prevent it from
20 molding or any problems like that. We dry it and
21 are trying to get less than 10 percent moisture,
22 usually somewhere between six and eight percent,

1 but certainly no more than 10, and that's pretty
2 dry to be put into a cigarette. If it's too dry,
3 it's usually crushed in a machine and it becomes
4 very fine, and they don't make good cigarettes.

5 So at RTI, they actually have to humidify
6 the bulk plant material before they put them into
7 the cigarette-making process. Now, to add humidity
8 means that you're adding some moisture to the plant
9 material. That actually loses some of the THC
10 content. So that also has to be accommodated for
11 in terms of the potency of the material you are
12 providing to RTI.

13 All this happens right at the time the
14 batch is being manufactured.

15 JUDGE BITTNER: Thank you.

16 BY MR. BAYLY:

17 Q Dr. El Sohly, when you're talking about
18 THC content and potency, again for the record, THC
19 would mean what?

20 A Tetrahydrocannabinol, Level 9.

21 Q Now, referring back to this same
22 subparagraph that you testified about it, it talks

1 about developing the standardized marijuana
2 cigarettes within a specified THC content, placebos
3 for use in preclinical and clinical research
4 programs. Can you tell us the distinction or what
5 is meant by preclinical versus clinical research
6 programs?

7 A The preclinical is basically all the work
8 that you do before you take the drug into humans.
9 That could be the chemical analysis. That could
10 be, you know, the formulation. That could be
11 animal toxicology, animal pharmacology, all this
12 work that's done prior to saying, okay, now we're
13 ready to take this drug to humans. It's
14 preclinical work. The clinical is actually what
15 you do in the clinic with humans. So clinical
16 studies means human studies.

17 Q Okay. Now, Dr. El Sohly, what range of
18 THC content have you, that is the University of
19 Mississippi, produced to date for, first of all,
20 cigarettes?

21 A For cigarettes, we have produced anywhere
22 from placebo, of course, to the highest content we

1 made was eight percent.

2 Q And what range of THC content have you
3 produced to date for bulk marijuana?

4 A For bulk marijuana, we have material as
5 high as--I believe in our inventory today, as high
6 as 14 percent, 13, 14 percent, something like that.

7 Q Based upon your knowledge of the
8 University of Mississippi production capability,
9 are you able to testify to the maximum percent of
10 THC content level that the University of
11 Mississippi is capable of producing?

12 A Well, I can tell you that we can produce
13 any potency that is required. I wouldn't say
14 produce it in hundreds or thousands of kilos like w
15 can produce now, but we can certainly produce as
16 high as 20 percent or higher on a small scale; but
17 we do have bulk material in tens and tens and tens
18 of kilos, plant material of about ten percent, nine
19 percent, eight percent, eleven percent. We have
20 the material.

21 So in bulk, meaning growing outdoors in
22 the field, we have the capability of getting in

1 bulk more than ten percent.

2 Now, I have to explain to Your Honor about
3 why we do it the way we do it, and also, you know,
4 there is a reason why we're not making those
5 materials that extremely high potency in bulk. We
6 can produce any amount in a small scale that need
7 be. That's not a problem. We can selectively
8 harvest materials with any THC content. That's no
9 problem. We can even produce sensimilla outdoors
10 if need be on a small scale. That's, again, no
11 problem. The reason we haven't done that on a
12 large scale is, first of all, it's not needed.
13 There was no request for such high potency
14 material, and I have to also even tell you that the
15 higher the potency is, that means it's really very
16 fine material that is very difficult, as I
17 indicated before, to roll using the
18 cigarette-making machine. So you have to do it all
19 by hand.

20 I have expressed to NIDA and to some of
21 the investigators that if they want to, they can
22 order material of a certain potency. They can roll

1 their own cigarettes. They can get it in bulk and
2 roll their own cigarettes, simply because the
3 highest potency is in the fine material. The fine
4 material is not easy to make cigarettes from. If
5 you just think about tobacco, tobacco are leaves.
6 You can cut tobacco, shred the tobacco leaves and
7 make it fine so they stick together in a way that
8 makes the rolling process of cigarettes a very easy
9 thing.

10 With marijuana, marijuana is a leafy
11 structure just like mint. If you dry mint and you
12 crush it and it's broken pieces, and if those are
13 not of a certain size, you can't roll a cigarette.
14 If it's finer, you can't roll a cigarette out of
15 that.

16 JUDGE BITTNER: Obviously if I knew a
17 great deal about marijuana, I probably wouldn't be
18 working here. Marijuana is an annual?

19 THE WITNESS: Yes, ma'am.

20 JUDGE BITTNER: What is the length of time
21 from seed to maturity?

22 THE WITNESS: Well, it depends on where

1 you are in the country. In Mississippi, it's
2 somewhere from--you plant about mid-April and it
3 goes all the way depending on the variety. Some
4 varieties are earlier maturing, varieties that will
5 be done by September. Some are not done until
6 October, and some, November comes and goes and
7 they're still not fully mature depending on where
8 the original seeds are coming from that are not too
9 mature yet. So there's a variety, but basically
10 the from the spring to the fall.

11 JUDGE BITTNER: And they're sensitive to
12 frost?

13 THE WITNESS: Light frost is okay. It
14 really don't--you know, frost will not get to the
15 plant unless it goes below 25 degrees. So 32, 33,
16 now you have frost, but it might burn a little bit
17 the tips of the leaves, but it doesn't kill the
18 plant.

19 JUDGE BITTNER: Okay. Go ahead, Mr.
20 Bayly.

21 By MR. BAYLY:

22 Q Dr. El Sohly, you have used the term

1 "kilos" several times in your testimony. Kilos
2 means what?

3 A Kilogram, a thousand grams. 2.25 pounds
4 is a kilo.

5 Q I want you to turn to page 7 of Government
6 Exhibit 13, and if you would go down to paragraph
7 9, quote, provide adequate DEA-approved storage
8 facility for storing marijuana cigarettes and other
9 cannabinoids. Do you see that paragraph?

10 A Yes.

11 Q And what is the purpose of storage? Can
12 you explain the storage requirements as it pertains
13 to storing marijuana?

14 A There's really two requirements here.
15 First, the storage is in a secured place. You have
16 to have a vault to secure the plant material,
17 meaning to prevent diversion or prevent theft. So
18 you have to put vault in place, and we at the
19 University of Mississippi, we have actual two vaults
20 that are constructed according to the guidance and
21 regulations that are authenticated of the DEA. As
22 a matter of fact, the DEA has to come and inspect

1 every stage of the building of the vault and all of
2 that. Plus the vault has to be secured, and it has
3 to have, you know, an alarm system and so on.

4 So the storage requirement in a secure
5 place is one thing. The other thing is the storage
6 requirement to have a low temperature storage,
7 minus 20 degrees or below. That requirement to be
8 protect the plant material and the THC from
9 degradation over time of storage.

10 So those are the requirements, and we have
11 this at the University of Mississippi, and RTI in
12 North Carolina, they have the same thing. They
13 have the big vault and they freezers inside the
14 vault. We have a walk-in freezer and chest
15 freezers and upright freezers in our vault, and so
16 does RTI.

17 Q Then I just want you to drop down to
18 paragraph 10. It starts out provide appropriate
19 information to assist NIDA in the project in
20 writing and preparing the drug master file, DMF,
21 and related submissions to FDA, if needed. Can you
22 explain to what a drug master file is?

1 A A drug master file is a document that is
2 submitted to the FDA that describes all of the
3 processes, procedures, qualifications, validations,
4 analytical data, manufacturing process, and so on
5 for the product that you are submitting the DMF
6 for. In this case, it's for marijuana. So it will
7 have--the DMF will have the, you know, growing
8 process, the cultivation process, the harvesting
9 process, the drying process, the de-seeding
10 process, the analytical process, validation of that
11 analytical process, validation of all of the
12 equipment that you are using in that process,
13 qualifications of the individual, quality control
14 procedures, quality assurance procedures, stability
15 studies on the product, that you have all this
16 information as part of the drug master file that is
17 submitted to the FDA.

18 That drug master file that is currently in
19 place for our product is actually submitted by
20 NIDA. It's not submitted by the University of
21 Mississippi or RTI. It's submitted by NIDA. NIDA
22 is holder or the owner of the drug master file, and

1 NIDA is the agency that would allow the reference
2 of that drug master file by anyone that wants to
3 reference that drug master file when they use that
4 plant material that is produced by this process at
5 these facilities. If you have to have, you know,
6 another manufacturer doing the same thing, they
7 have to have their own drug master file. So that
8 drug master file is very specific to that product.

9 Q All right. Now, Dr. El Sohly, I want to
10 ask you to drop down to paragraph 11 of the same
11 page of Government Exhibit 13. It starts out,
12 quote, carry out stability studies on bulk
13 materials, paren, harvested and stored cannabis and
14 related materials, closed paren. Do you see that?

15 A Yes.

16 Q What is the purpose of stability tests?

17 A Again, as I indicated, you have--you make
18 the product. That product, if it's not going to be
19 consumed soon after it's manufactured, it will be
20 stored. It might be stored under different
21 temperatures, and you have to have some idea about
22 the stability of that product under these storage

1 conditions. So as I also mentioned before, the THC
2 content drops down as the temperature goes up. So
3 if you store it in the freezer, it is expected, but
4 not necessarily a hundred percent unless you do the
5 work, that it would stay stable longer than if you
6 put it in the refrigerator and if you put it in
7 room temperature.

8 So you have to generate the data to
9 support any claim of the stability of the product
10 in any given storage condition.

11 Q Does U. Miss. perform such tests on the
12 cigarettes?

13 A We perform such tests on the bulk plant
14 material, different potencies of the plant material
15 that we have in place. We have performed some on
16 the cigarettes that we have in place, but the bulk
17 of the stability on the cigarettes is carried out
18 at RTI because they do have the cigarettes in their
19 storage facility, and they carry out the stability
20 because every time they ship the product, they have
21 to put down what the last analysis that they had on
22 the product is.

1 Q Now, Dr. El Sohly, could you explain to us
2 how U. Miss. charges the researchers for the
3 marijuana it supplies to them? How is this cost
4 covered fore any marijuana supplied to researchers?

5 A Well, it really depends on the researcher
6 and on the process that the researcher goes
7 through. Most of the material that we produce, the
8 researchers don't pay anything for it. If the
9 material is provided to a research group that has
10 NIH funding, that project has been fund by NIH.
11 Then they get the material free of charge. If it
12 goes from NIDA to NIH, they get it free of charge.
13 There is no charge for it.

14 But starting with contract that started in
15 '99, there was a provision there that if there is a
16 research protocol has been submitted NIDA and has
17 not gotten the federal funding, but yet it has been
18 approved by the bio--I can't remember the name of
19 the board, but there is a research board at NIH
20 that reviews the proposals. If the protocol is
21 approved by this group, but it's not funded, then
22 they have the option of actually doing the work and

1 getting materials from NIDA, but they have to pay
2 for that material just like they would pay for any
3 other supply or chemical or something that is used
4 in the research.

5 Q Dr. El Sohly, who sets the price under
6 these circumstances?

7 A The NIDA contracting officer actually sets
8 the price. We have not been involved in
9 any--putting prices on any of these products.

10 Q Do you make any kind of profit on the sale
11 of marijuana?

12 A No. Actually, when we provide materials
13 to researchers and those researchers pay for that
14 material, that money that we receive--and it does
15 actually come to the University of
16 Mississippi--that material that comes to the
17 university is deducted from the money that we would
18 have otherwise gotten from NIDA. So it doesn't
19 really change the price of the contract.

20 Q Dr. El Sohly, you have mentioned the CMCR
21 research group previously in your testimony. Do
22 you recall that?

1 A Yes.

2 Q And are they under--in terms of those
3 researchers paying for marijuana through the NIDA
4 contract, do they pay in the manner that you just
5 described?

6 A Yes, they do.

7 Q Now, if you would turn to Government
8 Exhibit 13--I guess you still have that there--I
9 think I'd like you to turn the page over to 47.
10 It's the signature page at the top.

11 A Yes.

12 Q Can you tell us who the signatories are on
13 this page and what their roll is in the contract?

14 A These are the signatories that
15 actually--were the signatures that a binding to
16 both agencies. The first signature is Dr. Alice
17 Clark. She is the Vice Chancellor of Research and
18 Sponsor Programs at the University of Mississippi.
19 She is the one that can bind the university. I
20 cannot bind the university on the contract. I do
21 the work, but I don't bind them. She does. And on
22 behalf of NIDA, Mr. Kenneth Goodling. He is the

1 contracting officer and the one that is signing on
2 behalf of the government.

3 Q Now I'd like you to flip back to Exhibit
4 12 and ask you to turn to page 52.

5 A Okay.

6 Q Can you tell me us what that page entails?

7 A This is, again, the signatory page, and on
8 behalf of the University of Mississippi at that
9 time, Dr. Ronald Borne was Interim Vice Chancellor
10 of Research, and he signed for the university, and
11 again, Mr. Kenneth Goodling, the contracting
12 officer signed on behalf of the government.

13 MR. BAYLY: Your Honor, I'd like to at
14 this time move into evidence Government Exhibits 12
15 and 13.

16 MS. CARPENTER: No objection, Your Honor.

17 JUDGE BITTNER: Received.

18 [Government Exhibits 12 and 13
19 were received in evidence.]

20 MR. BAYLY: And, Your Honor, I'd like to
21 now present the witness with Government Exhibit 15
22 marked for identification. That has not been moved

1 into evidence yet.

2 JUDGE BITTNER: Okay.

3 MR. BAYLY: Maybe it has.

4 JUDGE BITTNER: No. You have it. You
5 have the original, Mr. Bayly. You have what we're
6 using as the original.

7 MR. BAYLY: May I approach the witness?

8 JUDGE BITTNER: You certainly may.

9 MR. BAYLY: Thank you.

10 BY MR. BAYLY:

11 Q Now, Dr. El Sohly, I'm giving you what has
12 been marked as Government Exhibit 15. Can you tell
13 us what this document is?

14 A This is the request for proposal that was
15 advertised back in 1999.

16 Q And did you submit a bid for this
17 proposal?

18 A Yes, sir.

19 Q And, roughly, about when did you submit
20 this bid for this NIDA contract?

21 A Well, this bid had a July 29th due date.
22 So we submitted a few days before that, certainly

1 before the 29th of July.

2 Q All right.

3 A I can dig in my documents here and find
4 out the exact date if it's important, but it's just
5 a few days before. Usually this is a very lengthy
6 process. It's a huge document that we submit, and
7 it takes an enormous amount of time to prepare. So
8 we--I know we didn't submit it one week after the
9 came out. I know we submitted it just barely
10 making the deadline.

11 Q At this time, I won't be any more
12 specific. I don't think we need to be. At any
13 rate, is Government Exhibit 12 the result of your
14 submitting the bid pursuant to Government Exhibit
15 15?

16 A Yes, sir, it is.

17 Q Did you receive a similar bid prior to
18 being awarded the current contract in 2005?

19 A Yes.

20 Q And did you see a similar advertisement as
21 is denoted in Government Exhibit 15 for the current
22 contract which is Government Exhibit 13?

1 A Yes, sir. It was around the same
2 timeframe in the year. It was July of 2004. When
3 the RFP came out, it was July of 2004.

4 Q Is that the time you put in your bid for
5 the current contract?

6 A We put the bid in before the due date for
7 the contract, but the advertisement, I believe came
8 out around sometime in July.

9 Q All right. Based upon that bid, were you
10 awarded the current contract for 2005 in Government
11 Exhibit 13?

12 A Yes. We submitted--I just happened to
13 have this handy. We submitted the request for--the
14 RFP in September 14th of 2004. The due date was
15 September 16th. So, again, we were just--we
16 executed in on the 14th and submitted it on the
17 15th for a 16th deadline.

18 MS. CARPENTER: Your Honor, if I may, I
19 don't know if the witness is looking at something
20 that the Court has not seen. I don't think I've
21 seen it.

22 THE WITNESS: It's just a note for myself

1 on the date.

2 MR. BAYLY: That is what I was going to
3 bring up.

4 JUDGE BITTNER: Okay.

5 MR. BAYLY: Certainly I would submit that
6 Respondent's counsel and Your Honor can see that.

7 JUDGE BITTNER: Would you like to look at
8 that?

9 MS. CARPENTER: I would like to.

10 JUDGE BITTNER: You may approach, Ms.
11 Carpenter.

12 MS. CARPENTER: Thank you.

13 [Pause.]

14 JUDGE BITTNER: Mr. Bayly, I got lost a
15 little bit. You talked about Government 15, and
16 what was the other exhibit?

17 MR. BAYLY: Twelve was the '99 contract.

18 JUDGE BITTNER: Thirteen was the--

19 MR. BAYLY: Thirteen was the current
20 contract, 2005, March 2005. I believe that was
21 admitted. The only other one we talked about is
22 Government Exhibit 15, which is a request for

1 proposal.

2 JUDGE BITTNER: Okay. We don't have a
3 document that was the request for proposal for
4 2005. That's where I got lost.

5 MR. BAYLY: No, we didn't. We had
6 testimony on it, but no document per se.

7 JUDGE BITTNER: Thank you.

8 MS. CARPENTER: May I approach, Your
9 Honor?

10 JUDGE BITTNER: Yes.

11 MS. CARPENTER: I would ask that that be
12 made part of the record.

13 JUDGE BITTNER: Then now I need to see it.
14 I guess Mr. Bayly does too.

15 MR. BAYLY: Sure. I would submit that
16 would be fine, for copies for both Respondent's
17 counsel and Your Honor.

18 JUDGE BITTNER: So you want it as a
19 Government exhibit?

20 MS. CARPENTER: Yes, Your Honor.

21 JUDGE BITTNER: Which would be number
22 what?

1 MR. BAYLY: 94.

2 MS. CARPENTER: 94, I think.

3 JUDGE BITTNER: Mr. Bayly, would you--you
4 have no objection to having this in? It's one
5 page?

6 MR. BAYLY: Yes. I believe so.

7 THE WITNESS: I have a lot of other things
8 that might refresh my memory. As the time comes,
9 I'll be glad to at any point, if I need to use any
10 of it, to make copies.

11 JUDGE BITTNER: Well, I think what you
12 need to do is any time you're refreshing your
13 memory, you need to say that you're referring to a
14 document, and that way, everybody knows. It may or
15 may not be the case that somebody will want it in
16 evidence.

17 THE WITNESS: I'll be more than happy to.

18 JUDGE BITTNER: Okay. Why don't I just
19 not rule on Government 94 since we don't actually
20 have it yet, and, Mr. Bayly, if you would arrange
21 to make copies during the break and then introduce
22 it, we'll reserve the exhibit number.

1 MR. BAYLY: Yes, Your Honor. Maybe during
2 the break or lunch, we can make a copy of it, and
3 if Respondent wants to put it in--well, I don't
4 know if you want it to be a Respondent exhibit. I
5 don't know.

6 JUDGE BITTNER: I think it's actually
7 yours since it's your witness and you used it
8 during his direct.

9 All right. So we're reserving Exhibit No.
10 94 for the Government.

11 Go ahead, Mr. Bayly.

12 BY MR. BAYLY:

13 Q Dr. El Sohly, did you indicate that you
14 were awarded the 2005 contract in the same type of
15 bidding process?

16 A Yes.

17 Q As you were in the '99 contract?

18 A Yes, sir.

19 Q And the 2005 contract, was that advertised
20 similarly as in Government Exhibit 15?

21 A Yes, it had.

22 Q Do you know why the latest, the current

1 contract as we're calling it, was not awarded until
2 March 2005 instead of 2004 when it normally would
3 expire?

4 A The contract, the old contract, the 1999
5 to 2004 contract, was extended without additional
6 funds until March of 2005. There was--again, as I
7 indicated, this is a cost reimbursement contract.
8 The amount of money is put in every year, added in
9 there. There was some money that was left over in
10 the contract that allowed us to operate without
11 additional funds until the new contract was put in
12 place in March of 2005.

13 Q The contracts in Government Exhibit 12 and
14 13, do they have any huge substantial differences
15 from each other?

16 A In terms of the requirements?

17 Q Right.

18 A There are some differences, but I wouldn't
19 say huge differences. There are some differences.

20 MR. BAYLY: Your Honor, I'd like to move
21 now in evidence Government Exhibit 15.

22 MS. CARPENTER: No objection, Your Honor.

1 JUDGE BITTNER: Received.

2 [Government Exhibit No. 15 was
3 received in evidence.]

4 MR. BAYLY: At this point, I think we
5 should have Government Exhibits 12, 13, 15, and 93
6 admitted under the witness' testimony.

7 JUDGE BITTNER: Yes.

8 BY MR. BAYLY:

9 Q Just a few more questions about Government
10 Exhibit 13. Do you have that up there still with
11 you, Dr. El Sohly?

12 A Yes, I do.

13 Q All right. If you would turn to page 6 of
14 this exhibit, I think we're looking at 1(f), quote,
15 THC and other cannabinoids. Do you see that
16 provision?

17 A Yes.

18 Q Does your facility actual do what is
19 called for in this provision?

20 A Yes, it does.

21 Q Can you just explain to us what is meant
22 by isolate these constituents?

1 A When you prepare an extract of the plant
2 material in the process as I described earlier, you
3 really have a very, very crude extract that
4 contains all the constituents or most of the
5 constituents of the plant, and we have determined
6 from our previous work that there over 400 or 500
7 different chemicals that exist in plant material.
8 All of these or most of these actually have been
9 extracted. In order to separate or isolate or
10 purify a single component out of that, it's a very
11 elaborate process of purification. So to isolate
12 is to purify or separate one component out of this
13 mixture of different components.

14 Q Thank you, Doctor. Now I want you to turn
15 to page 7, the next page on Government Exhibit 13,
16 and look at paragraph six, manufacture small
17 batches of marijuana containing a high
18 concentration of delta-9-THC. Do you see that
19 provision?

20 A Yes.

21 Q All right. Does the university of
22 Mississippi do what's called for in that provision?

1 A Yes, it does.

2 Q Was this provision in the '99 contract to
3 your knowledge?

4 A There was a provision similar to that in
5 the '99 contract, but it did not, to my
6 recollection, define the potency. It was just
7 hand-rolling cigarettes, but didn't say what
8 potency cigarettes that might be. The option of
9 hand-rolling cigarettes was in the '99 contract.
10 In this contract, it was determined that there
11 should be a definition if need be.

12 Q In the last sentence in this provision, in
13 No. 6 which was referred to, says may include
14 hand-rolling of the cigarettes, end quote. What is
15 the significance of that? Why is it that U. Miss.
16 would need to hand roll cigarettes?

17 A Again, as I described earlier, the higher
18 the potency, the more sticky the plant material is,
19 the more difficult it is to roll it using the high
20 volume production machine; however, I might add
21 that maybe a couple of years ago, we were able to
22 change the conditions in the machine so that a six

1 percent batch was actually rolled using that
2 machine. So we know now we can produce six percent
3 six or six and a half percent in that, using the
4 high volume machine.

5 So we don't need hand roll unless it's
6 just a specific batch that they don't need as much
7 or they don't want to use, for some reason, the
8 bulk material at the six percent. Then it's just
9 easier to hand roll it.

10 Q Now, Dr. El Sohly, I want to refer you
11 again to page 7, but at paragraph eight. It says,
12 quote, reduce one hundred G of cannabinal, paren,
13 CBN, closed quote, one hundred G of cannabibiodol,
14 CBD, closed quote. Do you see that provision
15 there?

16 A Yes, I do.

17 Q Can you, first of all, tell us what is
18 cannabinal?

19 A Cannabinal is another cannabinoid that
20 exists in the plant material, a natural cannabinoid
21 that exists in the plant material that is
22 really--if you look at it from a chemical

1 standpoint, it's an oxidation product of the
2 delta-9-THC, and but it's a component in the plant
3 material. In any plant material, you will have
4 some amount of this cannabinal or CBN. Some
5 material will higher levels than others, but
6 invariably, every plant material will have some of
7 this CBN.

8 Cannabibiodol, on the other hand, is
9 another component that exists in the plant
10 depending on the variety. It's a variety-specific
11 component. Some varieties have a very small amount
12 of CBD and some varieties will have a higher
13 percent of CBD. It just depends on the variety and
14 the purpose that the plant material is produced
15 for.

16 Usually in the drug-type cannabis,
17 drug-type marijuana, it's a very low level of CBD,
18 a small amount of CBD. On the other hand, in the
19 fiber plant, the material produced may be higher.
20 It will have a higher content of CBD and low
21 content of THC. In this provision, we have a
22 requirement to prepare a hundred grams of CBN and a

1 hundred grams of CBD and five to ten grams of other
2 cannabinoids as needed by NIDA to be used in the
3 drug supply inventory. The actual provision for
4 that No. 7 requires that we prepare one kilogram of
5 pure THC, again to be used as a standard for doing
6 research with that particular chemical, because,
7 Your Honor, right now, there is no supply of THC
8 available to do, you know, research with.

9 JUDGE BITTNER: So tetrahydrocannabinol is
10 not a component of cannabinol?

11 THE WITNESS: No. Cannabinol, you start
12 out with tetrahydrocannabinol and so produce
13 cannabinol.

14 JUDGE BITTNER: Okay

15 THE WITNESS: It's a degradation product
16 of THC.

17 JUDGE BITTNER: Is CBD also?

18 THE WITNESS: No CBD is not. It only
19 exists in the plant material if it was there
20 genetically speaking. It's a
21 genetically-controlled material, CBD, whereas CBN
22 is a chemical degradation product that the older

1 the plant material is, the more CBN you will have
2 in that plant material.

3 JUDGE BITTNER: Okay.

4 BY MR. BAYLY:

5 Q Dr. El Sohly, now under Provision 7, which
6 you mentioned in your testimony, has U. Miss.
7 complied with that provision to produce one
8 kilogram?

9 A We haven't produced the whole kilogram,
10 but we are producing some of that material now.
11 The kilogram, by the way, would be approximately 20
12 grams per year.

13 Q So that's your goal then?

14 A Yes, sir.

15 Q Do you see any reason why you would not
16 meet that goal?

17 A I do see not see any reason why not.

18 Q Under Provision 8, have you at this time
19 produced a hundred grams of CBN?

20 A No. We are actually in the process. We
21 made a large amount of extract that is currently
22 being processed by separating those different

1 components.

2 Q Do you anticipate that you'll meet that
3 goal?

4 A Yes.

5 Q Same question for the CBD. Have you
6 produced that yet?

7 A No, we have not. We actually, because the
8 CBD and the current supply, we only have a small
9 amount of material that has enough CBD for
10 hydration purposes. We would grow some specific
11 variety that has a high CBD content so that we can
12 make that hydration process more much simple than
13 trying to push it out of plant material that has
14 very little CBD to start with.

15 Q Do you anticipate that you'll be able to
16 reach that goal?

17 A Yes. We have the genetic material that
18 would allow us to do that.

19 Q Thank you. Dr. El Sohly, now if I ask you
20 to please flip over to page 51 of Government
21 Exhibit 13. It looks like the last page and says
22 release of indemnity agreement.

1 A Yes, sir.

2 Q Can you just explain briefly why this is
3 part of the contract?

4 A This is a document that's required by NIH
5 to be submitted by the investigator. So we
6 actually send this to the investigators when they
7 order the materials under this program to fill out
8 that form and sign it and send it as part of the
9 document that we have to have before we release the
10 shipment to the investigator.

11 Q Dr. El Sohly, was there a similar release
12 and indemnity agreement under the '99 contract?

13 A Yes, sir, there was.

14 Q Now, under the both the '99 and the
15 current contract, Dr. El Sohly, the NIDA contract
16 with your facility at the University of
17 Mississippi, how would a researcher initially go
18 about trying to obtain marijuana? I think you
19 already testified it couldn't come directly to you.
20 So how would that process work?

21 MS. CARPENTER: Excuse me. I think that's
22 been asked and answered.

1 JUDGE BITTNER: Not completely, but I was
2 thinking if you're past the contract, which I
3 gather we are, Mr. Bayly--

4 MR. BAYLY: I'm sorry?

5 JUDGE BITTNER: You're done with 12 and
6 13, basically?

7 MR. BAYLY: Yes.

8 JUDGE BITTNER: And if we want to go late
9 today, then I would think we want to take a late
10 lunch. So would you like a short break now?

11 MS. CARPENTER: That would be great.

12 JUDGE BITTNER: Is this a good time?

13 MR. BAYLY: Yes.

14 JUDGE BITTNER: All right. Let's take 10
15 minutes.

16 [Recess.]

17 JUDGE BITTNER: Mr. Bayly, we're back to
18 you.

19 MR. BAYLY: Thank you, Judge Bittner.

20 At this time, I'd like the witness to be
21 given the following exhibits. They're all
22 Respondent's exhibits: Respondent Exhibit 28, 29,

1 30, and 32.

2 Your Honor, I request that I be able to go
3 up to the stand with Dr. El Sohly because at this
4 time, we don't have Respondent's copies. We were
5 provided with them, but we don't have them at the
6 moment.

7 JUDGE BITTNER: Okay. No objection, I
8 assume, Ms. Carpenter.

9 MS. CARPENTER: No.

10 MR. BAYLY: Thank you.

11 BY MR. BAYLY:

12 Q Dr. El Sohly, we've given Respondent's
13 Exhibits 28, 29, 30, and 32, and just prior to the
14 break, I had one question, and I'll let you peruse
15 just quickly if you like before I resume
16 questioning. We'll need to identify these
17 documents for the record.

18 In any event under the 1999 and current
19 2005 NIDA contracts, a researcher wanting marijuana
20 from you, how would he go about getting it?

21 A They have to address it with NIDA, and
22 NIDA will give me the order to ship either the raw

1 material from our facility or the cigarettes from
2 RTI.

3 Q Dr. El Sohly, I'd like to first of all ask
4 you about these exhibits. I want to identify them
5 for the record. If you need time to look at them,
6 feel free to do.

7 Respondent Exhibit 28 is identified as a
8 letter dated May 10, 1995. It's addressed to you,
9 Dr. El Sohly, and it's a letter from Dr. Rick
10 Doblin. And then I'd like you to look at this
11 letter, please. Just let us know when you're
12 finished reviewing that.

13 A Yes.

14 Q Then Exhibit 29, this is--Respondent
15 Exhibit 29 is noted as a memorandum. Again, it's
16 addressed to you, Dr. El Sohly, and again it's from
17 Dr. Rich Doblin. That's dated May 12, 1995. I'd
18 ask you to please look at this that.

19 A Okay.

20 Q Thank you. Put your Respondent Exhibit 29
21 aside just for a second, and then the last one I'm
22 going to ask you look at and identify for the

1 record--I'm skipping over Respondent Exhibit 32,
2 and that's entitled a memorandum. Again, that's to
3 you, Dr. El Sohly. Again, that's from Dr. Rick
4 Doblin, and it's dated May 25, '95. Would you
5 please just review this document, memorandum?

6 A Okay.

7 Q Thank you. Dr. El Sohly, other than
8 reviewing these particular exhibits in Respondent's
9 Exhibit 28, 29, and 32, do you recall--do you have
10 any independent recollection of corresponding with
11 Dr. Rick Doblin about supplying marijuana to Dr.
12 Donald Abrams for research?

13 A I have a recollection of getting these
14 documents from Dr. Doblin or at least have
15 the--remember these documents or something to that
16 effect; however, I have looked in my files to see
17 what kind of response I gave to Dr. Doblin, and I
18 didn't really see anything there in the file. So
19 I'm not sure whether I responded and I lost that or
20 didn't respond or what. Maybe Dr. Doblin can say
21 whether I did or not.

22 But the basic gist of these documents is

1 requesting that I provide materials for studies
2 outside of the NIDA contract, and I really didn't
3 feel that that is possible for me to do that from
4 two standpoints. First of all, the material that I
5 have is owned by NIDA. It's not my material.
6 Second, it had come to my attention, also, that I
7 could not even do that even if it was something
8 that wed produce for--not under the NIDA contract,
9 for our own research. In other words, the
10 distribution of the materials would have to go
11 through NIDA, and that was really the bottom line,
12 that I couldn't--if I can use the word "cooperate"
13 or "collaborate" in this venture because of the
14 regulations and because of what we are supposed to
15 do and not supposed to do.

16 Q Now, Dr. El Sohly, the last respondent
17 exhibit I want to show you here, I'll identify it
18 for the record. It is a memorandum. It's to Dr.
19 Donald Abrams from Rick Doblin, and it's dated May
20 15, 1995. In relation to this Respondent exhibit,
21 do you recall that you declined to test marijuana
22 that was obtained from the Buyer's Club?

1 A Yes. I actually remember that, and also
2 simply because, first of all, I couldn't just get
3 materials from an individual just coming to me
4 through the mail, which would be an illegal act on
5 my behalf or on behalf of the individual sending
6 this material to me. So I declined to do that, and
7 the second reason is, of course, for me to do an
8 analysis, it's going to come through NIDA again,
9 because we do the work for NIDA. It's done under
10 the NIDA contract, and I couldn't just
11 independently do some work for somebody and be paid
12 for the government, but without the government's
13 approval.

14 I also recall that Mr. Dale Gallagher, who
15 I think was a counsel for NORML, the National
16 Organization for Reform of Marijuana Laws,
17 contacted me about a similar situation, similar
18 samples and so on. He said that really the buyers,
19 the people that are using it, like to know what
20 they are using. I told him I couldn't do that, and
21 because all the staff and people that I have in the
22 university is under the contract with NIDA, I

1 couldn't do that under the NIDA contract; but I can
2 do that in my private lab and as a service, but I
3 have to receive the materials through a hundred
4 percent legal route. The legal route is for me to
5 receive those materials from a laboratory, somebody
6 that is registered with the DEA to handle
7 marijuana, to handle the controlled substance under
8 a Schedule I license that can send me the samples
9 to do the analysis on them and report the results
10 back, and he was able to get such a lab in
11 California. I don't recall. I even tried to
12 actually find those records. I can't find them,
13 it's been so long, but my recollection is that Mr.
14 Gallagher found a laboratory that transferred the
15 samples to in California. The laboratory sent me
16 the samples. I sent them the DEA-232 to acquire
17 the samples. They sent me the samples. I did the
18 analysis. I reported the results in a very upfront
19 and totally legal way of doing this.

20 So that's really the gist of my
21 recollection on this issue.

22 MR. BAYLY: Thank you, Dr. El Sohly.

1 Your Honor, I'm going to--first of all,
2 before I resume, I want to switch to another topic
3 here. So I want to return these back to the clerk
4 so these can be--I think these are actually
5 admitted documents.

6 BY MR. BAYLY:

7 Q All right. Dr. El Sohly, are you familiar
8 with the acronym GMP as it pertains to the Food and
9 Drug Administration of HHS?

10 A Yes. I am.

11 Q And what is stand for?

12 A GMP is Good Manufacturing Processes or
13 Good Manufacturing Procedures. This is a
14 requirement by the Food and Drug Administration if
15 you are going to make anything that would be used
16 in clinical trials or will be used in human trials
17 or in human use as a final product, that the
18 material will have to be prepared under the Good
19 Manufacturing Practices, GMP.

20 Q Were you required under the both of '99
21 and the current NIDA contracts to comply with GMPs?

22 A Yes, we are.

1 Q Were you ever inspected by the FDA in
2 terms of--let me rephrase. Did the FDA ever
3 inspect the University of Mississippi for
4 compliance with the GMP?

5 A Yes, it has.

6 Q Do you recall approximately when that
7 inspection took place?

8 A Yes. It was in April of 2004.

9 Q And what was the result of that
10 inspection?

11 A The result was no finding. Basically, we
12 did not get a 483. A 483 is a form that would
13 given to the facility for any deficiencies that the
14 facility might have regarding the manufacturing
15 practices and any of documentation, records,
16 quality control procedures and so on, on the issue
17 that the FDA is inspecting for. So we did not get
18 a 483. That means they did not have any findings.
19 So, basically, we got a clean bill of health.

20 JUDGE BITTNER: And this was all the
21 University of Mississippi, not your own lab?

22 THE WITNESS: Yes, ma'am, the University

1 of Mississippi. That's all we're doing the NIDA
2 contract on.

3 JUDGE BITTNER: Okay.

4 BY MR. BAYLY:

5 Q Now, as part of your current NIDA
6 contracts, Dr. El Sohly, does the U. Miss. facility
7 conduct research on marijuana to
8 indicate--pertaining to high potencies, THC,
9 delta-9-THC?

10 A Yes, we do.

11 Q As part of these contracts, does U. Miss.
12 conduct research on marijuana pertaining to low
13 potencies of delta-9-THC?

14 A Yes, sir.

15 Q Do you also currently produce placebo
16 material?

17 A Yes, we do.

18 Q Can you explain to us what vegetative
19 propagation is?

20 A You have several ways of propagating plant
21 material. You propagate plant material by planting
22 seeds or you can propagate--you can do what is

1 called vegetative propagation. When you plant from
2 seeds, as I indicated earlier in my testimony, you
3 get 50 percent of the plants are males and 50
4 percent are females. When you do vegetative
5 propagation, if you know that six of the plants
6 that you are propagating--let's say you take a
7 female plant and then you take cuttings from that
8 plant, you root those cuttings, and then you plant
9 them. Then the new plants coming up would have the
10 same sex, the same genetic makeup as the mother
11 plant. That's what we refer to a vegetative
12 propagation.

13 Q So has the University of Mississippi
14 actually conducted those kinds of--

15 A Yes, we have.

16 Q Now, as a part of the current contract,
17 does the University of Mississippi conduct research
18 for indoor cultivation of marijuana?

19 A Yes, we have.

20 Q Are there any advantages of the indoor
21 cultivation of marijuana? What purposes for your
22 research in the facility that does that serve?

1 A The indoor growing basically helps in that
2 you have control over the environmental conditions.
3 You can control the temperature, the humidity, the
4 carbon dioxide content, control the fertilizers.
5 You can control the watering of plants. You can
6 control the amount of light. When you want the
7 plants to be in the vegetative stage of growing,
8 which means they just keep growing and growing,
9 getting bigger but not produce any flowers, you can
10 induce flowering at any point in time at any size
11 at the plant. You can induce flowering by cutting
12 the amount of light, the period of time, how long
13 you put the plants under light that will make the
14 plants bloom. They start blooming when the amount
15 of light starts coming down, and then basically you
16 can have more. Also, by doing that, you can put it
17 in a vegetative stage for a month or six weeks or
18 so, and then you can turn the light down in terms
19 of the length of time. You can go from 24 hours of
20 light and no hour of dark to 12 hours of light, 12
21 hours dark. The plants will start blooming, and
22 you leave them there six weeks or so and they're

1 fully mature.

2 So you can harvest in three or four
3 months. You can have a crop. The plants, of
4 course, will not be very big, but nonetheless, they
5 will be a good size enough to harvest, and also you
6 can do the vegetative propagation starting from the
7 male plants. You can produce indoors a hundred
8 percent female plants, a hundred percent sensimilla
9 without fear of those plants getting fertilized
10 from outside and coming from whatever.

11 So there are a lot of advantages for this
12 growing indoors, but the disadvantage, of course,
13 is the amount of material that you can produce.
14 Unless you have a tremendous facility to produce a
15 large scale, then you are limited by the size of
16 the facility that you have. That is not to say
17 that if need be, we could expand our current
18 facility. Right now, we have about 1200 square
19 feet of indoor growing room that is equipped to
20 handle quite a number of plants, but certainly in
21 the neighborhood of tens of kilos a year, but not
22 in the hundreds of kilos as we are currently

1 producing outdoors.

2 So the disadvantage is the amount of
3 material that you can produce indoors. Also, one
4 of the advantages of growing indoors, you can have
5 much higher potency if need be. Now, I have to
6 qualify that by saying that the amount of THC that
7 is currently produced outdoors is comparable to
8 some of the materials that could be produced
9 indoors. So if need be, that is not an issue. We
10 the facility. We can do and we have done that, and
11 we have produced material, sensimilla indoors, up
12 to 20 percent THC.

13 Q Dr. El Sohly, is there a difference
14 between the way the University of Mississippi is
15 grown outdoor as opposed to the way it's grown in
16 your indoor facility?

17 A A difference from what standpoint?

18 Q From how it's grown.

19 A Well, the growing indoors or outdoors, I
20 mean, it's a plant that is grown. It's just the
21 conditions under which you subject the plant is the
22 difference, the controls that you have and the

1 timing and so on. Outdoors, of course you are
2 bound by the growing cycle and the timing. You
3 cannot start in December or January. It wouldn't
4 survive. You have to wait until April to start,
5 and then you can't just determine when you're going
6 to harvest. You just wait for the plant to mature
7 as opposed to indoors when you decide when you want
8 to start and when you want to finish a particular
9 cycle.

10 So the amount of control that you have on
11 the plant material is much higher, of course,
12 indoors than it is outdoors.

13 Q Dr. El Sohly, are you familiar with the
14 term "hydroponics"?

15 A Yes.

16 Q How does that term relate to your--

17 A Hydroponics is basically growing the plant
18 material without the need of soil, without having
19 actual soil. So the roots are not put into soil,
20 but put into liquid, hydro. Hydro is water. So
21 you have the fertilizer into the system and the
22 roots are suspended in there. You get moist in the

1 fertilizer, water and so on, but there's no soil
2 involved in the hydroponic operation. We have done
3 that also in our current facility that we have.

4 Q Is that, the hydroponics method, is that
5 conducted indoors or outdoors?

6 A Hydroponics is by definition an indoor
7 operation. I mean, you can have it outdoors, but
8 you're in a greenhouse. So essentially it's
9 indoors.

10 Q The majority of the marijuana that's grown
11 at the University of Mississippi, is that outdoors
12 or in your indoor facility?

13 A I'm sorry. Can you repeat the question?

14 Q I'm sorry. The marijuana that is grown in
15 your total development, your total project there at
16 the University of Mississippi, is a majority of it
17 grown outdoors or indoor?

18 A It's grown outdoors.

19 Q Now, Dr. El Sohly, you previously
20 testified under these--the contracts, Government
21 Exhibits 12 and 13, that the University of
22 Mississippi performed analysis of marijuana; is

1 that correct?

2 A Yes.

3 Q All right. And can you tell us what the
4 these studies have revealed in terms of potency
5 when the material tests positive for marijuana
6 within, say, the last year or most recently?

7 A Well, the potency, we have been monitoring
8 the potency, actually, since 19--the late sixties
9 or early seventies. I remember '71, '72, '73,
10 there was definitely enough samples coming in to
11 have a good idea about what the average THC content
12 was, and we have been doing this every year, and I
13 can tell you that starting from 1991, '92, in that
14 time frame, the THC was averaging about three
15 percent or so, three and a half percent maximum,
16 and then it has been on the increase, gradually on
17 increase, until 2004. I believe the average was
18 right average 7.3, 7.4 percent. So it has
19 gradually increased over the years where now the
20 average potency is about seven percent, give or
21 take.

22 Q Dr. El Sohly, the samples that we're

1 talking about, are these seized samples?

2 A Yeah. These are seized samples. We have
3 no way of really getting samples from actual users
4 per se. So the next best thing is to--whatever
5 sampling material that is confiscated that come in,
6 we do the analysis, and by the sheer number of the
7 seizures, that would be a good representation of
8 what's out there on the illicit market. I'm not
9 sure of the percentage of number of seizures made
10 versus the material that's already out there, but
11 it certainly would be a good representation. Those
12 samples are--you know, we get them from the DEA
13 labs and we get them from the State narcotic
14 agents.

15 Q Dr. El Sohly, these samples are
16 considered, quote, street marijuana or illicit
17 marijuana?

18 A Yes, because it's a shipment that's going
19 to be distributed. So it's dried before
20 distribution, if you will.

21 Q Now, these samples that you're talking
22 about, these illicit samples that you do the

1 analysis on here at the University of Mississippi,
2 are they limited to samples discovered in just the
3 United States or are there samples coming in from
4 other countries that you're asked to do analysis
5 on?

6 A Well, most of the samples are actually
7 seized here in the U.S. There would be some
8 samples, a few samples would be coming in from the
9 DEA special testing lab where those samples might
10 have been seized in other parts of the world, but
11 the number is not really significant to change the
12 overall picture. So the majority of samples are
13 seized here in the U.S.

14 Some of the samples, if you had a chance
15 to look at our potency monitoring report, some of
16 those samples that are seized here in the U.S. are
17 seized in the U.S. at the grower's place, you know,
18 in the field somewhere in the U.S. or in a grow
19 room somewhere so that we know for sure that these
20 domestic samples, domestically-produced samples.
21 Those samples are identified as such in our report,
22 and we say this is the potency of domestic

1 materials.

2 Now, other seizures, just maybe a seizure
3 of narcotic material somewhere but we don't know
4 whether produced this was produced in the U.S. and
5 was being shipped around the country or material
6 that's coming from abroad, so since we don't know
7 that it's for sure domestic, we call it
8 non-domestic. So we our report will show domestic
9 material versus non-domestic material, and the
10 domestic represents about a third of the number of
11 samples that we analyze each year.

12 Q Dr. El Sohly, are you familiar with the
13 acronym ONDCP?

14 A Yes, I am.

15 Q And do you know what that is?

16 A Yes. The Office of National Drug Control
17 Policy at the White House.

18 Q Is any information pertaining to these
19 marijuana potency studies that you just testified
20 about shared with that office by your University of
21 Mississippi facility?

22 A Yes. We actually do supply the ONDCP with

1 a copy of our quarterly potency monitoring report.

2 Q Now I'd like to turn to another subject
3 here, Dr. El Sohly, and ask you under the '99 and
4 current contracts, which party in the contract is
5 responsible for deciding how much marijuana will be
6 cultivated or harvested in a given year?

7 A NIDA is the agency that has to determine
8 and has to inform us of the amount of material that
9 we need to produce and the potency range that needs
10 to be produced.

11 Q Can you tell us when the last crop--and
12 again, I'm referring to the major outdoor crop--of
13 marijuana was actually grown and harvested at your
14 facility?

15 A It's the 2001--2002 timeframe.

16 Q Why was that the last crop and why didn't
17 you grow anymore after that?

18 A Well, because we have quite of bit of
19 inventory, really covering all the ranges of any
20 material that investigators would need. If there
21 are needs for materials outside of that in small
22 amounts, we can certainly do it indoors and it

1 wouldn't cost the government any more money to do
2 it indoors, because we have the security in place.
3 Everything is in place. The employees are there.

4 Q Dr. El Sohly, I'd like to ask you next, if
5 necessary, does the University of Mississippi have
6 the capability of producing marijuana with a
7 potency, again, at the delta-9-THC level in bulk
8 form with 15 percent or more greater THC content?

9 A I would say, yes, definitely because we
10 have already material that is produced outdoors
11 that us--I believe the highest I have in inventory
12 may be 13 or 14 percent, which is very high. I
13 don't think subjects can actually tolerate that
14 high potency, but nonetheless, we have it, and then
15 we can produce indoors small quantities of any
16 potency that is required. So I would say, yes, we
17 have the capability of bulk production.

18 Q When you say capability of bulk
19 production, Dr. El Sohly, can you give us a
20 ballpark figure of what you mean by bulk, how much?

21 A Well, bulk, if you're talking about 10
22 percent or more, 12, 13 percent, I'm talking about

1 50 kilos, a hundred kilos, a lot of material. If
2 you're talking about a few kilos, then we can
3 produce that indoors, but still bulk.

4 Q Now, in cultivating the marijuana, let's
5 go back to the start now. Here I want to ask you
6 from what source or where do you obtain the seeds?

7 A We have had seeds from different parts of
8 the world that was brought into inventory
9 throughout the years, you know, from Mexico,
10 Columbia, Jamaica, Thailand, all different
11 countries that are known to produce, India, Turkey,
12 just different seed stocks that we have received
13 over the years, and we have used quite of number of
14 those plants and did some genetic selection to have
15 genetic material of high potency. Within any
16 population, there are some seeds that would
17 have--if they grow them, they produce low to medium
18 potencies. Some will produce high potencies. Some
19 will produce very high potency, and it's just a
20 matter of genetics that you do to acquire the types
21 that you need for future production.

22 During the growing season, we tag plants

1 in the field. We tag them with number and so on,
2 identification, and we monitor the THC content of
3 those plants over the growing season and determine
4 at the end of the season which plants are going to
5 be used as the seed providers for the next season
6 and for the specific type of production either
7 based on the potency or based on the cannabinoid,
8 comparing the ratio of different cannabinoids to
9 one another. So we have seeds that can give us the
10 high potency materials and seeds that give us low
11 potency materials, seeds that can give high THC,
12 low CBD, seeds that produce high THC, high CBD, and
13 all kinds of different ranges. We have those
14 materials in stock.

15 Q Dr. El Sohly, you're talking about these
16 seeds that result in perhaps a higher or lower
17 potency. Are these seeds that were developed at
18 the University of Mississippi or did they come from
19 another source?

20 A Well, we have both, actually. We have
21 seeds that, you know, we--when you say produce at
22 the University of Mississippi, the original seeds

1 on day one when we first started had to come from
2 somewhere. We didn't have them when we started
3 this program 1968. So we had acquire seeds from
4 somewhere, and we collaborated with the DEA to
5 bring the seeds from different parts of the world
6 and then used those seeds in the development
7 process and selecting some genetic materials. I
8 have also, you know, imported some seeds from the
9 Netherlands and imported some seeds from
10 Switzerland, and so we have seeds from different
11 parts of the world.

12 Q Now, after obtaining the seeds, what's the
13 next step for outdoor planting of marijuana?

14 A Basically, what we try to do, we used to
15 put the seed directly in the grown. We decided it
16 was not a good practice in Mississippi given the
17 heavy rains that happen around the time when we
18 plant. So now we start the seeds indoors. We
19 start them in different pots, making seedlings of
20 about maybe three, four inches tall, and by that
21 time, the weather is improved and we can take them
22 outside to plant the seedlings directly into the

1 field. Then it goes through the routine, the
2 agricultural process of cultivating the plants and
3 taking care and weeding and so on and watering, if
4 need be. When we have a draught, we have a
5 watering system in the field outdoors, going all
6 the way into the production, the maturity, the
7 harvesting, the drying, the processing, the
8 de-seeding, and bringing the plants in, analysis,
9 inventory and so on.

10 Q Dr. El Sohly, are you familiar with the
11 term "micro propagation", and if so, can you
12 explain?

13 A Yes. Micro propagation is a technique
14 that is used to--it's just like vegetative
15 propagation that I described earlier except that
16 you don't take a whole cutting to make a new plant.
17 You take a very small amount of genetic material
18 from the plant, and you put that in dry conditions
19 and allow this to develop as a plant, and so from
20 one plant, you can have hundreds of little
21 plantlets, and then later, if need be, you can take
22 those plantlets and transfer them into soil or

1 hydroponic operations, and this becomes new plants
2 that you can either vegetative propagate or, again,
3 micro propagate.

4 So it's a way of continuing the genetic
5 material that you have selected for specific
6 purposes.

7 Q Now, does the University of Mississippi
8 under your direction actually perform micro
9 propagation?

10 A Yes, we have.

11 Q Take us through the next steps up to
12 harvesting.

13 A After harvesting--when you get to the
14 harvesting process, you can harvest so many
15 different ways. Either you can cut the whole plant
16 at the base and then just dry the whole plant and
17 then strip the whole plant, or you harvest only the
18 top or the buds. If you have the female plants,
19 then you take those and you put them in trays.
20 Those trays go into a dryer. The dryer--of course,
21 everything that we do, as I indicated earlier, is
22 under the Good Manufacturing Practices, which is

1 the dryer has to be calibrated so when you're
2 drying, you don't overdry, you don't underdry. You
3 dry it to a certain moisture content.

4 Then you pull the plants out of those
5 trays with the bud out of the dryer, and you
6 manicure those buds or those plants, and then you
7 take the manicured material and put it through--we
8 have put in place in 2001 a machine that actually
9 helps in the processing of the plant material and
10 also the de-seeding at the same time. Once we go
11 through that process, then the final product is the
12 final product that comes out that has low moisture
13 content low, no seeds, which of course has to be
14 qualified later on in the laboratory, and then the
15 THC content is determined, the potency is
16 determined, and only then the material goes into
17 inventory.

18 Q How is the potency determined?

19 A The potency is determined by an analytical
20 method. It's a gas chromatography process with a
21 flame, high ionization detector. It's identified
22 as G-C, slash, F-I-D, and this is the process of

1 analysis using the internal standard method to
2 determine the amount of THC in the plant material
3 on a weight-to-weight basis of the dried plant
4 material.

5 Q Does your facility at the University of
6 Mississippi test for potency, or is that done
7 elsewhere?

8 A It's all done in-house at the university.

9 Q And can you tell us what the University of
10 Mississippi does to store, first of all, bulk
11 marijuana?

12 A We store bulk marijuana in containers.
13 These are drums. Those drums are lined with
14 FDA-approved plastic bags, big plastic bags, that
15 go inside the drum. The drug actually goes into
16 those polyethylene plastic bags, and it's put into
17 the barrel. It gives the weight, and we subtract
18 the weight of the barrel and the liner to get the
19 actual net weight of the plant material in there,
20 and that's what goes into the inventory. The
21 inventory is stored in the vault. If the plant
22 material is of average potency, like three, four

1 percent or lower or up to maybe even five percent,
2 then it's stored in the vault without
3 refrigeration.

4 Now, I might add that the vault itself,
5 the room, the vault has in addition to the air
6 conditioning system that's in the building, it has
7 its own air conditioning unit so that the
8 temperature really inside the vault is pretty cold.
9 It's like maybe 18 to 20 degrees C. That would be
10 about 68 degrees Fahrenheit, so somewhere at about
11 65, 68 degrees.

12 Q What about storing the higher potency?

13 A Yeah. The higher potency, of course, is
14 put into the walk-in freezer that we have inside
15 the vault so that the potency is protected during
16 storage.

17 Q Now, is the University of Mississippi ever
18 involved in de-thawing any of that marijuana so it
19 can be used for research purposes?

20 A Of course as we have--again, most of the
21 material that we ship out, it's shipped to the
22 Research Target Institute. It's taken out of the

1 freezer. It's then prepared for shipment, and it's
2 under room temperature conditions. There's no
3 refrigeration during shipping. It goes to the
4 Research Target Institute. If they're going to use
5 it to make cigarettes, they don't refreeze it. If
6 they have to wait several days or whatever, then
7 they put it back into the freezer. So that time,
8 the exposure time, for the material at room
9 temperature is not that long.

10 Then they take it out and let it come to
11 room temperature and start the manufacturing
12 process of the cigarettes which involves so many
13 different steps. I'll be glad to go over the steps
14 if need be, but it's a very elaborate process that
15 includes a blending of different types of materials
16 that are dried. I referred to it a little bit
17 earlier in my testimony.

18 Q Is the University of Mississippi able to
19 conduct those steps?

20 A We are not set up to do those steps. We
21 can do the blending and all the humidifying and so
22 on, but we do not have the facility to do the large

1 scale cigarette production, and there is no reason
2 to do those steps at the University of Mississippi
3 and then send the blended material to the Research
4 Target Institute.

5 Q Who conducts those steps?

6 A RTI.

7 Q Now, Dr. El Sohly, just for the record,
8 any time we're talking about potency, we're talking
9 about potency of what?

10 A We're talking about the THC, the
11 delta-9-THC content of the plant material. The
12 higher the THC content, the more potent the product
13 is.

14 Q Now, Dr. El Sohly, does the University of
15 Mississippi produce marijuana for researchers under
16 the NIDA contract based upon research orders for a
17 specified potency amount of THC?

18 A In my opinion, that's the way that it
19 works or should work anyway, that if there is a
20 need in the scientific community for certain
21 materials, those needs are communicated to NIDA.
22 NIDA makes a decision on what needs to be done,

1 what needs to be prepared. We make the material
2 and send it to RTI. The cigarettes are made. We
3 have an inventory of cigarettes already in place,
4 different potencies. We have 1.5, 2.5, 2.8, 3,
5 3.2, 3.5, 4, 6, 7. All these different materials
6 are already in stock right now in the supply
7 program. If there are needs outside of those and
8 these are communicated to NIDA, they certainly
9 could be--there is no reason why we couldn't make
10 such materials.

11 Q These inventories potencies that your
12 mentioned, Dr. El Sohly, are you talking about bulk
13 or cigarettes or both?

14 A Both. Actually, the figures I just
15 described, these are cigarettes in the supply at
16 the Research Target Institute, RTI. We have a
17 supply of cigarettes already made, put in the
18 freezer, analyzed, qualified, ready to go. They're
19 everywhere from zero to low potency, all the way to
20 seven-plus percent.

21 Q Dr. El Sohly, I want to ask you one
22 question that I kind of missed it. I'm jumping out

1 of order. I'm sorry, because it never helps the
2 record this way. But can you give us a ballpark
3 figure of what your current inventory is of bulk
4 marijuana at the present time?

5 A At the present time, we have actually gone
6 through a--we had a lot of material, you know, from
7 previous harvests and so on that we had to
8 re-process because at that time, some of that
9 supply was a little bit older supply that we had to
10 get rid of some of those materials and de-seed some
11 of it and so on and so forth, but the current
12 inventory now is about a thousand kilograms, about
13 a ton, literally.

14 JUDGE BITTNER: A metric ton?

15 THE WITNESS: I'm sorry?

16 JUDGE BITTNER: A metric ton, not an
17 American ton?

18 THE WITNESS: Yeah.

19 BY MR. BAYLY:

20 Q All right. I'm sorry to go out of order.
21 So I'll jump back to the questions pertaining to
22 research requirements. Say a researcher

1 wants--they specific a six percent THC content.

2 How do you ensure that the marijuana provided to
3 the researcher will have the six percent THC that's
4 requested?

5 A First of all, there are two answers to
6 that. First of all, if the researcher needs some
7 material from what's already inventory, they have
8 to look at the inventory and decide which
9 cigarettes, what potency they want the materials
10 from and identify it as such. So it's already
11 predetermined that this is what we have, this is
12 what we have on the shelf, all the products that we
13 have, and they select they want this one, this one,
14 this one, this one, and put in an order for those
15 to NIDA, and it comes to us and we go through the
16 process.

17 If there is something that is not there,
18 in the current inventory, then they would ask NIDA
19 can we get some material of such and such potency,
20 and we have actually done that. In a lot of the
21 new material, the six percent, seven percent, eight
22 percent material came in place a few years ago

1 because of special requests that came from CMCR.

2 Q Now, you talked about or testified about
3 this, Dr. El Sohly, about your storage capacity for
4 bulk marijuana, but does the University of
5 Mississippi have storage capacity to store
6 marijuana cigarettes?

7 A We don't have to because all the
8 cigarettes are stored--the short answer is, yes, we
9 have the facility to store the cigarettes, but we
10 don't have to worry about that because the
11 cigarettes are stored at RTI, because they're
12 shipped from there.

13 Q Can marijuana in bulk form or cigarette
14 form be stored without losing its potency?

15 A Only if it's put in the freezer, minus 20
16 degrees or lower, and even then, there is maybe a
17 very slight degradation or a very slight loss in
18 potency over time, but not very much. So the
19 longer you need to store it, the lower the
20 temperature you should store it at.

21 Q Dr. El Sohly, what percentage of THC is
22 the University of Mississippi capable of producing

1 at this time in terms of potency?

2 MS. CARPENTER: Objection. Asked and
3 answered several times.

4 JUDGE BITTNER: Sustained.

5 BY MR. BAYLY:

6 Q At what level of potency can marijuana not
7 be stored?

8 JUDGE BITTNER: I didn't understand the
9 question.

10 MR. BAYLY: Let me see if I can rephrase
11 that then.

12 BY MR. BAYLY:

13 Q Is there a certain THC level, marijuana
14 potency level, that's so high that it just cannot
15 be stored even under refrigeration conditions?

16 A I would say no. If you have low enough
17 temperature, you can see store any THC. So far,
18 the plant materials in general have not really
19 been--with the exception of just a very, very few,
20 have not been more than 20 percent, and we have had
21 20 percent material from our production that's been
22 in the freezer for some time that's still good.

1 Q When certain potency of marijuana is sent
2 to a researcher, is there an issue that it will
3 lose any of its potency in transit?

4 A No, because we actually have--first of
5 all, I do believe that the cigarettes, as they are
6 shipped from RTI to the investigators, they are
7 shipped with a freezer pack so that they are
8 shipped refrigerated. Now, the bulk material that
9 is sent to RTI is the material that is shipped under
10 room temperature, but the cigarettes, once they are
11 shipped to the investigators are with a
12 refrigeration.

13 However, we have conducted stability
14 studies on bulk material and on cigarettes at room
15 temperature, refrigerated temperature, and freezer
16 temperature, and we can say without a doubt that if
17 it takes two or three or four or five days at room
18 temperature to ship somewhere, that there is not
19 any significant loss. It's only if you store it
20 for an extended storage period that you start
21 getting into trouble with this, at room
22 temperature.

1 Q Dr. El Sohly, are you aware of any
2 instructions or other information provided to
3 researchers in terms of how to preserve the potency
4 or store the marijuana?

5 A Yes. RTI provides with the shipments that
6 go to the investigators, provide more of an
7 instruction, a sheet, that tells them how to deal
8 with the material, how to store it and how to
9 humidify it.

10 Q All right. I think, Dr. El Sohly, you've
11 already testified that you are aware of a research
12 organization called CMCR.

13 A Yes, I am.

14 Q All right. And does the University of
15 Mississippi through the NIDA contract supply
16 marijuana to the CMCR researchers?

17 A Yes, we do. All of it, I think has been
18 cigarettes, not bulk marijuana.

19 Q Now, are these researchers--what kind of
20 research do they do in terms of is it clinical or
21 nonclinical?

22 A They do clinical research.

1 MR. BAYLY: Your Honor, I request that the
2 witness be handed Government Exhibit 5. We have it
3 here. We haven't introduced it yet.

4 JUDGE BITTNER: Okay. You may approach.

5 BY MR. BAYLY:

6 Q Dr. El Sohly, I have handed you what has
7 been marked for identification as Government
8 Exhibit 5. Can you just generally identify what
9 this document is for us?

10 A This is the letter that I wrote to Deputy
11 Assistant Administrator, Federal Register
12 Representative, in response to the University of
13 Massachusetts request for a manufacturer
14 registration. It's a copy of my comments.

15 Q All right. Just tell us generally why you
16 have decided to file comments and objections to the
17 University of Massachusetts' application to
18 manufacture or cultivate marijuana?

19 A First of all, it's the prerogative of any
20 registrant with the DEA that has a similar license
21 or similar registration to file comments on a new
22 registration, and so I had that obligation to file

1 comments when I see that the comments deserve to be
2 made. The application, as I read it, was for a
3 manufacturer's registration to cultivate and
4 distribute marijuana for research, which in my
5 judgment was exactly the same as we were doing
6 under contract with NIDA, and I wanted to make the
7 Deputy Assistant Administrator reviewing the
8 application reviewing the application for
9 registration aware that there us a process in place
10 to do just that and that in all the--whatever
11 material that is needed could be provided under
12 that registration, under that process that is
13 currently in place.

14 I made my comments and I indicated that
15 should the University of Massachusetts feel that
16 they have the expertise, the facilities, the
17 know-how and so on to do this, that that contract
18 is a competitively renewed contract. They could
19 apply and possibly if they are selected through
20 that competitive process, they would be the
21 contractor and do their thing, and we would be out
22 of doing this.

1 So those are the comments that I make, and
2 basically in the two or three pages that I have
3 there, I outline the capabilities that we have
4 there, how long we have been doing this, some of
5 the aspects of the project that we have been doing
6 and, you know, close it by saying, okay, if there
7 is a need, put in a bid for the contract, which
8 actually the contract came about a year after this
9 letter was up for renewal--less than a year,
10 actually, from the date of my letter, it was up for
11 renewal.

12 Q Dr. El Sohly, you still have Government
13 Exhibit 5 up there, your comments?

14 A Yes, sir.

15 Q I want to ask you to turn to last page of
16 the letter, near the top, above where you have
17 signed it.

18 A Okay.

19 Q I'm going to quote for reference here the
20 next question. Quote: It is important to note
21 that we have not received any formal complaints
22 from researchers about the adequacy of the

1 marijuana for research purposes, end quote. I ask
2 you now since you submitted these comments,
3 particularly this statement, have you received to
4 date any formal complaints in this regard?

5 A I have not received any formal complaints
6 regarding the material. If the people at CMCR call
7 me and say, well, Dr. El Sohly, all the cigarettes
8 that are available right now, the maximum is four
9 percent and we need some material at eight percent
10 because we have a study, that we want to do a
11 placebo at two percent, four percent, and eight
12 percent, and the current supply doesn't have it, I
13 don't consider this as a complaint. So I have
14 received, you know, things like that and telephone
15 calls, but I have not received any written or
16 formal complaints per se regarding the adequacy of
17 the supply or the material.

18 Q Well, then in an informal nature, have you
19 ever discussed with any anyone at CMCR any mentions
20 regarding the THC content not being quite as strong
21 as the researchers would prefer it?

22 A Yes, I have. I have initially from the

1 statement that they needed eight percent material.

2 I said, Well, you can talk to NIDA and I can call

3 NIDA on your behalf and tell them what you need,

4 and then if they approve it, we have the raw

5 material to make the cigarettes. Through the

6 process of--the three-part process between NIDA,

7 CMCR, and my office, we agreed to make a batch of

8 eight percent material, or approximately eight

9 percent material. We made the batch. We analyzed

10 it. It was eight percent material, and this is the

11 material that was given to CMCR, and I'm not sure

12 where they--somewhere along the line, this material

13 analyzed for seven-point something percent. I

14 don't remember the exact figure.

15 Q How did you find about that, Dr. El Sohly?

16 A What?

17 Q How did you find out that the potency was

18 determined or measured to be that extent?

19 A Well, through the regular routine GC,

20 slash, FID analysis that you get the potency of the

21 cigarettes. This is done at our facility, and it's

22 also done at RTI, and when the material came

1 out--you know, remember this was a small batch.
2 There's not a lot of material that was put together
3 to make a batch, and it came out at 7.4, you know,
4 something like. I don't really remember the exact
5 figures, but it was a little above seven, and I got
6 a phone call from CMCR, Helen--not Helen, but
7 Heather Bentley. Heather said, Dr. El Sohly, the
8 material is coming out at seven-point something. I
9 said so, basically, because the analytical process
10 has a variation in it. This is biological
11 material, that you aim at a certain concentration,
12 and then you analyze it. You have to live with
13 what you get.

14 The variation between seven-point
15 something and eight is really not large enough
16 given the potency of this material to really make a
17 difference and say, well, scratch that batch and
18 make a new batch.

19 But I also might add, Your Honor, that
20 this very same material, it was actually used in a
21 study, and the subjects would not tolerate that
22 material, whether it's eight percent or seven

1 percent. The subjects would not tolerate it.

2 MS. CARPENTER: Objection, Your Honor.

3 Lack of foundation.

4 JUDGE BITTNER: Sustained.

5 THE WITNESS: I should say, Your Honor,
6 that I was told by--

7 JUDGE BITTNER: Wait a minute. There is
8 no question pending.

9 MR. BAYLY: I'll follow up with some
10 questions.

11 BY MR. BAYLY:

12 Q First of all, Dr. El Sohly, is Heather
13 Bentley--you mentioned she was with CMCR. Do you
14 know what her position is? Is she one of the
15 researchers?

16 A She's the coordinator all the activity
17 that is going on there, acquiring the materials.
18 She is the liaison between the investigators and
19 the program.

20 Q Now, Dr. El Sohly, when did you talk to
21 Heather Bentley about this issue?

22 A I don't remember, to be honest.

1 Q Any ballpark figure? Has it been within a
2 year or much more than a year ago?

3 A Probably more than a year.

4 Q Now, did she call specifically about this
5 issue of the potency of the marijuana for this
6 researcher?

7 A The first time, when the first request
8 came, it was specifically for that, but after that,
9 regarding the potency not being eight percent or
10 seven-point something percent, I don't recall
11 whether it was specifically to that or we were
12 talking regularly about this and setting up the
13 orders and setting up the payment schedule and the
14 forms and all that kind of different things. So I
15 don't remember whether she called specifically for
16 that or there was just as one of our items that she
17 discussed.

18 Q Well, did she, in fact, ask you to send
19 eight percent THC or try it again, basically?

20 A No. I don't think so.

21 Q Was there any follow up by any CMCR
22 administrators or researchers concerning this

1 particular potency issue?

2 A Not that I recall.

3 Q Why is that?

4 A I believe they--

5 MS. CARPENTER: Objection, Your Honor.

6 Lack of foundation, how he could know whether there
7 was0 follow-up from somebody else.

8 JUDGE BITTNER: Sustained. Rephrase the
9 question.

10 BY MR. BAYLY:

11 Q Dr. El Sohly, were you ever informed by
12 anybody at CMCR why they didn't want to follow up
13 with the eight percent potency marijuana?

14 A In other words, why they wouldn't want
15 another batch?

16 Q Yes.

17 A Yes. There was a discussion after that,
18 after they actually used this batch.

19 Q All right. Do you recall--

20 A I was told by not only Heather Bentley,
21 but by one of the investigators that the material,
22 the subject couldn't tolerate that, and if we can

1 make a six percent, that would be more appropriate.
2 That was the gist of the discussion, that we needed
3 a six percent batch.

4 Remember the original study was designed
5 for zero, two, four, and eight, and they found out
6 that eight was too much. So they wanted something
7 higher than four, but less than eight, and they
8 selected six.

9 MR. BAYLY: Your Honor, at this time, I
10 think before I forget, I want to introduce into
11 evidence Government Exhibit 5. That's the comments
12 submitted by Dr. El Sohly.

13 MS. CARPENTER: No objection, Your Honor

14 JUDGE BITTNER: Received.

15 [Government Exhibit No. 5 was
16 received in evidence.]

17 MR. BAYLY: May we take a five-minute
18 break?

19 JUDGE BITTNER: Sure. Off the record.

20 [Discussion held off the record.]

21 [Whereupon, at 12:59 p.m., the hearing was
22 recessed, to reconvene at 2:15 p.m. this same day.]

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

[2:25 p.m.]

JUDGE BITTNER: We're back on the record.

Mr. Bayly.

MR. BAYLY: Good afternoon, Judge Bittner.

Just a few housekeeping matters here: The document that Dr. El Sohly looked at, when he was testifying, to refresh his recollection marked now as Government Exhibit 94, I am giving a copy of it here to the clerk.

JUDGE BITTNER: Okay.

MR. BAYLY: If Respondent wants to admit it, that's fine. If not, we cannot admit it.

JUDGE BITTNER: Would you like it in the record, Ms. Carpenter?

MS. CARPENTER: We have no objection to it being admitted, Your Honor.

JUDGE BITTNER: Okay. Do you want it in?

MS. CARPENTER: Yes.

JUDGE BITTNER: Okay. Do you have a copy for me, Mr. Bayly?

MR. BAYLY: Is that it?

1 JUDGE BITTNER: That's the official copy.

2 MR. BAYLY: Do you have another one?

3 JUDGE BITTNER: We can make a copy of it.

4 MS. CARPENTER: We have three on our team,
5 so I am happy to give you this one.

6 JUDGE BITTNER: Thank you.

7 All right. Government Exhibit 94 is
8 received.

9 [Government Exhibit No. 94 was
10 received in evidence.]

11 JUDGE BITTNER: Okay.

12 MR. BAYLY: All right. We are ready to
13 continue and we would request that Dr. El Sohly be
14 given a copy of Government Exhibit 16. I believe
15 that has been admitted.

16 BY MR. BAYLY:

17 Q Dr. El Sohly, do you have a copy of
18 Government Exhibit 16?

19 A Yes, I do.

20 Q Turn, please, to page 17, the bottom of
21 page 17 and the top of 18. Paragraph 40 at the
22 bottom of page 17 focuses on the approval from NIDA

1 to ascertain the feasibility of producing a higher
2 potency product, and there is an answer filled in
3 yes.

4 My question to you regarding this excerpt
5 of Government 16, Dr. El Sohly, is do you recall
6 anyone from CMCR contacting NIDA to ascertain the
7 feasibility of producing a higher potency of
8 marijuana?

9 MS. CARPENTER: Objection as to
10 foundation.

11 JUDGE BITTNER: Right.

12 MS. CARPENTER: The contact is with NIDA.

13 JUDGE BITTNER: Would you rephrase it,
14 please?

15 MR. BAYLY: I don't know that--I could ask
16 the witness directly without even using this as a
17 foundation, I would think.

18 JUDGE BITTNER: Right. I mean, you can
19 ask him if he knows.

20 BY MR. BAYLY:

21 Q All right. Do you know?

22 A I'm sorry. Now I lost the question.

1 Q Do you recall anybody from CMCR contacting
2 you about the feasibility of producing a higher
3 potency product of marijuana?

4 A Yes.

5 Q Okay. And can you say about when that
6 was?

7 A Maybe three, four years ago.

8 JUDGE BITTNER: I'm sorry. I didn't hear
9 that.

10 THE WITNESS: Three or four years ago,
11 Your Honor. A long time ago.

12 BY MR. BAYLY:

13 Q Do you recall your response to that?

14 A Yes. My response was that we can talk to
15 NIDA, and we certainly have the plant material to
16 make a batch. We can contact NIDA, and if they
17 approve it, we can certainly make it. And we did
18 contact NIDA and we did make a batch and NIDA
19 approved it.

20 Q All right. Next, I think maybe to move
21 this on a little quicker, I ask that the witness be
22 given Government Exhibits 17, and 18, and 21.

1 A Page 21?

2 Q 17, 18, and 21.

3 A Exhibits, okay.

4 MR. BAYLY: I believe they've all been
5 admitted.

6 JUDGE BITTNER: Yes.

7 [The law clerk presents exhibits.]

8 BY MR. BAYLY:

9 Q Dr. El Sohly, I first want to have you
10 refer to Government Exhibit 17, and if you could
11 turn to page 6, I'm going to refer you to the top
12 there of page 6 where the question is, quote, is
13 the potency of the product consistent, end quote,
14 and there's a handwritten answer of no and a
15 handwritten explanation, quote, at least two
16 shipments, some variability in stated THC and the
17 actual measured may have been very responsive, end
18 quote.

19 Other than, of course, looking at this
20 particular document here, this trip report, were
21 you aware of any issues brought to you from any
22 source, either NIDA or CMCR, about source

1 variability and the stated THC content?

2 A I do believe that this refers to the eight
3 percent batch of cigarettes that was stated as
4 being eight percent. And remember, this was
5 prepared at our facility with our analytical
6 procedure, and it was stated to be the eight
7 percent cigarettes, and then it was sent to RTI
8 where it would be shipped from RTI. RTI, they do
9 their own analysis, and there are variability in
10 the analytical process between one laboratory and
11 the other, and the RTI analysis might have been
12 that seven-point something percent, and therefore
13 the stated concentration would be eight percent
14 cigarettes, but the analytical data that was coming
15 with the batch was seven-point something.

16 So I do believe that this is what they are
17 talking about in this statement here, because I am
18 not aware of any other batches that came up with
19 such discrepancy between the stated and the actual
20 analysis; and, however, as I testified before, the
21 variation between the eight and the 7.1 and or 7.2
22 or 7.4 is really within the analytical variability

1 that you see in any analytical laboratory.

2 Q Referring to the last handwritten quote,
3 again I'll quote it again, re-quote it: May have
4 been very responsive, end quote. Is that a
5 statement that you agree or disagree with?

6 A I certainly agree, because we have really
7 tried everything that we know how to accommodate
8 the needs of CMCR. We offered to make another
9 batch, and that was, you know, something that was
10 not acted upon, and I think later on, that was the
11 alternative, based on the clinical testing and so
12 on, to have a batch at six percent, which we have
13 prepared.

14 Q All right. Now I would like to you to--I
15 think we're still on Government Exhibit 17, and if
16 you would turn to page 7, please, and look at
17 paragraph 14, I will read you--the preprinted
18 question is, quote: Have any patients ever
19 complained about the, quote, freshness, end quote
20 of the marijuana, end quote. Do you see that
21 paragraph there?

22 A Yes, I do.

1 Q Now I want to refer you to part of the
2 handwritten explanation underneath that question,
3 and I'll quote that. Some of the handwriting is
4 not that easy to read, but I'll quote it as I read
5 it. Quote: Some patients have reported that the
6 smoke was, quote, harsh, end quote, and it was hard
7 to finish the cigarette.

8 First of all, all of them from this
9 particular report that you're looking at, did you
10 get any complaints, formal, informal or otherwise,
11 about this issue, Dr. El Sohly, on the harshness?

12 A I didn't get any formal complaints about
13 the harshness. I did hear unofficially about the
14 harshness of the cigarettes, and that was
15 particularly indicated for the placebo material.
16 As I discussed earlier, the placebo material, all
17 of the components have been extracted out. So all
18 you have there really is just psilocybins. So this
19 will be just like smoking just literally grass or
20 smoking hay or something like that or just paper
21 that might have this harshness, and there's no
22 soothing effect of the other components in the

1 plant material. That would make the cigarettes to
2 be harsh, but that's the nature of the placebo.

3 This statement here doesn't really say
4 which subjects complained of the harshness or maybe
5 those subjects that complained of the harshness
6 were those that were given the placebo. At the
7 time that they were being administered placebos,
8 it's unknown to the patients. So I'm not sure
9 which subjects complained about that.

10 But the other issue is, you know, these
11 materials, you know, the freshness of the material,
12 you know, to do a clinical trial and to do trials
13 with research materials, you can't just have it
14 right off the garden and just dried it and then
15 roll it to make your research. Regardless of who
16 prepares these materials, they're going to have to
17 be stored. They might lose some humidity over time
18 in storage, and if they did lose humidity, they
19 would be harsher than perfectly humidified
20 cigarettes. So, you know, I see that as a nature
21 of the material that's been being administered and
22 not a deficiency in the product.

1 Q Dr. El Sohly, you mentioned that you did
2 hear informally something about this issue
3 pertaining to the harshness. Can you tell us about
4 when you heard about this issue informally?

5 A It might be five or six years ago.

6 Q Do you recall the source, who?

7 A I recall Dr. Abrams mentioned that during
8 one of the cannabis meetings that I had attended
9 and he was there.

10 Q For the record, would that be a Donald
11 Abrams?

12 A That's correct.

13 Q Can you tell us as a result of hearing
14 from Dr. Abrams about this, did Dr. Abrams request
15 that you do anything or take any action?

16 A No, and to be honest with you, Dr. Abrams
17 at that time had been, you know, critical of NIDA
18 and of the program, and so I just heard the
19 comment. He didn't ask any further. He didn't
20 request anything, and I just--and certainly there
21 was nothing I could do about that particular
22 situation.

1 Q Did he indicate to you that as a result of
2 this complaint, his research was curtailed?

3 A No. It was just offered as a criticism of
4 the material, but not to take any particular
5 action, which we certainly would have listened.

6 Q Now, I would like you to again refer to
7 Government Exhibit 17, and at this time, turn to
8 page 9, the top of the page, paragraph 16. Do you
9 see that, Dr. El Sohly?

10 A Yes.

11 Q Let me quote it so we can make sure we
12 have it in the record here, quote: What is the
13 potency of the marijuana cigarettes currently
14 approved for use in your research, end quote.

15 Then I want to refer you to the
16 handwritten comments underneath provided in the
17 blanks for the comments, and I'll quote that as
18 well, the context here. Eight percent have not
19 received, correction, colon, eight percent
20 received, but tested potency was approximately
21 seven percent.

22 First of all, were you ever made aware of

1 this discrepancy other than through this exhibit
2 that you're looking at now?

3 A As I testified before, I heard about the
4 lower amount, lower than the eight percent, from
5 Ms. Heather Bentley of CMCR around the time when
6 this was being used at CMCR.

7 Q Was there any follow-up or further
8 inquiries from anyone at CMCR regarding this
9 comment here?

10 MS. CARPENTER: Objection, Your Honor. I
11 think this has been asked and answered.

12 JUDGE BITTNER: I'm not sure with respect
13 to--I'd have to go back and read through
14 everything, which I probably will--I will do it,
15 but not today. Specifically with respect to Dr. El
16 Sohly, I just don't know.

17 MS. CARPENTER: All right.

18 THE WITNESS: Again, I lost it, forget
19 what you're asking.

20 BY MR. BAYLY:

21 Q Was there any follow-up or further
22 inquiries from anyone from CMCR regarding this

1 discrepancy that we just talked about in paragraph
2 16 here, the, quote, correction that the potency
3 was approximately seven percent?

4 A Okay. Yes. This discrepancy came up. We
5 talked about it, and I explained that the
6 analytical variability could be up to plus or minus
7 20 percent of the stated amount, so that if you
8 have an eight percent, what's labelled as being
9 eight percent, it is acceptable for the analytical
10 method to provide you a value somewhere between 6.4
11 and 9.6. This is the range, what you would call as
12 an eight percent with an acceptable analytical
13 value within that range; however, we strive to make
14 that acceptable range a lot tighter than what's
15 commonly acceptable in the scientific community,
16 making it within the 10 percent range. And,
17 therefore, an eight percent could be somewhere
18 between 6.2 to 8.8, and certainly the stated value
19 that Heather had reported to me at the time was
20 within that acceptable range, and I explained to
21 her that this is really not an issue that's a
22 matter of consistency or stated as different than

1 the analytical.

2 This is just the nature of the material.
3 You analyze it. This is a biological material that
4 because the batch was a small batch, you might have
5 some cigarettes that might be eight percent. Some
6 might be a little bit less. Some might be a little
7 bit more, but on the average, they should be within
8 the acceptable range.

9 There was no other discussions beyond that
10 point until the next time I heard about this
11 particular batch, is when I was told by Heather and
12 by Dr. Maddes, Andrew Maddes of CMCR, at the ICRS
13 meeting, the International Cannabinoid Society
14 meeting in Canada, that the subjects would not
15 tolerate this and can we discuss the possibility of
16 making a six percent batch.

17 So the six percent that's written here
18 actually came way after making the eight percent,
19 and so that was the response. It was the full up
20 to the eight percent batch.

21 Q Dr. El Sohly, I now would like you to look
22 at Government 18. I think that should be

1 underneath Government Exhibit 17. Government
2 Exhibit 18, I'd ask you to turn to page 7,
3 paragraph 14.

4 For the record, I'll quote it: Have any
5 patients ever complained about the, quote,
6 freshness, end quote, of the marijuana, end quote.

7 Now, I will read the handwritten comments right
8 below that: Recently one of ten patients complain
9 of the product being, quote, harsh, end quote,
10 didn't explain what that means, comma, don't know
11 if it was placebo or active.

12 The first question is is this--other than
13 what's in this exhibit here, did you receive any
14 comments or complaints regarding this issue?

15 A No. And I just might add, Your Honor,
16 that one out of 10--as I indicated, those subjects
17 are randomized, and the statement here says did not
18 explore--not explain--did not explore what that
19 means, don't know if it was placebo or active. So
20 the possibility that the person, one out of ten,
21 that found the material to be harsh were actually
22 being administered placebo.

1 Q Dr. El Sohly, going back to the prior
2 questions about the--remember we were talking about
3 the one comment in Government Exhibit 17 that
4 talked about eight percent received, but tested
5 potency was approximately seven percent?

6 A Yes.

7 Q I'm sorry. I want to just jump back in
8 that for a second. Did you ever find out how CMCR
9 made this determination in the calibration?

10 A No, I didn't, actually. I was not
11 convinced that that was really enough difference to
12 investigate what the source of that difference is;
13 and, you know, as I testified later on, it was a
14 moot point since the material was too strong
15 anyway. So it doesn't matter whether it was seven
16 or eight. It was too strong for the subjects, and
17 therefore they requested the six percent.

18 So I didn't explore it any further.

19 Q Okay. Now, Dr. El Sohly, I'd like to move
20 on to another subject. Has the University of
21 Mississippi, yourself or anybody involved in the
22 NIDA marijuana project there, been formally

1 apprised of problems with the marijuana having too
2 many stems and/or seeds to be used for clinical
3 research?

4 A No, not formally. We haven't received
5 anything along those lines at the University of
6 Mississippi.

7 Q Have any of the CMCR researchers talked to
8 you about this issue informally?

9 A No, not really, but I'm not sure I know
10 everybody at CMCR. I don't know if Dr. Abrams is a
11 member of CMCR or not, but Dr. Abrams, again in the
12 very same meeting that I mentioned earlier, you
13 know, when he was saying it's harsh, it's got
14 seeds, it's got stuff like that in it, it was just
15 a general statement, but not an addressed complaint
16 or a formal complaint.

17 Q Has the University of Mississippi taken
18 any steps to limit stems and/or seeds in the
19 marijuana that it provides to researchers?

20 A Well, we have actually--you know, all the
21 way through the program from its inception, there
22 was an effort put forth to eliminate any seeds, any

1 stems out of the plant material, and that started
2 at the University of Mississippi when we had only
3 the production contract and RTI had the cigarette
4 manufacturing contract, two separate contracts. In
5 preparing our material early on, we had de-seeding
6 machines that we acquired for the purpose of
7 removing all the seeds and any large particles from
8 the plant material. Those de-seeding machines
9 actually rendered the plant material more to the
10 fine particles rather than the large particles.

11 So when we delivered some of those
12 materials to RTI, they informed us, you know, some
13 of the batches that were taken from the de-seeding
14 machine, that this material is too fine to roll
15 into cigarettes, so please don't de-seed it, leave
16 it as it is and send us the material and we will
17 take care of the de-seeding and the removing of all
18 these particles during our cigarette manufacturing
19 process.

20 And so we did. So we have the product
21 that we have--we used to have, anyway, before 2001,
22 2002, was just the bulk material that is really

1 rough-looking material. It has seeds. It has
2 stems. It has particles and things like that by
3 design so that if we take it through that
4 de-seeding machine, it will be too fine. It
5 wouldn't--you'd just have like a very, very fine
6 powder that doesn't roll into cigarettes. It will
7 just come right off of the cigarette, and RTI was
8 doing--cleaning it up to the best of their ability
9 in the manufacturing process to remove those, which
10 might have left some particles in there.

11 Certainly I wouldn't say that to any
12 measure or extent of anything, but some of that
13 might go through that process of getting into the
14 cigarettes. So to find the occasional seed, a
15 little seed--and I'm not talking about the big
16 seeds that are definitely of a different density
17 than the plant material, but I'm talking about
18 small seeds, immature seeds, that might come
19 through the process because it had the same density
20 as the rest of the plant material.

21 And so that's the material that was used
22 prior to all the cigarettes manufactured prior

1 to--from material produced prior to 2001, have been
2 processed that way. In 2001, we worked with a
3 de-seeding equipment company in Canada to help us
4 to design a special machine for us to de-seed
5 that's specific to the cannabis plant, to de-seed
6 that material. We have put that, the machine, in
7 place. We have put it in operation in 2001, and
8 we're able to provide plant material going through
9 that de-seeding machine, removing all the seeds,
10 all the stems, all the heavy particles, and have a
11 product that has the right particle size and has no
12 seeds that we can ship directly to RTI and they can
13 manufacture the cigarettes without further
14 processing other than blending and humidifying and
15 so on.

16 JUDGE BITTNER: Doctor, you said that RTI
17 said ship us the stuff and we'll take care of any
18 problems with extraneous material in house,
19 basically?

20 THE WITNESS: That was prior to 2001.

21 JUDGE BITTNER: Right.

22 THE WITNESS: And we had de-seeding

1 machines, old de-seeding machines that really kind
2 of crushed the plant material as it went through
3 the de-seeder, that old de-seeder.

4 JUDGE BITTNER: Oh, I see.

5 THE WITNESS: So we have two kinds of
6 de-seeders. We have old ones that would render the
7 plant material too fine to roll into cigarettes,
8 and then in 2001, we installed a totally new
9 machine that is based on the exact needs of the
10 program.

11 JUDGE BITTNER: Did RTI have--because I
12 was trying to figure out if you sent them stuff
13 with seeds in it, how were they--are they going to
14 use that to roll the cigarettes and then get the
15 seeds out?

16 THE WITNESS: No.

17 JUDGE BITTNER: Okay. No. That didn't
18 make any sense.

19 THE WITNESS: Not as it is, they have to
20 do the de-seeding prior to putting it into the
21 machine.

22 JUDGE BITTNER: But they had equipment

1 that would do that?

2 THE WITNESS: They had to do it by more or
3 less like manually. They actually had to do it in
4 a very, I should say, elementary way or old
5 fashioned.

6 JUDGE BITTNER: So the problem was that
7 the same process that got the seeds and the
8 extraneous material out before--I think you said
9 2001.

10 THE WITNESS: Right.

11 JUDGE BITTNER: In order to do that, the
12 machine crushed the plants?

13 THE WITNESS: That's correct.

14 JUDGE BITTNER: Okay.

15 THE WITNESS: So they had to use a more
16 gentle process to get the seeds and the stems out
17 before they put it into the cigarette manufacturing
18 machine, which that machine also has a capability
19 of removing many more seeds or stems that might be
20 in there during the manufacturing process.

21 You know, any excessive amount of seeds or
22 stems is not going to--this machine, Your Honor, if

1 you saw that machine, it goes so fast,
2 manufacturing those cigarettes so fast, I think
3 like a thousand cigarettes a minute or something
4 like that. Any of these extraneous materials, this
5 is--after all, this is just cigarette rolling
6 paper, very thin paper. Any of those particles in
7 any significant amount would actually break the
8 cigarette, will puncture the paper, will make the
9 cigarette unusable.

10 So anything that I'm saying, material or
11 cigarettes manufactured prior to 2001, production
12 material, if it has any seeds, it would be
13 insignificant, really insignificant.

14 THE WITNESS: Okay. Thank you.

15 Go ahead, Mr. Bayly.

16 MR. BAYLY: Thank you, Judge Bittner.

17 I request now that the witness be handed
18 Respondent Exhibit 19, and I would note for the
19 record that a majority of this exhibit has been
20 excluded except any references to the quality
21 supply of marijuana to NIDA.

22 THE WITNESS: I still have--Your Honor, I

1 still have 21.

2 MR. BAYLY: Hold on to that, please.

3 THE WITNESS: Okay.

4 MS. CARPENTER: I'm sorry. What Exhibit
5 number are you on, Mr. Bayly? Nineteen?

6 MR. BAYLY: Right now, I'm referring to
7 Respondent Exhibit 19, and I'll ask everyone to
8 turn to pages 49 and 50.

9 BY MR. BAYLY:

10 Q Dr. El Sohly, I'm going to refer you
11 particularly to page 50 of this exhibit and
12 particularly with Figures 5 and 6 and ask you if
13 you are aware of this exhibit. Have you seen it
14 before?

15 A Yes, I have.

16 Q Have you seen it before in the context of
17 any complaints or in the context outside of this
18 litigation?

19 A Yes, I have.

20 Q When was that?

21 A It was maybe a year or two years ago.

22 Q Do you know how you came across these

1 particular pictures in Government Exhibit 19--I'm
2 sorry--Respondent Exhibit 19?

3 A I came across this in response to a
4 publication that I along with some of my colleagues
5 at the University of Chicago submitted an article
6 for publication. It actually came out and appeared
7 in the literature, and then Dr. Ethan Russell and
8 someone else with him--I don't remember. Maybe--I
9 forgot the name of the other person that wrote the
10 letter to the editor, along those lines, and
11 mentioned the seeds and this and that in that
12 response; and in looking at this, there is just no
13 way that this is material that is actually in the
14 cigarettes.

15 Q Why do you say that?

16 A Why I say that is because if you look at
17 Figure 6, Figure 6 says--you're looking at the
18 seeds there. If those seeds--those seeds almost
19 approximate the actual size of the marijuana seeds.
20 Maybe this will be a little bit larger. It says
21 it's a close-up. So how larger it is, it seems to
22 me like it's no more than one and a half, maybe two

1 times of the size--of the actual size of a cannabis
2 seed or marijuana seed.

3 Looking at that and looking at the stems
4 and things that are there under the seeds, if you
5 reduce that, if you say even a maximum of twice the
6 size of an actual seed, then those stems and things
7 that are in this picture, Figure 6, would be--the
8 actual size would be half of that, and I cannot
9 imagine this kind of material would be present in
10 cigarettes that look as good as those in Figure 3,
11 in the consistency like that. Those cigarettes,
12 they go through very intensive quality control
13 procedures. Those things would definitely puncture
14 that very thin--this is not several layers of
15 paper. This is just one layer, tube of cigarette
16 paper. Those things would definitely tear that
17 paper, and there was just no way.

18 So my personal view is that those might be
19 some materials from--remember, Your Honor, when I
20 talked about getting materials that are sent to RTI
21 in bulk as is? Maybe some of the bulk material
22 would look like that, but I don't have any problem

1 with this. This is normal. This is expected. But
2 to say that this kind of material is in cigarettes,
3 I have to challenge that.

4 Q Dr. El Sohly, do you still have Government
5 Exhibit 21 up there?

6 A Yes, I do.

7 Q All right. I'll ask you just to put
8 Respondent Exhibit 21 aside for now.

9 JUDGE BITTNER: You mean 19? Or you
10 don't?

11 MR. BAYLY: Respondent 19. Thank you,
12 Judge Bittner.

13 JUDGE BITTNER: Okay. You know the first
14 rule, don't confuse me.

15 MR. BAYLY: It's too many exhibits at one
16 time. My brain can't keep them straight. So thank
17 you for correcting me.

18 BY MR. BAYLY:

19 Q Now we are definitely on Government
20 Exhibit 21, and I ask you, Dr. El Sohly, to turn to
21 page 6 and paragraph 11, the preprinted question is
22 have you observed any physical deformities in the

1 appearance of the cigarettes, and then the
2 handwritten comment underneath that question is,
3 quote: No, nicely rolled, but there is a loss of
4 material in the case from dropping out of the
5 cigarette as a result of--

6 A In the can.

7 Q What?

8 A It says loss of material in the can, not
9 in the case. In the can, C-A-N.

10 Q All right. Let's make sure we're on the
11 same page.

12 MS. CARPENTER: I would object for lack of
13 foundation there. I don't think Dr. El Sohly wrote
14 this.

15 MR. BAYLY: If I may start again on this.

16 JUDGE BITTNER: Sure.

17 BY MR. BAYLY:

18 Q All right. Let me make sure we're all in
19 agreement on what is the handwritten comment after
20 that Question 11: Quote, no, nicely rolled, but
21 there is loss of material in the case from dropping
22 out of the cigarette as a result of the pre, slash,

1 thaw process.

2 JUDGE BITTNER: And the issue before us is
3 what is the word between "the" and "from" in the
4 top line, whether that word is can or case.

5 THE WITNESS: May I explain, Your Honor?

6 JUDGE BITTNER: Well, no, not yet. We
7 just don't know at this point. Right, Mr. Bayly?

8 It's C-A, squiggle.

9 THE WITNESS: But if I explain, Your
10 Honor--

11 JUDGE BITTNER: Okay. But there is no
12 question pending.

13 MR. BAYLY: In the context and the way
14 it's written, I would submit that it's in the case.

15 JUDGE BITTNER: Okay. In any event, it's
16 C-A, squiggle.

17 MR. BAYLY: But if there is any
18 cross-examination or perhaps another interpretation
19 of that word, that's fine.

20 BY MR. BAYLY:

21 Q Dr. El Sohly, first of all, other than
22 this comment here in Government Exhibit 21, did you

1 receive any complaints, informal or formal,
2 concerning the issue commented on here?

3 A The answer is no, I did not, but that's
4 really not a complaint or a problem.

5 Q Why not?

6 A Because these are--again, these are
7 cigarettes that are made out of dried leaves of
8 plant material that is not shredded like tobacco,
9 and you would expect that some of that material
10 would fall out of the top of the cigarette when
11 there's not seeds on top.

12 Your Honor, I say can because the
13 cigarettes are provided to the subjects, to the
14 investigators, in cans. A can has 300 cigarettes.
15 They come in cans like this, and the can has a
16 bottom covering and a top covering, and the
17 cigarettes are in between. They are inserted like
18 one after the other inside.

19 JUDGE BITTNER: So they're vertically
20 placed inside?

21 THE WITNESS: They're vertically placed in
22 the can, and then they're covered with a Styrofoam

1 ring on op to guard against in shipping and so on.
2 If it gets rolled, there's not much of the material
3 out of the top of the cigarettes that will actually
4 fall. But regardless of how hard you try, there
5 will be some plant material that will fall off of
6 the top of the cigarettes in the bottom of the can,
7 not of the case.

8 So that's why I say it's a can and not a
9 case.

10 JUDGE BITTNER: Okay.

11 THE WITNESS: They say here rolling the
12 ends would prevent loss.

13 JUDGE BITTNER: Okay.

14 THE WITNESS: You can roll the ends when
15 you make your own cigarettes, but when you have a
16 standardized program, you can't roll the cigarettes
17 and do the ends like you do the regular things.

18 JUDGE BITTNER: I have no idea.

19 THE WITNESS: Like doing the joints.

20 BY MR. BAYLY:

21 Q Next, Dr. El Sohly, I'd like you to turn
22 to page 7 on Government Exhibit 21. At the top of

1 the page, it looks like a preprinted question under
2 13, quote: In your professional opinion, do any of
3 the plant parts make these cigarettes unacceptable
4 for your research, end quote. Then a handwritten
5 yes is in the column. Do you see that?

6 A Yes.

7 Q Then, I'm going to ask you to comment on
8 the following answer, which I'll quote, which is a
9 handwritten underneath of the explanation blank
10 there, quote: The goal is to make that which is
11 being consumed in the S.F. area. Then it would
12 seem inappropriate to have stems and seeds in them.

13 First, other than the comment written in
14 here, did you ever hear of any complaints, formal
15 or informal, in regard to this comment?

16 A Again, only what Dr. Abrams mentioned
17 during the ICRS meeting.

18 Q Is this the same conversation that you've
19 already testified about with Dr. Abrams?

20 A Yes. Yes, sir.

21 Q All right. Can you tell us, then, what
22 was the context of this conversation? First of

1 all, where did it occur?

2 A Actually, it was not a conversation. It
3 was a statement that was made as he was walking
4 away. That was actually the first time that I ever
5 met Dr. Abrams. I knew who he was. It was at the
6 meeting. We were coming out of the meeting and
7 walking, and he was just saying that as he was
8 walking out. He was not necessarily discussing
9 that issue with me.

10 JUDGE BITTNER: And this is the
11 International Cannabis Research--

12 THE WITNESS: Society meeting, yes, ma'am.

13 BY MR. BAYLY:

14 Q All right. And what is your response to
15 this comment?

16 A Well, actually I have two responses.

17 MS. CARPENTER: Just a clarification. I'm
18 sorry. To Dr. Abrams' comment then or to this
19 comment in the exhibit?

20 JUDGE BITTNER: Right. Did he say
21 anything to Dr. Abrams; is that the question? Or
22 asking for a response to what's written here ?

1 MR. BAYLY: Well, let's back up.

2 BY MR. BAYLY:

3 Q Did he have any comment, Dr. Abrams, if
4 you can recall at this time?

5 A No. Like I said, we were not really
6 discussing it or anything. He was just making a
7 comment as he was walking away or going.

8 Q What is your response to this comment as
9 it appears here in Government Exhibit 21?

10 A I think the comment in my judgment is not
11 an appropriate comment, because if we want to do
12 research similar to the material being used in San
13 Francisco, are we also going to also have to
14 generate material that is similar to Washington,
15 D.C. and Detroit, Michigan and Boston,
16 Massachusetts and Pittsburgh, Pennsylvania and so
17 on? I think it doesn't make any sense.

18 What makes sense is, number one, to look
19 at the national data for the potency, for what's
20 out there on the street and what we can make to
21 mimic what's out there and to do research with
22 these kinds of materials. That's number one, and

1 that's exactly what we have been doing all these
2 years. We were monitoring--the potency monitoring
3 program that I referred to, Your Honor, before
4 where we analyzed confiscated materials from
5 throughout the United States is designed to provide
6 information and data to assist the government
7 agencies in developing the kinds of material that
8 need to be developed for research.

9 We want to know what the health effects of
10 marijuana that's being consumed in this country is.
11 So we have to know what people are consuming, and
12 that's what we're doing with the potency monitoring
13 program.

14 As I indicated before, all the way from
15 1971 and all the way to 1992 or '93, the average
16 potency was three percent or four percent or lower.
17 So starting in the seventies with about half a
18 percent to one percent and then going up, up, up to
19 the eighties and the nineties, early nineties, to
20 about three, three and a half percent, and then
21 from that point on, 1992 to 2004, the potency has
22 increased all the way to seven percent. So we are

1 moving with the direction that the material people
2 are consuming and making cigarettes available at
3 the level that represents the average of what's out
4 there.

5 Certainly another point that we have to
6 remember is that making those cigarettes, those
7 cigarettes have, you know, a certain weight,
8 certain amount of material in there, and the
9 subjects have to--whether the material is one
10 percent or two percent or eight percent, they have
11 to consume the same kind of cigarette for the
12 investigator to be able to tell difference between
13 the two and the four and the eight and not just
14 because this is eight, only smoke a fourth of that
15 and pass the rest to someone else. No. You cannot
16 do this in an investigation. It's a blind
17 investigation so the subjects will not know what
18 they're being provided, only to be totally blind;
19 and, therefore, you're having material above the
20 average and giving those cigarettes. I think it
21 would be--in my judgment, it would be
22 irresponsible.

1 MS. CARPENTER: Objection as to lack of
2 foundation as to whether it would be responsible or
3 irresponsible.

4 JUDGE BITTNER: He said it was his
5 opinion.

6 MS. CARPENTER: Not as a matter of his
7 expertise though.

8 JUDGE BITTNER: No, but he won't be the
9 only witness in this proceeding to give an opinion
10 that may be beyond his expertise.

11 So overruled.

12 Mr. Bayly, your next question.

13 THE WITNESS: I haven't finished
14 answering, Your Honor.

15 JUDGE BITTNER: I think you answered.

16 THE WITNESS: No. There is another point
17 as far as San Francisco and so on goes. It's an
18 important issue. You need to design the material
19 based on the national and not just based on one
20 city or one county or whatever; but the other thing
21 is even if you look at the data from the
22 confiscated material from the State of California,

1 which I can't segregate it by San Francisco and Los
2 Angeles and San Diego, but I have the whole State
3 of California data from confiscated materials, it
4 exactly replicates the national average. There
5 might be some samples that are real high, some
6 samples that are not so high, but on to average,
7 it's very similar to the national average, and I
8 will be glad to provide Your Honor with the actual
9 data if you so desire.

10 JUDGE BITTNER: We're back to don't
11 confuse me.

12 MR. BAYLY: We'll move on.

13 JUDGE BITTNER: But, unfortunately, I am
14 confused, because are you referring to potency?

15 THE WITNESS: Yes.

16 JUDGE BITTNER: Okay.

17 Mr. Bayly, would you like to go ahead?

18 BY MR. BAYLY:

19 Q Dr. El Sohly, I want to again draw your
20 attention to Government Exhibit 21, page 7. I'm
21 sorry.

22 A The rest of that statement there, also

1 trying to minimize those components--

2 MS. CARPENTER: Objection, Your Honor.

3 JUDGE BITTNER: There is no question.

4 MS. CARPENTER: There is no question
5 pending.

6 MR. BAYLY: That's fine.

7 BY MR. BAYLY:

8 Q All right. Government Exhibit 21, page 8,
9 at the top of there--actually, the question is at
10 paragraph 15 at the bottom of page 7. It says,
11 quote: Have any of the issues discussed regarding
12 the quality, quote--I'm sorry, paren, visual
13 differences, deformities, plant parts, freshness,
14 closed paren, of research grade marijuana adversely
15 impacted your research. The answer handwritten in
16 is yes, and you turn over to page 8, and the
17 handwritten explanation is, quote, a few patients
18 have terminated early due to the harshness, paren,
19 quality, closed paren, clinical, "N" equals 20 or
20 21; out of that, two or three dropped, period,
21 quote.

22 Did you receive any complaints regarding

1 this explanation and answer in paragraph 15 here,
2 informally or formally

3 A No, I have not.

4 Q Do you have an opinion as to this
5 complaint in paragraph 15?

6 A Yes, I do, certainly do.

7 Q What is that?

8 A Number one, we don't know, again, whether
9 those two or three subjects out of 20 that dropped
10 out were actually consuming--dropped out because of
11 the harshness of the placebo or the active. We
12 don't know that. Number two, if you have, as here
13 in this, you have four out of 50 patients have
14 dropped out for whatever reason, harshness or
15 otherwise, you still have 46 subjects out of 50.
16 That's 92 percent of the subjects completed.
17 That's a pretty good record for actually people
18 completing a clinical trial, and the important
19 thing is that people drop out of clinical trials
20 for a variety of reasons, and to have only eight
21 percent of the subjects dropping out is really not
22 a critical--not to be taken as a criticism of the

1 quality of the material. Regardless of the quality
2 of the material, you're going to have people
3 dropping out, and you drop out and then you
4 reorganize the group of who is there, how many
5 people, and you complete that trial.

6 And obviously that did not impede the
7 clinical trial as it was.

8 Q Thank you, Dr. El Sohly. One more
9 question regarding these, what I call trip reports.
10 I should have had covered this earlier, but can you
11 flip back to page 7, please?

12 A Yes.

13 Q I'm going to refer you back to 13. You
14 already commented about the first part of that
15 answer, about the goal mimicking that which is
16 being consumed in the S.F. area. Do you recall
17 that line of questioning?

18 A Yes.

19 Q Then the last handwritten comment there
20 underneath is paragraph 13 on page 7, quote: Also
21 trying to minimize those components resulting from
22 smoke that are harmful while at the same time,

1 upward arrow--I assume that means increase,
2 medicinal value of THC, end quote. Is this a
3 comment you were aware of other than seeing it on
4 this particular exhibit?

5 A I think the comment is very much well
6 taken regarding the increase of the amount of THC.
7 If you increase the amount of THC, the potency,
8 then in the general sense in the illicit market,
9 how people are using it, increasing the amount of
10 THC and people are using it the way they're using
11 it and titrating themselves, they will probably use
12 less material to get the same pharmacological or
13 biological effect or the same high, if you will.

14 In a clinical trial, when you're doing a
15 clinical trial, again everything has to be
16 standardized. So you cannot increase the THC
17 content and give less of the plant material. But
18 the comment is very well taken by saying that
19 minimizing all the other components and increasing
20 the medicinal value of THC. We have always
21 advocated, and it came out in the IRN report, that
22 the value of marijuana is not necessarily in the

1 smoke material, but in the components of the plant
2 material that have certain specific biological
3 activities such as THC. So there is a lot of
4 encouragement for formulating THC in different
5 preparations, pharmaceutical preparations, that
6 contain one active ingredient, which is THC, or a
7 derivative thereof to get the maximum effect
8 without having all of these other components that
9 are in the plant material, and once you burn them,
10 then each one of those gets converted to another
11 hundreds of chemicals, and then you smoke a
12 marijuana cigarette and you get thousands of
13 chemicals.

14 So if Dr. Abrams wants to increase the
15 value of THC by doing THC, why not administer THC?
16 Why are we even trying to do--you know, work with
17 marijuana? I'm not saying don't do it. I'm just
18 saying the comment is true, and it's along the line
19 of what the IRN report is indicating.

20 MR. BAYLY: Dr. El Sohly, if you'll put
21 Exhibit 21 aside now.

22 And, Your Honor, I want to hand the

1 witness what's been marked for identification as
2 Government Exhibit 6, 7, and 8. The official
3 copies that are going into the record actually are
4 colored copies and they're slightly more legible
5 than the informal copies that the Government has or
6 that we supplied to you, Judge Bittner, or
7 Respondent's counsel.

8 JUDGE BITTNER: So, Ms. Carpenter, do you
9 want to look at the actual ones?

10 MS. CARPENTER: I think we're fine with
11 our copies, Your Honor. They're legible.

12 MR. BAYLY: Yes. It may be that, Your
13 Honor, if you want us to blow these up, I can read
14 these, but parts of it are certainly not easy.

15 BY MR. BAYLY:

16 Q In any event, Dr. El Sohly, I'm handing
17 you Government Exhibit 6, 7, and 8, and just tell
18 us very generally what these exhibits represent,
19 and then I'll just have maybe a question or so on
20 each one.

21 A Exhibit 6 just shows the different types
22 of plant material, you know, the plants that we

1 have tagged in the garden during the season, and I
2 don't remember whether this is the 2001 or 2002
3 season where we actually tagged the plant material
4 during the growing cycle and analyzed the plant
5 material as we go through the growing process and
6 then identify the plants that have the highest THC
7 content, the best yield, and the right proportion
8 of the different cannabinoids that we wanted to
9 select.

10 So those numbers that we have there are
11 the plant numbers that are shown on the picture and
12 then analytical data on those plants during the
13 vegetative process, during the flowering stage, and
14 at harvest. And if you look at those plant
15 materials at harvest, you have the first plant,
16 1091, has 10.6 percent THC; 1552 has 10.1; 1821,
17 11.5; 1826, 14.14; and 1864, 11.07.

18 I might add, Your Honor , that when we
19 harvested those plants, we harvested the whole
20 entire plant, leaves, buds, everything, and those
21 percentages are reflective of the total harvest of
22 that plant material. Now, if we want to be

1 selective in our harvesting, we can remove the big
2 leaves and that would be a certain percent and then
3 the inner buds of those plants, and as you can see,
4 those plants have really good sized buds. Then the
5 inner buds will have even much higher THC content
6 than those values that are given in this abstract.

7 So this just shows the process that we go
8 through for the selection of the genetic material
9 that we will use in future growings and so on.

10 JUDGE BITTNER: Could I just ask in each
11 set of pictures--

12 THE WITNESS: Yes, ma'am.

13 JUDGE BITTNER: The first picture, the one
14 with the single-digit number, it's the same plant,
15 just taken from a different perspective or from
16 further away? I'm trying to figure out the
17 difference between the first and the second picture
18 in each set.

19 THE WITNESS: Yes. It's just a close-up
20 for the second one.

21 JUDGE BITTNER: Okay. So the close-up--in
22 other words, it's the same plant, the same place.

1 You didn't move though, for example--

2 THE WITNESS: Just focused more.

3 JUDGE BITTNER: It's just focused closer
4 in so you can get a sense of the--

5 THE WITNESS: Structure of the bud.

6 JUDGE BITTNER: All right. Thank you.

7 THE WITNESS: Yes.

8 BY MR. BAYLY:

9 Q Then can you explain what Government
10 Exhibit 7, Dr. El Sohly, as it pertaining to the--

11 A Exhibit 7, I believe we went through some
12 of that testimony earlier on when we talked about
13 the vegetative propagation of the plant material
14 indoor growing, and so indoor, we grow the plant
15 material. We isolate the female plant, and then
16 from that, we make cuttings from the female plants
17 and then propagate those indoors, get them to root
18 and so on, and you can see that in the top of the
19 picture where the root system is developed. And
20 then after a while, we can take them out to the
21 field and plant them in the field, and in the top
22 frame, the top--the right-hand bottom one, the

1 darker colored one, these are the plants that
2 actually started indoors from vegetative
3 propagation, sensimilla were moved out in the
4 field, and there is no problem producing a large
5 scale if we need to.

6 This was a trial study to show that we can
7 actually get them started inside, and then we can
8 take them outdoors and put them out and they will
9 survive and flourish and so on. Then, of course,
10 at the bottom is all the results of the analytical
11 data on some of those plants.

12 Q Then moving to Government Exhibit 8, Dr.
13 El Sohly, can you explain what this is?

14 A Yes. Exhibit 8 is basically talking about
15 the selection of some of the different fertilizers
16 and the effect of those fertilizers on the amount
17 of biomass, the THC content, potency, and the value
18 of the material that comes out, how much material
19 you can get out of the plant, not only seeds, but
20 seeds and biomass. And it's very clear that one
21 product has much better influence on those
22 parameters, on the biomass of the plant material,

1 usable plant material, on the seed production, and
2 also on the THC content. As shown in the table,
3 the THC content of that Fertilizer A is 11.35 while
4 the B is 7.88 for the same--you know, material from
5 the same genetic make-up.

6 MR. BAYLY: Your Honor, I'd like to move
7 into evidence Government Exhibits 6, 7, and 8.

8 MS. CARPENTER: No objection, Your Honor.

9 JUDGE BITTNER: Received.

10 [Government Exhibit Nos. 6, 7
11 and 8 were received in
12 evidence.]

13 MR. BAYLY: Next we have a series of
14 exhibits labelled--I think if we give the whole
15 package to the witness, we can perhaps--I believe
16 it's going to be Government Exhibits 65 through 71.

17 Your Honor, may I approach the witness?

18 JUDGE BITTNER: Yes.

19 MR. BAYLY: These are Government exhibits
20 marked. They haven't been introduced yet. We'll
21 start backwards here, 65, 66, 67, 68, 69,
22 Government Exhibit 70 and 71, and the witness has

1 been presented with these exhibits marked for
2 identification, and we'll start with Government 65.

3 [Government Exhibit Nos. 65
4 through 71 were marked for
5 identification.]

6 BY MR. BAYLY:

7 Q Dr. El Sohly, what is Government Exhibit
8 65?

9 A Exhibit 65 is a copy of the patent that I
10 have entitled "Method of Preparing
11 Tetrahydrocannabinol". This is a patent, Your
12 Honor, on a method, on a process, that we have
13 developed for the isolation of tetrahydrocannabinol
14 from the plant material in an economic process to
15 produce GNT-delta-9-THC for pharmaceutical
16 development.

17 Q When was this patent obtained?

18 A It was May of 2004.

19 Q All right. The next exhibit is Government
20 Exhibit 66, and I'll ask you what this document
21 represents.

22 A This is another patent that we have

1 actually acquired for the process of isolating THC
2 out of the plant material prior to the one on
3 Exhibit 65. This one predates that one. This
4 second patent, which is here as Document 65 or
5 Exhibit 65, is a continuation to the one that is
6 Document or Exhibit 66. That issued in 2002.

7 Q All right. Now I will refer to you
8 Government Exhibit 67 and ask you what this
9 document represents.

10 A 67 is a process patent for, you know,
11 method of preparing tetrahydrocannabinol esters.
12 These are prodrugs that you prepare to help the
13 bioavailability process of THC. THC as is
14 currently available in the soft gelatin capsules
15 for oral intake has some problems with
16 bioavailability, and we developed a prodrug,
17 delta-9-THC hemisuccinate, which is an ester the
18 delta-9-THC that could be formulated into a
19 suppository, and once it's administered, the drug
20 gets into the body and immediately breaks off into
21 THC along with another component, which is a
22 natural component of the blood. So it doesn't

1 introduce any extraneous materials, but, rather,
2 helps the THC to be made bioavailable from that
3 formulation.

4 This patent here reflects the chemical
5 process for manufacturing the prodrug.

6 Q When was this patent obtained?

7 A That was December of '99.

8 Q All right. Now next please turn to
9 Exhibit 68?

10 A 68 is a patent that I have on the
11 suppository formulation that I just referred to in
12 the previous patent. The previous patent deals
13 with the process of making the chemical itself.
14 This patent refers to the actual pharmaceutical
15 formulation that incorporates the delta-9-THC
16 hemisuccinate in it with a stability profile that
17 allows it to have a shelf life of two years, or at
18 least two years, to be useful in the pharmaceutical
19 industry. This patent issued in 1996.

20 Q Then the next document I'd like you to
21 explain, Dr. El Sohly, is Government Exhibit 69.

22 A This is another patent that we have had

1 along the same line for the suppository
2 formulations affecting bioavailability, and this
3 patent issued in February of '95.

4 Q The next one I'd like you to explain is
5 Government Exhibit 70?

6 A This is the--I had presented some
7 testimony earlier regarding the fingerprinting of
8 cannabis of marijuana for different origins. This
9 particular patent described the process that you
10 use to enable you to determine the country of
11 origin based on a chemical analytical procedure.
12 That's the method of identifying country of origin
13 of cannabis, and it issued in 1993.

14 Q All right. Then the next one I'd like to
15 have you please explain is Government Exhibit 71.
16 It looks like the last one, is it not?

17 A Yes, it is. Exhibit 71 refers to a
18 process of preparing cannabichromene, abbreviated
19 as CBC. Cannabichromene is a cannabinoid that has
20 biological activities of its own. It doesn't have
21 psychological activity, but has other biological
22 activities such as anti-inflammatory and

1 antimicrobial activity, and this is a process for
2 manufacturing this material and not having to rely
3 on the plant material to produce that particular
4 cannabinoid. This patent was issued in 1982. I
5 think it's expired by now.

6 MR. BAYLY: Your Honor, I would like to
7 move into evidence Government 67, 68, 69, 70 and
8 71.

9 JUDGE BITTNER: Okay.

10 MS. CARPENTER: No objection, Your Honor.

11 JUDGE BITTNER: Received.

12 [Government Exhibit Nos. 65
13 through 71 were received in
14 evidence.]

15 JUDGE BITTNER: Doctor, what is Citral,
16 C-I-T-R-A-L? It's referenced on the first page of
17 Government Exhibit 71, the cannabichromene. It
18 refers to condensation of Citral with a substitute.

19 THE WITNESS: Citral is a terpene. It's a
20 monoterpene.

21 JUDGE BITTNER: Thank you.

22 THE WITNESS: It smells like citrus. It's

1 actually the terpene in citrus fruits. That's
2 where the name is coming in from. It smells like a
3 freshly-squeezed orange.

4 JUDGE BITTNER: And I'll never make a
5 lemon pie again without thinking of marijuana.
6 That's going to confuse my family.

7 Okay. And the exhibits that I just
8 received were Government Exhibits 65 through 71.
9 Right?

10 Yes.

11 MR. BAYLY: Thank you, Judge Bittner.

12 Dr. El Sohly, we're on the last topic, and
13 this is regarding DEA registrations that you
14 currently have.

15 And, Your Honor, I would like to present
16 the witness with Government Exhibits--let me make
17 sure I've got them all here--74, 75, 76, 77.
18 That's it.

19 JUDGE BITTNER: Okay.

20 MR. BAYLY: May I approach the witness?

21 JUDGE BITTNER: You may.

22 BY MR. BAYLY:

1 Q Dr. El Sohly, I now am going to present
2 you with what's been marked for identification as
3 Government Exhibits 74, 75, 76, and 77, and these
4 are facsimiles or copies of facsimiles of DEA
5 registrations. So I would like you to refer to
6 these documents as I ask you to just a few
7 questions about these registrations.

8 Let me ask you first to turn to Government
9 Exhibit 76, and would you please identify it?

10 A Exhibit 76 is a manufacturer's
11 registration that we have at the National Center
12 for Natural Products Research specific to NIDA
13 marijuana project. It's a manufacturer's license
14 that is specific to the NIDA marijuana project.

15 Q Is this, then, the DEA registration under
16 which the University of Mississippi contracts with
17 NIDA and supplies marijuana to researchers pursuant
18 to the NIDA contract?

19 A Yes. It's part of the registrations that
20 are required to do this work.

21 Q And when was this registration as a
22 manufacturer initially granted to the University of

1 Mississippi?

2 A I don't recall. Maybe two or three years
3 ago or maybe more. I don't really remember.

4 Q Okay.

5 A Because the date on this here only gives
6 the expiration date, and it's only for one year.

7 Q How often do you have to renew the
8 registration?

9 A This has to be renewed every year.

10 Q Okay. Let's move on now to Government
11 Exhibit 75, and I'll ask you to please identify the
12 registration, what kind of registration it is and
13 what specifically it's used for.

14 A Exhibit 75 is a manufacturer's
15 registration that we have at the National Center
16 for Development of Natural Products, University of
17 Mississippi, and this registration here has not
18 anything to do with the NIDA contract. This is a
19 registration that we have in the center to be able
20 to develop pharmaceutical preparations that might
21 be based on the natural components in the cannabis
22 plant, including but not limited to delta-9-THC.

1 Q Now just to make sure we're clear on the
2 record, both Government Exhibit 75 and 76 are
3 manufacturing registrations pertaining to what
4 controlled substance?

5 A This would be Schedule I and Schedule II.

6 JUDGE BITTNER: Okay. It doesn't say two.

7 THE WITNESS: Well, I'll take that back,
8 Your Honor. Schedule I.

9 JUDGE BITTNER: Okay.

10 THE WITNESS: I thought I had Schedule II
11 also.

12 BY MR. BAYLY:

13 Q Which Schedule I controlled substance?

14 A Marijuana and cannabinoids.

15 Q Is that for all these manufacturing
16 registrations?

17 A That's correct.

18 Q Now turning to this one you're testifying
19 about in Government Exhibit 75, about when did you
20 apply for this registration, what year?

21 A 75 was much older than 76. We applied for
22 the 75 back in around 1977--'97. 1997.

1 Q About when was it initially granted?

2 A It was granted in '99, 1999, almost the
3 end of '99, October or November of '99. It took
4 three years to get that registration almost.

5 Q Now turn and look at Government Exhibit
6 77.

7 A 77 is the registration as an analytical
8 laboratory, which is really the kind of
9 registration that we have been operating under with
10 NIDA since the inception of the program, the
11 analytical lab license or registration.

12 Q All right. Now, Dr. El Sohly, what does
13 this analytical lab registration allow you to do in
14 terms of--first of all, what Schedule I substance
15 does it pertain to?

16 A It pertains to marijuana, cannabinoids,
17 and any of the other substances.

18 Q And what does this registration authorize
19 you to do in terms of marijuana and its
20 cannabinoids?

21 A Well, it authorizes us to handle those
22 materials, to provide these materials to other

1 investigators, to allow us to acquire materials
2 from other investigators, from other labs. It
3 allows us to do research for these materials.
4 Analytical license is a broad spectrum license that
5 if you have it, you can do a lot more than doing
6 just a researcher license or a manufacturer
7 license. Manufacturer licenses are restricted to
8 the research and operations that would require the
9 manufacturer license.

10 MR. BAYLY: Your Honor, I'd like to admit
11 Government Exhibits 75, 76, and 77.

12 MS. CARPENTER: We have no objection.

13 JUDGE BITTNER: Received.

14 [Government Exhibit Nos. 75,
15 76, and 77 were received in
16 evidence.]

17 BY MR. BAYLY:

18 Q All right. Dr. El Sohly, I'd like to now
19 have you turn your attention to Government Exhibit
20 74, and first of all, what kind of registration is
21 Government Exhibit 74?

22 A This registration is a researcher

1 registration that would allow you only to do
2 research for the material that you have a
3 registration for, in this case, Schedule I and II.

4 Q Now, under this registration, is the
5 University of Mississippi permitted to research
6 with marijuana as cannabinoids?

7 A Yes, sir, it does.

8 Q And has, actually, the University of
9 Mississippi utilized this registration?

10 A Yes, sir.

11 Q Can you tell us very roughly how long the
12 University of Mississippi has had this
13 registration?

14 A This was 1995, I believe is when I
15 acquired that registration, around that timeframe.

16 Q All right. Is this a registration--how
17 often does this registration have to be renewed?

18 A All DEA registrations are renewable
19 annually. You have to submit a renewal application
20 and get the registration renewed annually. It
21 takes a lot longer to get the manufacturer's
22 registration renewed because of the process that it

1 goes through, but it's an annual registration.

2 MR. BAYLY: Your Honor, I'd like admit
3 Government Exhibit 74.

4 MS. CARPENTER: No objection.

5 JUDGE BITTNER: Received.

6 MR. BAYLY: And if I may just have a brief
7 moment, Your Honor, a quick pause.

8 [Mr. Bayly confers with Ms. Paredes.]

9 MR. BAYLY: That's it for the direct,
10 Judge Bittner. I request, perhaps, if we could
11 take a short break before the cross commences.

12 JUDGE BITTNER: I think that's an
13 excellent idea. How about 15 minutes?

14 Off the record.

15 JUDGE BITTNER: On the record. Ms.
16 Carpenter.

17 MS. CARPENTER: Thank you, Your Honor.

18 CROSS-EXAMINATION

19 BY MS. CARPENTER:

20 Q Good afternoon, Dr. El Sohly.

21 A Good afternoon.

22 Q I'm Julie Carpenter, and I represent the

1 respondent in this matter, as you probably know.

2 A Yes, ma'am.

3 JUDGE BITTNER: He might have figured that
4 out.

5 BY MS. CARPENTER:

6 Q So I have some questions for you, as you
7 also probably figured out.

8 A Sure.

9 Q First, let me ask you--I think you
10 indicated that the UMiss program, in terms of
11 cultivating marijuana for NIDA, has been in
12 existence since about 1968; is that right?

13 A That's correct.

14 Q Now, prior to that--and I know you weren't
15 there--but prior to that, University of Mississippi
16 didn't have any experience growing marijuana; isn't
17 that correct?

18 A That's correct.

19 Q Did I have experience or expertise in
20 plant and soil sciences?

21 A Yes. There is a department in the School
22 of Pharmacy. Again, I refer back to one of the

1 terms that I used, pharmacognosy. That department
2 is the department that deals with natural products,
3 deals with herbal medicines, deals with
4 cultivation, harvesting, drying, processing of
5 plant material. We had at the University of
6 Mississippi at the time, we had back then and we
7 continue to have, a medicinal plant garden where
8 plant material is produced, that is to say,
9 medicinal plants are produced, not just any plant
10 material but medicinal plants are produced at the
11 medicinal plant garden at the University of
12 Mississippi way prior to 1968,

13 Now, the School of Pharmacy at the
14 University of Mississippi also houses the Research
15 Institute of Pharmaceutical Sciences, which is a
16 separate institute from the academic departments,
17 where it specializes only in the research and
18 development activities, and that particular
19 research institute was created in 1964 with the
20 charge of developing natural products as
21 medicinals, and medical products out of natural
22 materials, and also agrochemicals. So there's a

1 lot of history at the University of Mississippi in
2 that regard.

3 Q And it would be fair to say that that
4 expertise in plants and soil sciences and in
5 developing medicinal plants was a good foundation
6 for the University of Mississippi to get this
7 contract in the first place, wouldn't it?

8 A That's correct.

9 Q Now, at that time, when the University of
10 Mississippi first got this contract, you wouldn't
11 have had expertise in security measures, would you?

12 A I would say no, probably not.

13 Q So is it fair to say that probably the
14 expertise required at that time to grow the
15 marijuana, cultivate the marijuana, not the testing
16 part of it, but the growing and the cultivation,
17 was the expertise you described in the plant and
18 soil sciences in the development of medicinal
19 plants?

20 A That's correct.

21 Q Dr. El Sohly, are you familiar with Dr.
22 Lyle Craker; do you know him?

1 A To be honest with you, I didn't know who
2 he was until this case came up, but then I met him--there
3 was a meeting of medicinal plants and herbal
4 products and quality controls and so on for these
5 herbal products that was in collaboration or in
6 association with the society that he heads right
7 now, and that was held in Mississippi. And he came
8 to Mississippi, and I met him personally for the
9 first time. I had a pleasant talk with him.

10 Q And so you're aware that he has this
11 particular society that you just referred to?

12 A Yes, yes.

13 Q And so you don't have any reason to
14 question his expertise in plant and soil sciences--

15 A No, absolutely not, no.

16 Q So you would agree he would have an
17 expertise in that area?

18 A Sure, yes.

19 Q Now, let me ask you a few questions about
20 the marijuana you grow at the University of
21 Mississippi, the research marijuana. I think you
22 indicated that you grow it in a space. The outside

1 space is about 12 acres.

2 A That's correct.

3 Q And I think you indicated that the
4 majority of what you grow is outside; is that
5 right?

6 A That's correct.

7 Q And are those 12 acres located in the same
8 place or are they--

9 A It's in the same place.

10 Q All in the same place.

11 A Yes.

12 Q So if--well, we all know hurricanes hit
13 Mississippi from time to time, don't we, from
14 recent experience? If a natural disaster were to
15 strike there, the entire crop you had currently
16 growing would be at risk; is that right?

17 A That's correct.

18 Q If there were a tornado or--

19 A God forbids it, yes, that is a
20 possibility. We actually had problems this year,
21 but we--did not affect us. This is the worst
22 hurricane in the history of the country, and it did

1 have--we had some plants in the garden actually,
2 but you know, those plants survived. We had to
3 prop them back up and everything, but nonetheless,
4 they--we were hit this year, but it did not affect
5 the outcome of what we had in the ground.

6 Q I know you answered some questions about
7 the timeline of your registrations, but I just want
8 to go back over that so I have them in my own head,
9 what they were. When did University of Mississippi
10 first obtain its DEA registration as a bulk
11 manufacturer of marijuana?

12 A The first one was 1999.

13 Q 1999. And is that the registration that
14 was related to the NIDA project?

15 A No. The one that's related to the NIDA
16 project came after that.

17 Q Okay. And that was--and what year was the
18 NIDA project--

19 A Honestly, unless you allow me to look, I
20 don't remember. But they're all, you know, pretty
21 close.

22 Q If you have something there that would

1 refresh your recollection as to when you got the
2 bulk registration for the NIDA project, it would be
3 helpful to me.

4 A Actually, I have asked my staff to give
5 you some dates and things like that because of some
6 of the questions that Mr. Bayly had asked me, and I
7 didn't remember, so I asked them to put it on this,
8 but that was not one of them. So I don't have the
9 date for you actually, but that's easy. I can get
10 it for you by tomorrow sometime.

11 Q Okay. So maybe we could follow up on that
12 tomorrow.

13 A Sure.

14 JUDGE BITTNER: Can I just ask--so the
15 University of Mississippi didn't have any
16 manufacturing registration before 1999 for
17 anything?

18 THE WITNESS: That's correct, Your Honor.
19 We had analytical registration which allows to do
20 the same thing, yes. The analytical registration,
21 as I testified before, is somewhat--it's a very
22 broad registration that will allow you to do--

1 JUDGE BITTNER: And that's an analytical
2 level--

3 THE WITNESS: As analytical level, it will
4 allow you to do a lot of things including
5 manufacturing, but not manufacturing for
6 pharmaceutical development.

7 JUDGE BITTNER: Okay.

8 THE WITNESS: Bulk manufacturing for--if
9 you manufacture for research, no problem under the
10 analytical license, but for manufacturing for
11 putting a product out on the market, the you have
12 to have the manufacturer registration.

13 JUDGE BITTNER: And is that why you got
14 it?

15 THE WITNESS: Yes, ma'am.

16 JUDGE BITTNER: Okay.

17 BY MS. CARPENTER:

18 Q So the 1991 one--1999 registration, bulk
19 manufacturer registration, was for--how should we
20 separate this--for University of Mississippi
21 privately, not connected with the NIDA contract; is
22 that right?

1 A That's correct.

2 Q So I'll just refer to that as the private
3 one to distinguish it from the NIDA one, that--

4 A Well, how about the pharmaceutical
5 development manufacturing license.

6 JUDGE BITTNER: If you refer to the
7 private one, then you could be getting into--

8 THE WITNESS: Yeah. Because I have
9 personally, in my private lab, I have a
10 manufacturing registration also.

11 BY MS. CARPENTER:

12 Q So you have three, three manufacturing
13 licenses?

14 A Yeah. Maybe four before too long.

15 Q So in 1999 you got the pharmaceutical one
16 for University of Mississippi?

17 A Yes, because that--remember, that started
18 actually in 1997.

19 Q Okay.

20 A I mean the application for that
21 registration started in 1997.

22 Q The application did.

1 A The application, and did not come in until
2 October of '99. Now, the request for proposals
3 from NIDA supplied to the request for proposal that
4 came out in July of '99, there was no requirement
5 by NIDA for us or anybody that applies for the
6 contract to have a manufacturer registration.
7 That's why we didn't have it.

8 Q I see.

9 A Now, when the request for proposal came in
10 in 1999, July of '99, it had in it that the
11 applicant should have, you know, these
12 registrations or be qualified to have these
13 registrations. Of course in 1999 we already had
14 one registration as a manufacturer, and in my
15 judgment, a manufacturer registration is a
16 manufacturer registration, and would allow you to
17 do anything and everything that you want to do
18 under the manufacturer registration. So the one
19 that we had--even though we had for us as a
20 University of Mississippi, not specified for NIDA--would
21 qualify to do the NIDA work if that was a
22 prerequisite for getting the contract.

1 So we met the letter of the law for the
2 RFP, but when that came in for NIDA, you know,
3 requesting that the applicants have to have this,
4 we talked to NIDA and talked to the DEA, and
5 whether we can do everything under the same
6 manufacturing registration, and DEA preferred that
7 we separate the two registrations and apply for a
8 new one.

9 Q Do you know why that was?

10 A I don't like to have more than one, to be
11 honest with you, but--

12 Q Did anyone tell you why that was, why they
13 wanted you to have a separate one?

14 A Just to keep the two manufacturer
15 registrations separate, the one for--remember, the
16 manufacturer registration that we had for the
17 institute is not for distributing that marijuana.
18 It's for growing that marijuana, harvesting that
19 marijuana, and process that marijuana to prepare an
20 extract that could be used to develop the
21 formulations and the THC out of that material, but
22 not to distribute it to anybody.

1 Q And where were those limitations that you
2 just mentioned? Where are those founds? Because
3 they were not on the face of the license that you
4 showed us. How do you know that the manufacturer's
5 license that you got in 1999 was limited to
6 growing, harvesting, but not distributing?

7 A Because it was a growing, harvesting and
8 processing that plant material to prepare the
9 extract.

10 Q And how do you know that? Was that a
11 limitation the DEA put on that license?

12 A That's correct, yes.

13 Q And where is that found?

14 A Well, it's--actually, it's be regulation
15 that you cannot distribute because it has to be--the
16 government would have to--you know, the
17 distribution is a government function, not a
18 private organization function.

19 Q And what regulation is that, do you know?

20 A I'm not a lawyer so I can't quote you a
21 regulation, but I know the current Federal Register
22 probably refers to that.

1 Q But you're not aware of a specific
2 regulation that says that only the government can
3 distribute marijuana?

4 A Well, there's the Single Convention. I
5 believe it's part of the Single Convention
6 requirements, but I'm not getting into these legal
7 issues because I'm not really--all I know is that I
8 could not distribute marijuana as a institute on my
9 own, and therefore, they preferred to have a
10 separate registration for NIDA, and when I'm
11 distributing marijuana or cigarettes or whatever,
12 I'm not doing it as University of Mississippi, but
13 I'm doing it as a contractor for the government.

14 Q Now, are there any limitations you're
15 aware of, in addition to the ones you just
16 testified to, that apply to the--I think you
17 referred to it as the institute registration;
18 perhaps that's an easier way to refer to it--any
19 limitations that apply to your license as the
20 institute, the non-NIDA license other than the ones
21 you've just talked about?

22 A Of course, we're subject to the quota

1 requirements.

2 Q I'm sorry. To the what?

3 A The quota, quota, q-u-o--

4 Q Oh, quota, got it.

5 A Sorry about my accent.

6 Q That's quite all right.

7 A The quota requirement, so you have to, you
8 know, ahead of time ask for the quota. You cannot
9 start producing without getting a quota. Right
10 now, for NIDA, on the other hand, without getting a
11 quota, you know, NIDA will tell me how much
12 material they need and I can product that because
13 it's a government requirement, and--but for the
14 other license, I have to have the right quota for
15 both the plant material and extract, and I cannot
16 produce any more than I have a quota for
17 production.

18 Q So in connection with the institute
19 license that you hold, do you grow marijuana?

20 A Yes.

21 Q And how much, approximately?

22 A Just depends. As much as 1,000 or more

1 kilos.

2 JUDGE BITTNER: And that's the institute's
3 registration?

4 THE WITNESS: Yes, ma'am.

5 JUDGE BITTNER: What is the full name of
6 the institute so I don't get tangled up?

7 THE WITNESS: It's NCNPR, National Center
8 for Natural Products Research, NCNPR.

9 BY MS. CARPENTER:

10 Q And then I think you said at the El Sohly
11 Labs you hold a separate bulk manufacturer license;
12 is that right?

13 A Yes, I do, yes.

14 Q And do you know when you obtained that
15 license?

16 A That was a long time ago, in the early
17 '90s.

18 Q It would have been before 1999?

19 A Yes, a lot before. But that's for
20 manufacturing specific materials, not to
21 manufacture marijuana. It's for controlled
22 substances, Schedule I and II and III and IV and V<

1 and so on, all the different classes.

2 Q I'm sorry. Do you hold a bulk
3 manufacturer license for marijuana then as El Sohly
4 Labs?

5 A Not marijuana, no.

6 Q Not marijuana.

7 A But cannabinoids, still Schedule I.

8 Q Not marijuana.

9 A Yes, not the marijuana.

10 Q And can you, under that license that we
11 just spoke of, the one that El Sohly holds, the
12 bulk license, can you grow marijuana to obtain
13 those cannabinoids or anything else?

14 A Not right now, no. I don't have the
15 facility to do that.

16 Q But could you do so under the license if
17 you had the facility?

18 A Well, I don't know if--you know, first of
19 all, I would have to get a quota first for the
20 marijuana. There would be an investigation. DEA
21 would come and look and see if I have the proper
22 things in place to be able to do that. Then they

1 would make a decision whether I can do or I cannot
2 do, but certainly if I can do it, if I can do it
3 for the purpose of extracting the plant material
4 and making, you know, let's say THC out of the
5 plant material, my speculation is I should be able
6 to, but not to distribute that marijuana.

7 Q I understand that, but I'm a little
8 confused. Does El Sohly Labs grow marijuana?

9 A No.

10 Q Okay.

11 A And does not intend to.

12 JUDGE BITTNER: I'm sorry. Does El Sohly
13 Labs have a manufacturing registration?

14 THE WITNESS: Yes, ma'am, we do.

15 JUDGE BITTNER: And that's because of
16 product development hopes.

17 THE WITNESS: Yes, because we are a
18 company that manufactures standards and internal
19 standards for the analytical and forensic
20 laboratory community.

21 JUDGE BITTNER: Okay. So you have a bulk
22 manufacturing registration at El Sohly Labs, and

1 that includes Schedule I?

2 THE WITNESS: That's correct, and II and
3 III and IV.

4 JUDGE BITTNER: Okay. But under that
5 license you could not grow marijuana or you could
6 grow marijuana?

7 THE WITNESS: Right now I couldn't be it's
8 not specified in the list of controlled substances
9 that I'm allowed to manufacture.

10 JUDGE BITTNER: Understand, great.

11 Q All right. Dr. El Sohly, I want to turn
12 now to the issue of Dr. Craker's application to be
13 able to manufacture marijuana. Let me ask you:
14 How did you first hear about that application?

15 A It's advertised in the Federal Register.

16 Q And did you see it in the Federal
17 Register?

18 A Yes, I saw it in the Federal Register.

19 Q Okay. Had you heard about it before then?

20 A I had a copy of the Federal Register
21 comments come to me from DEA just like any other
22 Federal Register comments that go to other

1 registrants that have the same kind of
2 registration.

3 Q Okay.

4 A Like when I applied for one, it went to
5 all other registrants that have similar
6 manufacturer registration, so that's a normal
7 practice by DEA. So I did receive it from DEA, but
8 that's--I received not just Dr. Craker's but I
9 received Mallinckrodt's, I received, you know,
10 CIBA, I received Schering, I received Hoffman
11 LaRoche. It's a natural thing with renewals and
12 particularly new applications, all other
13 registrants who have similar registrations get a
14 copy of the Federal Register notice.

15 JUDGE BITTNER: Is it just in the same
16 format, or is it electronic or what? I mean, does
17 it look like the Federal Register I'm used to
18 looking at, the page from the Federal Register?

19 THE WITNESS: Yeah, it's a page from the
20 Federal Register. It's either faxed or e-mailed.

21 JUDGE BITTNER: Okay.

22 BY MS. CARPENTER:

1 Q Before you saw the Federal Register, did
2 anyone call you about it?

3 A No one called me.

4 Q Okay. Did anyone call you about it after
5 you saw the Federal Register notice?

6 A I believe I talked to Mr. Matt Strait
7 about it, because I wanted to see if my response
8 would be--if I can do a response to that and if I
9 can send it to look at it, just to make sure that I
10 don't say something that is not legal, if you will.
11 And he said no, that's not acceptable practice, so
12 I didn't. I did not send my comments to him.

13 Q To Mr. Strait?

14 A Yeah. That's correct.

15 MS. CARPENTER: Let me ask that the
16 witness be shown Respondent's Exhibit 4.

17 [Pause.]

18 JUDGE BITTNER: Are we through with the
19 registrations, Ms. Carpenter? Can I put them away?
20 The government exhibits that are the registrations?

21 MS. CARPENTER: With the licenses?

22 JUDGE BITTNER: Yes.

1 MS. CARPENTER: I believe we are, Your
2 Honor.

3 MR. BAYLY: Just for the record, has this
4 been admitted?

5 JUDGE BITTNER: Yes. Oh, you're talking
6 about Respondent's 4? I thought you were talking
7 about the licenses, the registrations.

8 MR. BAYLY: No, Respondent's 4. I'm
9 sorry.

10 JUDGE BITTNER: I haven't found it yet.

11 MS. CARPENTER: No, it hasn't.

12 JUDGE BITTNER: No, it hasn't.

13 [Pause.]

14 BY MS. CARPENTER:

15 Q Could you take a look at that?

16 A Yes, I have.

17 Q You have, great. Have you seen that
18 document before, Dr. El Sohly?

19 A I believe I did because the e-mail is
20 coming to me.

21 Q Okay.

22 A That's the e-mail that contained a copy of

1 the Federal Register notice.

2 Q Okay. And who is that from?

3 A That's from Matt Strait.

4 Q And who is he?

5 A He's with the DEA.

6 Q Okay. And do you know why he sent this to
7 you?

8 A Because I'm a registrant--

9 Q Okay.

10 A --for that exact same registration that
11 Dr. Craker is asking for. As a matter of fact, I'm
12 the only registrant.

13 MS. CARPENTER: Okay Your Honor, at this
14 point I would move admission of Respondent's
15 Exhibit 4.

16 JUDGE BITTNER: Any objection, Mr. Bayly?

17 MR. BAYLY: No, no objection.

18 JUDGE BITTNER: Received.

19 [Respondent's Exhibit No. 4
20 received in evidence.]

21 BY MS. CARPENTER:

22 Q What did you do after you received that e-mail

1 from Mr. Strait?

2 A What did I do?

3 Q Yes. I think you said you called Mr.
4 Strait. Was that after you received that e-mail?

5 A Yeah, sometime--we had some--you know,
6 talked sometime after that. The times are, of
7 course, you know, from memory, so I'm not sure
8 exactly when I talked to him. But I talked with
9 him, and I really wanted to get it to the agency
10 that I deal with in terms of the current
11 registration that I have, and that includes NIDA
12 and the DEA. And Matt told me that, no, you can't
13 send it to us.

14 Q You can't send what to us? I'm sorry.

15 A I can't show him my pre-comments copy.

16 JUDGE BITTNER: In draft.

17 THE WITNESS: Draft. A draft copy of my
18 comments. Not that he would write it for me, but I
19 intended to put--to write some comments, and I
20 wanted to ask him if I can send it to him to look
21 at it before I file it. He said, "No, please don't
22 do that. That's not acceptable practice." So,

1 really, I didn't think it was a big deal, but he
2 said no, so I said okay. I didn't send it to him.

3 BY MS. CARPENTER:

4 Q So you did draft up some objections?

5 A I'm sorry?

6 Q So you did draft up some comments?

7 A I wouldn't say objections. I--

8 Q No. Well, I should rephrase that. I'll
9 say comments.

10 A Yeah, I drafted comments, yes.

11 Q Okay. And did you send those to anybody
12 to take a look at?

13 A Yes, I sent them to my center director, I
14 sent them to my center associate director, and I
15 sent them to my project officer. And I believe--I
16 don't remember whether it was at the same time or
17 as a copy to my project officer at NIDA, and then
18 there's his boss, Dr. Gust. My project officer is
19 Dr. Harry Singh, and his boss is Dr. Steve Gust,
20 the associate director of NIDA. I don't remember
21 whether I sent it to both of them at the same time
22 or sent it to one and he got it to the other one.

1 But I did receive minor comments from both of them.

2 Q Okay. Let me step back just a minute and
3 ask, before you--after you talked to Mr. Strait but
4 before you drafted the comments, did you talk to
5 anybody else about the application?

6 A I'm sorry. Before I sent it to Mr.
7 Strait?

8 Q No, no, no. After you talked to Mr.
9 Strait.

10 A Yes.

11 Q But before you drafted the comments.

12 A I don't believe--

13 Q I'm sorry. Did you--

14 JUDGE BITTNER: Wait. We may be assuming
15 a fact not in evidence.

16 MS. CARPENTER: Okay.

17 BY MS. CARPENTER:

18 Q Did you talk to Mr. Strait before you
19 drafted the comments you wanted to file?

20 A Either before I drafted or as I was
21 drafting or right after I drafted or something. I
22 don't know the time frame.

1 Q All right. Let me just rephrase it this
2 way then. Did you talk with anybody else about the
3 Craker application prior to sending your drafted
4 comments to someone for review?

5 A I don't know what you mean by anybody
6 else. I don't remember who I talked to, but I
7 certainly talked to my project officer, talked to
8 Matt, and maybe talked to Dr. Gust or not, talked
9 to my director, talked to my associate director. I
10 don't know who else--

11 JUDGE BITTNER: And those are people at
12 the University of Mississippi?

13 THE WITNESS: Yes, ma'am.

14 JUDGE BITTNER: All right.

15 THE WITNESS: I don't remember who else I
16 talked to.

17 MS. CARPENTER: Okay.

18 THE WITNESS: If you have somebody
19 particular in mind, I'll be glad to tell you
20 whether I did talk with that person or not.

21 BY MS. CARPENTER:

22 Q Well, we'll get to that in a minute. I

1 just want to get your recollection right now of who
2 you spoke to.

3 A Okay.

4 Q So you said you talked to the project
5 officers. Those would be people at the University
6 of Mississippi or--

7 A No. At NIDA.

8 Q This would be NIDA?

9 A Yes.

10 Q Okay. And do you remember who at NIDA you
11 might have talked to about that?

12 A Dr. Harry Singh and Dr. Steve Gust.

13 Q Okay. And this was before you had drafted
14 any comments?

15 A This is when you're going to really get me
16 in trouble here because I don't remember when, but
17 it's possible that I just sent them the draft. I
18 don't remember the sequence of things.

19 Q Okay. Did anyone ever ask you to draft
20 comments?

21 A Absolutely not.

22 Q Okay. Did anyone draft up comments for

1 you?

2 A Absolute--I wouldn't do that. I wouldn't
3 ask somebody to draft something for me.

4 MS. CARPENTER: Okay. Let me ask that the
5 witness be shown Respondent's Exhibit 5.

6 [Pause.]

7 THE WITNESS: Okay. This is the--

8 MS. CARPENTER: Wait just a minute. Let
9 me ask you a question. And before we get to that,
10 let me just back up for one more minute.

11 BY MS. CARPENTER:

12 Q You are familiar with the statutory
13 criteria under which DEA grants an application for
14 a bulk manufacturing license, aren't you?

15 A To some extent, yes.

16 Q Okay. Did you discuss with anyone whether
17 Dr. Craker would meet those statutory criteria?

18 A No, because I didn't know Dr. Craker.

19 Q Did you discuss with anyone whether adding
20 one more bulk manufacturer to the field of one,
21 which would be you--I think you testified a few
22 minutes ago you held the only registration--whether

1 adding one more bulk manufacturer would increase
2 competition in the provision of marijuana?

3 A No, I didn't. But the competition is--if
4 I may just--

5 Q Well, if you'd just answer my questions,
6 that would be great.

7 A Well, that's answering your question to
8 the fullest, not just--

9 Q I think you said--I said did you discuss
10 it with anyone, so if the answer was no--

11 A No, but you said to increase competition,
12 so I need to comment on the competition part of it.

13 JUDGE BITTNER: No, sorry.

14 BY MS. CARPENTER:

15 Q The question is: Did you discuss it?
16 That's the only--

17 A No, I didn't discuss--

18 Q --yes or no--okay. Thank you.

19 At any time did you see Dr. Craker's
20 application?

21 A No.

22 Q Okay. So did you know how much marijuana

1 for medical research purposes he planned to grow?

2 A No.

3 Q Now, if you would turn again to Exhibit 5,
4 which I've given you, have you seen that document
5 before? It's an e-mail and a draft of a letter.

6 A That's an e-mail from me.

7 Q Okay. And can you--the e-mail is from you
8 to whom?

9 A Remember when I told you that I sent the
10 copy--I don't know whether I sent it at the same
11 time or a different time. Obviously in this e-mail
12 here, that was sent to all the people that I
13 mentioned, to Dr. Singh, Dr. Gust, Dr. Walker, who
14 is the director of the institute, and Dr.
15 Chambliss, who is associate director of the
16 institute, of our institute.

17 Q Of the it--okay.

18 A Of the University of Mississippi.

19 Q Right.

20 A So these are the people that I sent the
21 draft to.

22 Q Okay.

1 A But they had no input in that initial
2 draft whatsoever.

3 Q Okay. And is that a copy of the draft
4 that you sent?

5 A Yes.

6 MS. CARPENTER: Okay. At that point I
7 would move Respondent's Exhibit 5 into evidence.

8 MR. BAYLY: No objection.

9 JUDGE BITTNER: Received.

10 [Respondent's Exhibit No. 5
11 received in evidence.]

12 BY MS. CARPENTER:

13 Q If you will look in the second paragraph
14 of your cover e-mail, the second sentence begins,
15 "I understand, Dr. Gust and Dr. Singh, that I might
16 have information there that NIDA would not want me
17 to include, and I'll certainly remove it if that is
18 the case." Do you see that?

19 A I'm sorry. Say that again?

20 Q Do you see that, where I was reading from?

21 A No. I thought you--

22 Q The second sentence in the second

1 paragraph.

2 A Okay.

3 Q "I understand, Dr. Gust and Dr. Singh,
4 that I might have information there that NIDA would
5 not want me to include, and I'll certainly remove
6 it if that is the case."

7 A That's correct.

8 Q Okay. Did you have any particular
9 information in mind that you thought NIDA wouldn't
10 want--

11 A No, I--

12 Q --you to include in--

13 A You have the whole--

14 Q --that draft?

15 A You have the whole draft, and you also
16 have copies of the final draft, and you have copies
17 of the intermediate drafts.

18 Q Yes, I do. I'm asking you whether at the
19 time you wrote that letter there was information in
20 that letter that you thought NIDA might not want
21 you to include.

22 A No, I don't.

1 Q Okay. So why did you put that in there?

2 A Well, just in case. There's no reason to
3 send a draft to somebody if you didn't feel that
4 that somebody might have some information or
5 something that needs to be taken out or deleted or
6 added or whatever.

7 Q Okay.

8 A For whatever reason, not that, you know,
9 it's wrong or right or whatever, but it could be
10 some other reasons why, you know, some information
11 need not to be there.

12 Q Okay. If you would turn to the draft of
13 the letter itself.

14 A Okay.

15 Q And on page 1--they're unnumbered pages,
16 but the first page--if you would look at paragraph--the
17 fifth paragraph, do you see that?

18 A Yes.

19 Q Starting with, "Under NIDA's registration..."

20 A Yes.

21 Q Okay. Do you need a minute to read that

1 paragraph to--

2 A Well, if you tell me what you're after--

3 Q Okay. Well, it's that whole paragraph--

4 A --I can focus--

5 Q --so you might want to take--and the
6 sentence on the next page. That concludes it.

7 [Pause.]

8 THE WITNESS: Okay.

9 BY MS. CARPENTER:

10 Q Was it your understanding as you wrote
11 that paragraph of the letter that if a private
12 researcher wanted to do an FDA-approved medical
13 research project with marijuana, that that private
14 researcher could just request that from NIDA and it
15 would be provided at no cost?

16 A That was my understanding.

17 Q Okay. So there would be no need for NIDA
18 to approve the protocol or the request? Was that
19 your understanding at the time?

20 A Well, my understanding is first NIDA has
21 to approve it, regardless of whether the
22 individuals are paying or not, because this is

1 coming from another supply. If NIDA had some other
2 procedures--which I later on learned that there is
3 another protocol that, you know, going through the
4 NIDA process even for the researchers that will pay
5 for the material.

6 Q Okay.

7 A I wasn't aware of that part of it, but I
8 can assure you that I knew that NIDA had to approve
9 it. It's not just researchers, get me an approval
10 from FDA or another agency for the protocol and
11 then they get the material. I'm saying the
12 mechanism is there for researchers that are not
13 funded by NIDA to acquire material.

14 Q Okay. But in your letter, you understood
15 at the time that they didn't require NIDA approval
16 of the protocol, just NIDA approval of the request.
17 Is that correct?

18 A That's correct.

19 Q Okay. And so the next sentence--the last
20 sentence of that paragraph is, "Thus, there is no
21 gap to be filled by another registrant." And
22 that's because you assumed that any researcher who

1 had an FDA-approved protocol and a DEA license--

2 A I'm not sure FDA--

3 Q Wait, let me just finish the question for
4 the record. That is because you assumed that any
5 FDA-approved protocol with a DEA licensed
6 researcher would be eligible and would receive NIDA
7 marijuana. Is that right?

8 A That possibility is there, yes.

9 Q Okay. But was that your understanding at
10 the time you wrote this letter?

11 A Yes. I just said yes.

12 Q Okay. So that there--even if NIDA didn't
13 approve the protocol, that those researchers could
14 still get--

15 A Approving the protocol means that--it is
16 not approved for funding, with funding. I didn't
17 say with funding, but approved through the NIDA
18 process. There is a NIDA--there is two processes
19 there. There is a process where the protocol of
20 the proposal is going for NIDA's approval and
21 funding through a grant, for example, a grant
22 proposal that goes in, gets reviewed by NIDA, and

1 then it's funded. And there is a process where it
2 goes and gets approved by NIDA through the other
3 system that I wasn't aware of at the time when I
4 wrote this memo. Nonetheless, it has to be
5 approved by NIDA.

6 Q Okay. So was it your understanding when
7 you wrote the memo that there could be researchers
8 who had FDA-approved protocols and DEA licenses who
9 would not receive marijuana through the NIDA
10 program?

11 A I didn't think that there would be some
12 that would fall under that category.

13 Q You did not think there would be any?

14 A That's correct.

15 Q Okay. And that's why you said there's no
16 gap, because everybody would get--

17 A That's correct.

18 Q Every FDA-approved researcher with a DEA
19 license would get--

20 A Well, I didn't say FDA because I don't
21 know about FDA. I said...do not meet the
22 scientific criteria by NIDA for--and that would be

1 for funding.

2 Q But excluding the funding issue--

3 A Yes.

4 Q Okay? Just focusing on FDA researcher
5 with a DEA license--

6 A But, see, I didn't refer to any FDA here
7 because--

8 Q I understand.

9 A --I don't know that.

10 Q But you didn't know at the time that
11 anybody who wanted to do research, clinical
12 research on marijuana would require an FDA-approved
13 protocol?

14 A You have to have that as a given.

15 Q Okay.

16 A To do the--you have to file the IND.

17 Q Right.

18 A I assume that that's a process you have to
19 go through.

20 Q Okay. So a person has the IND, they have
21 the FDA-approved protocol, they have the DEA
22 license. Was it your understanding when you wrote

1 this letter that anybody in such a position would
2 be able to get a sufficient quantity of the
3 sufficient type of marijuana that they needed--

4 A And pay for it--

5 Q --from NIDA? And pay for it.

6 A That's correct.

7 Q Okay. Thank you.

8 I think you testified that your understanding
9 about that second component, that is,
10 access to NIDA marijuana if a researcher is willing
11 to pay for it, changed at some point. Is that
12 right?

13 A Well, not the--not the understanding. The
14 process. I understand that the process is not just
15 if it goes through the NIDA program for funding and
16 that protocol is not approved, then the process--there is
17 another organization or another group or
18 another committee that actually looks at the
19 protocol for, you know, scientific and technical
20 and ethical merit would have to review it to
21 approve it. That I didn't know.

22 Q Okay.

1 A That process I wasn't aware of at that
2 time.

3 Q Okay, fine. Are you aware that NIDA has
4 declined to provide marijuana for some FDA-approved
5 research to DEA-approved researchers?

6 A I don't know that, you know, that--I might
7 know that through what I heard about that, but not--not
8 directly through NIDA, because if the request
9 goes to NIDA and NIDA refuses it, I never know
10 about it.

11 Q Okay. But are you just aware of that from
12 other things that you know?

13 A Yes.

14 Q Okay.

15 JUDGE BITTNER: Other than this
16 proceeding?

17 THE WITNESS: Yes, because I think in some
18 of this, I go to these scientific committees, Your
19 Honor--not committees but meetings, and, you know,
20 the investigators talk, well, NIDA didn't approve
21 this, they didn't give that, you know, they just
22 mentioned that in those meetings. But I didn't

1 know firsthand whether NIDA's approved or not
2 approved. I'm not involved in that decisionmaking
3 process.

4 JUDGE BITTNER: Okay.

5 BY MS. CARPENTER:

6 Q And, I'm sorry, you just testified--were
7 you testifying about the meeting with Donald
8 Abrams?

9 A Meetings I have been going to, the ICRS
10 meeting for so many years.

11 Q Okay. Any--

12 A And I see, you know, people there.
13 Actually, the first time that I really heard about
14 this more intensively was about a year, two years
15 ago in the IACM meeting when they were talking
16 about it, and it was a forum for people to more or
17 less voice complaints about the program and the
18 materials and so on and indicated that NIDA doesn't
19 approve some of these protocols and doesn't provide
20 material. So I heard about it from the
21 investigators, not through the process.

22 Q Okay. And do you recall whether

1 investigators made those statements?

2 A I think there was--Dr. Abrams was probably
3 there. There was some from the San Francisco area,
4 some other investigators. Their names are escaping
5 me.

6 JUDGE BITTNER: And what is IACM?

7 THE WITNESS: IACM is International
8 Association for Cannabis for Medicine, for medical--
9 medicinal cannabis.

10 JUDGE BITTNER: But it's C-M, not M-C?

11 THE WITNESS: I-A-C-M, International
12 Association for Cannabis as Medicine.

13 JUDGE BITTNER: Thank you.

14 BY MS. CARPENTER:

15 Q So, I'm sorry, you said Dr. Abrams and
16 then some other investigators from the San
17 Francisco area. Do you recall anyone else?

18 A No. Maybe Dr. Rosso was there also.

19 Q Okay.

20 MR. BAYLY: I'm sorry. I didn't hear that
21 name.

22 THE WITNESS: Ethan Rosso.

1 MR. BAYLY: Okay.

2 THE WITNESS: I don't remember who else is
3 there, but in that meeting, there was the--what I
4 should say?--the...the association business meeting
5 or something where they described some of the
6 problems that they are having with, you know,
7 getting supply and so on. It came up in that
8 meeting.

9 BY MS. CARPENTER:

10 Q When you say it came up, you're talking
11 about the fact that they said that NIDA was not
12 providing--

13 A Some--some protocols that were not funded--were
14 not approved and, therefore, they didn't get
15 materials to do the work that they wanted--

16 Q Okay.

17 A So I heard from the investigators.

18 Q So FDA-approved protocols that were not
19 approved by NIDA.

20 A I mean, it wasn't explicit to me as
21 whether they were FDA approved or otherwise.

22 Q Okay. Now, if you look at page 2 of that

1 draft, the third paragraph.

2 A Third paragraph.

3 Q Well, the paragraph that begins, "Since
4 the inception of the program..."

5 A Okay.

6 Q And the sentence reads, "Since the
7 inception of the program and implementation of the
8 process of making marijuana and marijuana
9 cigarettes available for research, the objective
10 was to make cigarettes at potencies comparable to
11 that of average marijuana potency being used by the
12 general population."

13 Now, the objective you're talking about
14 there is NIDA's objective; isn't that right?

15 A Yes.

16 Q Okay. And that's because most of the
17 research done by NIDA goes to examine harm caused
18 by marijuana; isn't that right?

19 A I would say yes.

20 Q Okay.

21 A At that time, yes.

22 Q Okay. So the purpose--

1 A That is throughout the process.

2 Q Right. So you'd want to be studying--you'd want
3 to have marijuana available at potencies
4 that were generally available to the population so
5 that you could determine what the effects of that
6 illicit use were; isn't that right?

7 A That's correct.

8 Q Okay. But that objective isn't really
9 relevant when you're talking about the therapeutic
10 benefits of marijuana, is it?

11 A I think it's very relevant. Very, very
12 relevant. Do you want me to tell you why? If you
13 want, I will. If you don't, I won't.

14 Q Well, let me ask you this: Have you ever
15 spoken to doctors and researchers to determine what
16 level of potency they want to use for their
17 research?

18 A I think it's--it's kind of--takes the
19 point away from the scientific end of it when you
20 say what they want to do with it. I think you need
21 to--

22 Q It takes the point away--

1 A --look--yes, it takes it away from--

2 Q You don't talk to the researchers who are
3 doing the research?

4 A You're asking me about what they want to
5 do.

6 Q The researchers who are doing the research
7 with medical marijuana, have you talked to them
8 about what potencies they would like to use?

9 A They haven't talked to me.

10 Q And you haven't called them--

11 A Except--except the ones from CMCR.

12 Q Okay. And you haven't gone out and talked
13 to any of them; is that right?

14 A No.

15 Q Okay. Does anyone at NIDA go out and talk
16 to researchers to find out what potencies they
17 might need to conduct the research that they think
18 is necessary?

19 A I think you probably need--

20 MR. BAYLY: Objection--

21 THE WITNESS: --to ask NIDA about that.

22 MR. BAYLY: Dr. El Sohly, please, we have

1 an objection on the floor because I don't believe
2 that was covered in cross. It's not within the
3 scope. Plus I think the witness is being asked to
4 speculate what somebody from another agency has
5 done, and I don't think that's within his--

6 JUDGE BITTNER: Okay. With respect to the
7 scope issue, overruled. There were a lot of
8 questions on direct as to whether the witness had
9 spoken with various investigators about certain
10 specific things. I think it's reasonable cross to
11 ask about additional matters. So that's overruled.

12 With respect to what NIDA did, however,
13 would you rephrase the--

14 MS. CARPENTER: Yes, I will.

15 BY MS. CARPENTER:

16 Q Did anyone--have you--has anyone at NIDA
17 ever spoken to you about their efforts to determine
18 what level of potency anybody in the research
19 community might be interested in obtaining?

20 A Not until the CMCR group requested the
21 higher-potency material.

22 MS. CARPENTER: Okay.

1 JUDGE BITTNER: Could we go off the record
2 a minute?

3 [Pause.]

4 JUDGE BITTNER: On the record.

5 MS. CARPENTER: Thank you.

6 BY MS. CARPENTER:

7 Q Could you turn to page 3 of that letter?
8 The second paragraph on that page beginning, "In
9 addition to the above-described NIDA program..."
10 If you could just take a minute and read that
11 paragraph.

12 [Pause.]

13 THE WITNESS: Yes, I have.

14 BY MS. CARPENTER:

15 Q Okay. In the second line, you refer to
16 this University of Mississippi has a separate DEA
17 registration.

18 A Yes.

19 Q Is that the institute's registration--

20 A That's correct.

21 Q --that we talked about earlier?

22 A And I was mistaken on that assumption.

1 Q Okay. So this was your understanding of
2 what you could do under the license at the time--

3 A That was--

4 Q --of the letter?

5 A It was really--I should have known better,
6 but in just drafting, I didn't think about it
7 enough to realize that I really couldn't do that.

8 Q And why should you have known better?

9 A Because I knew that I couldn't provide
10 plant material.

11 Q Okay. So--and the--

12 A So that's a mistake on my part, and that's
13 part of the reason why, you know, you send it to
14 different people to look at it because you can say
15 something that is really not true.

16 Q Okay. So--

17 A Not intending for it to be not true, but
18 by overlooking facts.

19 Q Okay.

20 A So I put that in there and I realized
21 after it actually came back and said, ah, I should
22 have known better that I can't do that.

1 Q All right. Let me just--the last two
2 sentences there, let me just read those.

3 "Materials could be made available to researchers
4 that are probably registered with the DEA and that
5 for some reason do not want or choose to go through
6 the NIDA program or somehow do not qualify to
7 receive materials under the NIDA program. We are
8 prepared to meet any need qualitatively and
9 quantitatively in this area."

10 So is it your understanding now that you
11 cannot meet any need quantitatively and
12 qualitatively in this area?

13 A No, I can meet qualitatively and
14 quantitatively, but I cannot provide plant
15 material, is what I'm saying. The thing that I
16 could not do is provide plant material.

17 Q Okay.

18 A I can meet qualitatively and quantitatively under
19 either the NIDA program or the other
20 program. But really for, you know, research
21 activities and any activities dealing with the
22 plant material, I cannot provide as the University

1 of Mississippi. I can only provide that material--the plant
2 material--as NIDA, as a contractor for
3 NIDA.

4 Q Okay.

5 A Now, if someone is interested in doing
6 some work or research or whatever with extract, I
7 can certainly provide that.

8 Q Okay.

9 A I have the authorization by DEA to do that
10 because it's part of what we have the license for.

11 Q Okay.

12 A But I just--the only thing that I failed
13 here, I failed to remember or realize that I could
14 not give plant material, but I can give--

15 Q So the researchers--

16 A --extract.

17 Q --who want plant material, you cannot meet
18 that need?

19 A I cannot meet that need. That's correct.

20 Q Okay. Thank you.

21 If I could ask you now to turn to Exhibit
22 6--and I will get you a copy of that. This is

1 Respondent's Exhibit 6.

2 [Pause.]

3 BY MS. CARPENTER:

4 Q Have you seen that document before, Dr. El
5 Sohly?

6 A Yes. This is an e-mail from me with the
7 second draft to the same group that I sent the
8 first draft to.

9 Q Okay. And you created that second draft?

10 A Yes.

11 MS. CARPENTER: Okay. At this point I
12 would move the admission of Respondent's Exhibit 6
13 into evidence.

14 JUDGE BITTNER: There's a handwritten
15 notation on my copy of the e-mail, something in a
16 circle or an oval on the first page.

17 MS. CARPENTER: Yes, there is, Your Honor.
18 That's the way it came to us. I don't know if it
19 came from Dr. El Sohly's files or...

20 JUDGE BITTNER: Dr. El Sohly, do you know--there's
21 a notation that looks like D, an A or
22 something.

1 THE WITNESS: Probably DEA. See, when I
2 have--the E probably got lost in the shuffle.

3 JUDGE BITTNER: Okay.

4 THE WITNESS: It's to be filed in the DEA
5 file.

6 JUDGE BITTNER: Okay. That was your--

7 THE WITNESS: Yes, ma'am.

8 JUDGE BITTNER: Okay. All right. Any
9 objection to Respondent Exhibit 6?

10 MR. BAYLY: Just for clarification, Judge
11 Bittner, this entails the e-mail, which he
12 indicates it's from Dr. El Sohly, and it also
13 entails draft number two?

14 MS. CARPENTER: That's correct.

15 MR. BAYLY: All right. No objection.

16 JUDGE BITTNER: Received.

17 [Respondent's Exhibit No. 6
18 received in evidence.]

19 BY MS. CARPENTER:

20 Q Now, I know you said that you sent out the
21 first draft, which was Respondent's Exhibit 5, to
22 the four people that were on the list. Did you

1 send that to anybody else? Did you send your first
2 draft to anyone else?

3 A If I did, it would have been on the e-mail.

4 Q Okay. I just didn't know if there was
5 another e-mail or a second delivery.

6 A I don't believe so.

7 Q Okay. Can you tell us then what--how you
8 came to arrive at draft number two?

9 A Well, through the input that came from the
10 people that I sent the draft to.

11 Q Okay. Do you recall who sent you comments
12 back that were incorporated in draft number two?

13 A I do believe that just about everybody
14 made some minor comment here or there, but I think
15 the major, you know, thing was removing that--our
16 registration thing.

17 Q Okay.

18 A The one that was a big boo-boo in the
19 first draft.

20 Q In the first draft, I think you referred
21 to some tables. You can look back at Exhibit 5--

22 A Yeah, I just wanted to show the kinds of

1 materials that are already available in the
2 program, and I was going to put the tables for--the
3 inventory tables.

4 Q Okay.

5 A And if you'd like to see those, I'd be
6 happy to show you.

7 Q That's quite all right. I note that in
8 the e-mail you note--you particularly note, "Harry
9 and Steve, please note that this revised draft will
10 have no graphs or tables attached." Did they ask
11 you not to attach any tables or graphs?

12 A I don't remember, but--I don't remember
13 whether they did or maybe when my director,
14 associate director--somebody said that you probably
15 don't need the tables and graphs in the comments.

16 Q Okay.

17 A So I said okay, no problem.

18 Q Okay.

19 A But I don't remember exactly who.

20 Q All right. And then in your e-mail, in
21 the third paragraph you note, "I have inserted the

1 fact that the contract with NIDA is awarded through
2 an open competitive bidding process."

3 A Yes.

4 Q Why did you want to insert that fact in
5 the draft?

6 A I inserted that fact there because if the
7 University of Massachusetts wanted to manufacture
8 and be in the process of manufacturing and
9 distribution and so on, they can have the contract.
10 If they put a proposal and they are the winners,
11 they would be the contractors, and we would be out
12 of that process.

13 Q Did somebody ask you to put that comment
14 in?

15 A No.

16 Q Okay. That was your idea?

17 A Yes.

18 Q Okay. Now, in that letter, the boo-boo
19 paragraph I think you referred to it as, the
20 paragraph starting, "Under NIDA's registration..."

21 A Yes.

22 Q Which is the last paragraph on page 1.

1 That certainly shows some changes from the previous
2 draft. Is that because you realized--

3 A Yes.

4 Q --it had an error? Did anyone call that
5 to your attention, or did you--

6 A I think it was called to my attention
7 probably by Dr. Gust.

8 Q Okay. Do you recall--

9 A I can't swear to that, but I think that's
10 probably who brought it to my attention.

11 Q Were you surprised at all when he brought
12 that to your attention?

13 A No. Actually, I said, well, I should have
14 known that.

15 Q And in particular, you took out the
16 sentence we had talked about earlier about there
17 being no gap to be filled by another registrant.
18 That sentence is not here anymore, is it?

19 A I don't--to be honest with you, I don't
20 remember why this came out.

21 Q But it is out, right?

22 A Yeah, it is out, so somebody mentioned--you know,

1 not the gap per se, but the process is
2 different. It obviously was different than what I
3 had indicated in my first draft. So that's why it
4 was taken out.

5 Q Okay. And the last sentence of that
6 paragraph reads, "Therefore, approved researchers
7 already have access to research materials, and
8 approval of another registrant is unnecessary." Do
9 you see that sentence?

10 A Yes.

11 Q Okay. And when you say "approved
12 researchers" there, you're talking about both FDA
13 approved and NIDA approved; is that correct?

14 A That's correct.

15 Q And both FDA approves their protocol and
16 NIDA approves their protocol; is that correct?

17 A I would assume. Either NIDA or some other
18 body that translates in the final analysis to a
19 NIDA. If NIDA has another body that reviews and
20 gives them recommendations, to me that's NIDA.

21 Q Okay. To me, too.

22 So when you say that approval of another

1 registrant is unnecessary, that's--well, let me
2 rephrase that. If you have an FDA--a research with
3 an FDA-approved protocol but that protocol is not
4 approved by NIDA or any of their--anybody they
5 appoint to approve a protocol, that person does not
6 already have access to research materials; isn't
7 that true?

8 A That researcher--I'm sorry. I didn't--

9 Q That researcher does not have access to
10 research materials; isn't that true?

11 A They have access only if NIDA approves it.

12 Q Okay. So if they just have an FDA-approved
13 protocol and NIDA has not approved it in a
14 separate protocol-approving function, they don't
15 have access to those materials; isn't that--

16 A That's correct.

17 Q Okay. And if you'd look again--I'm sorry.
18 Turn over to the next page, and the first paragraph
19 there, right about the middle of the paragraph,
20 there's a sentence that begins--it's just after the
21 line that--it's the same line that has 1-percent
22 THC content to 10-percent THC content.

1 A Mm-hmm.

2 Q Beginning in that next sentence, "These
3 materials are enough both qualitatively and quantitatively
4 to satisfy any possible needs of the
5 research community." But, again, just to be clear,
6 if there's a researcher that has an FDA-approved
7 protocol, but that protocol is not approved by a
8 separate body at NIDA or NIH, then the material
9 that you could provide will not satisfy that
10 researcher's needs; isn't that true?

11 A So you--what you're telling me is there
12 will be a research out there that wants to test
13 material that's smaller than 10-percent THC on
14 humans?

15 Q No, not at all. This has nothing to do
16 with the potency. This is just the sentence that
17 begins, "These materials..." And I assume by that
18 you're referring to all the materials that you
19 grow. Is that correct?

20 A Yes. I'm saying that to have materials in
21 stock, ample supply from anywhere less than 1
22 percent to 10 percent or more.

1 Q Okay.

2 A And greater.

3 Q Okay. And then the next sentence is,
4 "These materials are enough to satisfy any possible
5 research needs of the research community."

6 A That's correct.

7 Q Okay.

8 A That's what I--

9 Q All right. But you cannot satisfy the
10 needs of people in the research community who have
11 FDA-approved protocols but they have not been
12 approved by NIDA. Is that correct?

13 A Well, if they're not approved by NIDA, no,
14 I cannot help them.

15 Q Thank you.

16 A Sorry.

17 Q Okay. If I could ask you--

18 MS. CARPENTER: Sorry, Your Honor. One
19 moment.

20 [Pause.]

21 BY MS. CARPENTER:

22 Q Let me just ask you one other quick

1 question about that document, Dr. El Sohly. Again,
2 turning back to page 1, the last paragraph.

3 A I'm sorry. Which paragraph?

4 Q Page 1, the last paragraph on that page.

5 A Okay.

6 Q The next to the last sentence, or
7 penultimate--I don't get to use that word very
8 often--"Those researchers with projects that do not
9 meet the scientific approval criteria by NIDA
10 receive marijuana at the cost of production." Is
11 that an accurate sentence?

12 A Those researchers with projects approved
13 by NIDA receive marijuana at no cost to them or the
14 institutions, that's correct.

15 Q Right. The next sentence, "Those
16 researchers with projects that do not meet the
17 scientific approval criteria by NIDA receive
18 marijuana at the cost of production." But I think
19 you just testified they had to be--meet the
20 scientific approval of NIDA to receive the
21 marijuana at all. Isn't that right?

22 A That's correct.

1 Q Okay. So that--

2 A That's their current stance on that.

3 Q I'm sorry?

4 A That's the current situation on that.

5 Q Okay. And did you just not understand
6 that at the time you wrote this document?

7 A Honestly speaking, at the time of this, I
8 wasn't really aware of that other part of the
9 evaluation.

10 Q Okay. So these--

11 A I understood, because it was not explicit
12 in the RFP, so I'm not sure what the process was at
13 NIDA.

14 JUDGE BITTNER: Dr. El Sohly, is there a
15 confusion here between approval and funding?

16 THE WITNESS: Could be, Your Honor.

17 JUDGE BITTNER: In other words, that
18 sentence, "Those researchers with projects that do
19 not meet the scientific approval criteria by
20 marijuana"--that's good--"by NIDA"--you can tell
21 it's getting late. Meaning in order to obtain NIDA
22 funding.

1 THE WITNESS: Yes.

2 JUDGE BITTNER: Is that what you're--

3 THE WITNESS: Yes.

4 JUDGE BITTNER: And you didn't know about
5 the other issue?

6 THE WITNESS: That's correct.

7 JUDGE BITTNER: Okay. I'm just trying to
8 get this straight.

9 BY MS. CARPENTER:

10 Q If you'll turn again to page 3--and I know
11 you talked about this paragraph before, but the
12 first full paragraph on that page, that's the one
13 where I think you indicated that you thought you
14 could provide marijuana plant product to
15 researchers outside of NIDA. So at least at the
16 time you wrote the second draft, you didn't know
17 there was the other procedure yet. Is that
18 correct?

19 A Yes.

20 Q Okay. Let's turn over to Respondent's
21 Exhibit 7. And, again, I'll ask you to take a look
22 at that. And I believe, for the record, it's two

1 e-mails. One is dated September 2, 2003, at 12:12
2 p.m., and the other is dated September 8, 2003, at
3 12:09 p.m. And then there's a document attached to
4 that called "Draft number two."

5 Have you seen those e-mails and that draft
6 document before?

7 A Yes.

8 Q And did you receive those e-mails and did
9 you draft that document?

10 A Well, this is actually the response of Dr.
11 Singh and Dr. Gust to the draft two.

12 Q Okay. All right. So these would be their
13 comments?

14 A These are their comments, that's correct.

15 Q Response, okay. That--

16 A And you can see that Dr. Gust or Dr.
17 Singh--I'm not sure the attachment is with which e-mail--
18 changed this paragraph or--

19 MS. CARPENTER: Okay. Before we get to
20 that, let me just move the admission of
21 Respondent's Exhibit 7 into the record.

22 JUDGE BITTNER: Mr. Bayly?

1 MR. BAYLY: Just a quick question. I
2 don't think there's going to be an objection, but,
3 Dr. El Sohly, on the second e-mail there's "Dr.
4 Gust" handwritten and then there's a phone number.
5 Is that something--is that your writing?

6 THE WITNESS: That's my writing, yes.

7 MR. BAYLY: No objection.

8 JUDGE BITTNER: Respondent's 7 is
9 received.

10 [Respondent's Exhibit No. 7
11 received in evidence.]

12 BY MS. CARPENTER:

13 Q And why don't I go ahead and get that out
14 of the way now. I was going to ask you if that's
15 your writing. Do you know why you wrote this
16 telephone number there?

17 A Just so I can call him or something.

18 Q Okay. Did you call him? Do you recall
19 speaking to him--

20 A I don't remember, to be honest.

21 Q --on the phone?

22 A I don't remember.

1 Q Okay. Do you know if anyone from the
2 University of Mississippi called him or spoke to
3 him--

4 A No, if someone called him, it would be me.
5 I mean, I would be the one calling him.

6 Q Okay.

7 A And it's possible that I called him to,
8 you know, clarify some of the comments that he had
9 or make sure that I understand the comments or
10 something. I don't remember.

11 Q Okay. So you just don't remember whether
12 you did.

13 A No.

14 Q Okay.

15 A And you can see on page 1 that, Your
16 Honor, the part in the last paragraph that refers
17 to the funding and so on, he clarified to me that
18 it's--if it has NIDA funding, it goes without
19 money, I mean without payment, and if it approves
20 NIDA, if it goes through the scientific review
21 process, passes that, then the investigator will
22 have to pay.

1 Q Okay. And we'll get to that in just a
2 minute. If you'll look at the top of the first e-mail
3 there, the comment at the top says, "My only
4 suggestion is to remove the last sentence from the
5 fourth paragraph of the last page about this
6 concept of renewal." Is that Dr. Singh's comment
7 to you?

8 A That's correct.

9 Q Okay. So do you believe the changes there
10 in draft two to be Dr. Gust's comments?

11 A The majority of the changes I would say
12 yes.

13 Q Okay. In fact, if you turn the page over
14 to the next e-mail, the one that's dated September
15 8th, Dr. Gust indicates, "I have made a few
16 suggested changes. Please take a look."

17 A Yes. It's also possible that some of
18 those changes would be from our group.

19 Q Okay. Somebody made these changes in a--

20 A Electronic.

21 Q --so that you can see the changes. Do you
22 recall making those changes or do you believe--

1 A No, not me. I didn't make any of those.

2 Q Okay. So--

3 A Those changes are coming to me from the
4 people that I sent the draft to.

5 Q Okay. If you would look at page 1, that
6 first paragraph--and I think you were just
7 commenting to the judge about those changes--do you
8 understand, or is it your view that those changes
9 came from Dr. Gust? I think you said he explained
10 to you--

11 A At least some of those changes, yes, came
12 from Dr. Gust, particularly the ones that refer to
13 the cost and who pays and who doesn't pay and so
14 on.

15 Q Okay. So was it clear to you then at the
16 time you had--after you had seen Dr. Gust's
17 comments or spoken with Dr. Gust, that there were--that
18 researchers who wanted to do research with
19 marijuana, could get NIDA marijuana either free of
20 charge, if they were funded by a NIDA grant--

21 A Yes.

22 Q --or they could pay for it themselves and

1 get it if they passed a NIDA--

2 A Review process.

3 Q --review process.

4 A Yes.

5 Q And that would be evaluating the protocol
6 for scientific merit?

7 A That's correct.

8 Q And again, I think you said earlier that
9 anybody who was looking to do this would first have
10 to go to the FDA and the FDA would already have
11 approved whatever protocol they had suggested; is
12 that right?

13 A I assume that's the sequence, but I don't
14 have first knowledge of that, but I just assume,
15 based on the process, I assume that's the case.

16 Q And in fact, in that first sentence you
17 says, "Under NIDA's registration, materials are
18 made available to research with proper registration
19 with the DEA," and then somebody added in "and
20 FDA."

21 A That's probably Dr. Gust.

22 Q Okay. And that last--I'm sorry, the next

1 to the last sentence again, which reads: "Those
2 researchers with projects that"--and then the words
3 have been stricken out--"do not meet the."

4 A Are we talking about page 1?

5 Q Yes, page 1. Last paragraph. The
6 sentence in the middle of the paragraph--I'm sorry,
7 the next to the last sentence, "Those researchers
8 with projects." Do you see that sentence?

9 A Yes. "...that are not funded by NIH."

10 Q "But have received scientific approval to
11 receive marijuana at the cost of production."

12 A That's correct.

13 Q And that scientific approval you're
14 referring to is from NIDA or NIH, isn't that right?

15 A That's correct.

16 Q Not from the FDA.

17 A Yes.

18 Q If you would turn over to page 2, the very
19 last paragraph. There's a section of that
20 paragraph that's been taken out, beginning with the
21 words, "Proponents of marijuana legalization," et
22 cetera. Do you know why that paragraph was taken

1 out?

2 A Because, you know, maybe it's not--doesn't
3 really add anything to the comments, per se. So
4 it's just my first thoughts, and put them down, and
5 somebody said, "You know, you don't really need to
6 put that in there." I took it out. I didn't think
7 there's a problem taking it out, but it wasn't
8 really something very meaningful to me to insist
9 that it be in, so that's the purpose of the review
10 process, I guess.

11 Q Did you discuss that change with anyone?

12 A Not really.

13 Q If you'll turn over to the third page,
14 there is some handwriting on that page. Do you
15 know whose handwriting that is?

16 A Yes.

17 Q Whose is it?

18 A That's my handwriting.

19 Q Your handwriting? Okay. In the last
20 sentence of that first paragraph, which has been
21 added in, it looks like, from the underlining--is
22 that right, is that added in by, I assume, Dr.

1 Gust?

2 A I don't remember. I don't remember who
3 made that change, because like I said, it was sent
4 to at least four people, so I don't remember who
5 made that particular change.

6 Q Do you remember getting comments back in
7 this form, that is, where you could see the
8 additions and deletions, from anyone except Dr.
9 Gust?

10 A Yeah. I had from Dr. Walker and Dr.
11 Chambliss from our institute.

12 Q You had a document that showed additions
13 and deletions?

14 A Yeah, probably.

15 Q If you had, would those be in your files?

16 A I gave you everything that was in my file.

17 Q So if there was nothing in that files, do
18 you believe there was nothing there?

19 A That's probably, you know, whatever comes,
20 it was forwarded as is to others to look at it or
21 something like that, or it may be some comments
22 that came from someone and sent as is to another

1 person, and looked at it and added additional
2 comments, or something like that.

3 Q Okay.

4 A But I have looked very carefully in the
5 file and I gave you everything I have in the file.

6 Q In that last sentence, you added in the
7 word "formal" there, that's your handwriting?

8 A Yes.

9 Q And why did you add that in?

10 A Again, because, my earlier testimony, I
11 just find that Dr. Abrams had informally mentioned
12 something about the seeds and harshness and things
13 like that, that I thought to be as accurate as I
14 possibly can be. That was not a formal complaint,
15 per se. That was just a comment, did not put the
16 formal complaint.

17 Q And in your mind, is there a procedure for
18 making formal complaints about the quality of NIDA
19 marijuana?

20 A Yeah. If someone writes me a letter, say,
21 "Dear Dr. El Sohly, we have noticed this, this and
22 that. Is there anything you can do to correct this

1 problem or something," I would say that this is
2 formal.

3 Q But if it's not in writing, it's not
4 formal?

5 A I'm sorry?

6 Q If it's not in writing, it's not formal?

7 A No. If somebody calls me specifically to
8 discuss, you know, issues, problems with this
9 material, with materials, you know, then it would
10 be formal. That would be considered as formal even
11 though it's not in writing.

12 Q Okay.

13 A But if there was no direct discussions
14 whatsoever with me regarding the quality of the
15 material.

16 Q Except for what you testified that Dr.
17 Abrams said to you--

18 A Well, he wasn't necessarily saying to me.
19 He was--we were walking, three and four people, and
20 discussing. There was talking about things, and I
21 was in the group, so I heard Dr. Abrams mention
22 those facts, but he was not discussing with me.

1 Q Okay. And the paragraph that begins, "In
2 addition to the above described NIDA program."

3 A Yes. That was struck from the beginning.

4 Q Struck from the beginning?

5 A From the first, after the first draft.

6 Q I think as we saw in Respondent's Exhibit
7 6, it was still in there.

8 A Right. But I mean, that was taken out
9 because of reasons previously discussed.

10 Q And do you recall, was it Dr. Gust who
11 asked you to take that out?

12 A It's quite possible because he's the one
13 that would be--he's more familiar with that process
14 then people from my organization.

15 Q Okay, all right. If you'd look at the
16 third paragraph there on page 3, the last sentence,
17 "Approval of the University of Massachusetts
18 Amherst would result in a duplication of existing
19 resources without any foreseeable benefits." Do
20 you see that?

21 A Yes, that's my belief.

22 Q Let me ask you this question. If a town

1 has one pharmacy and another pharmacy opens across
2 the street selling much the same products, the
3 townspeople would probably foresee some benefits,
4 wouldn't they, from another pharmacy opening up
5 across the street?

6 A Probably.

7 Q Perhaps a different variety of products?

8 A Probably different prices maybe.

9 Q Perhaps lower prices.

10 A Price competition.

11 Q Perhaps different store hours.

12 A Yes.

13 Q Perhaps different terms of credit.

14 A Yes, but we work 24/7, so.

15 [Laughter.]

16 BY MS. CARPENTER:

17 Q And isn't it true that competition
18 generally involves the duplication of existing
19 resources?

20 MR. BAYLY: Objection, Your Honor. We're
21 getting out of the scope of direct, but also
22 getting into an area where the witness has not been

1 qualified to testify about competition. In fact,
2 the witness has never tendered himself as a witness
3 in any way, shape or form about competition. So
4 I'm actually seeing two objections.

5 JUDGE BITTNER: I'm not considering the
6 term "competition" in the term of art sense at this
7 point. I'm taking it as a layman, i.e., one or
8 more entities engaged in providing similar products
9 or services to the same target population. So I'll
10 overrule the objection. I think we had a little
11 bit about this on direct, and certainly we had the
12 comments on direct.

13 THE WITNESS: May I answer, Your Honor?

14 JUDGE BITTNER: Ms. Carpenter, did you--

15 MS. CARPENTER: Yes.

16 JUDGE BITTNER: Yes.

17 BY MS. CARPENTER:

18 Q So, isn't competition, generally, doesn't
19 that involve the duplication of existing efforts?

20 A The competition is already there, it's
21 already I place by having--

22 Q Well, let me just ask you the question.

1 A --the contract put out--

2 Q Wait just a minute, just a minute. Can
3 you just answer the question that I'm asking, and
4 then you can follow up if you'd like. But isn't it
5 true that competition generally involves
6 duplication of existing efforts?

7 A Generally speaking, yes.

8 Q Okay, thank you. In fact when another
9 producer begins competing with a formerly existing
10 producer, it almost always involves two or more
11 participants making or growing the same product,
12 right?

13 MR. BAYLY: Your Honor, I'm going to have
14 to object. Again, we're starting to go down the
15 road of economic analysis, and if we're getting
16 into this sophisticated question, because the
17 answer, I think, under--as an economic expert my
18 answer is not necessarily what defense counsel
19 might be anticipating. I really think we kind of
20 crossed the line here.

21 JUDGE BITTNER: Let me look at something.
22 Hold on.

1 MS. CARPENTER: Okay.

2 JUDGE BITTNER: Ms. Carpenter, why don't
3 you ask him what he meant by that, rather than get
4 into what may turn into term-of-art issues?

5 MS. CARPENTER: Okay. What he meant by
6 his answer to my last question?

7 JUDGE BITTNER: No. The reference to
8 duplication of effort with no benefits.

9 BY MS. CARPENTER:

10 Q What did you mean by this sentence, or by
11 noting that the duplication of existing resources
12 wouldn't result in any foreseeable benefits?

13 A The duplication of efforts in terms of
14 production of marijuana for research and
15 distribution of that marijuana for research is a
16 duplication of effort where there is no deficiency
17 to be covered at this time as far as I can see, and
18 so there is no benefits other than you just have
19 another producer.

20 Q And that's the same benefit that a
21 pharmacy would bring to a new town, right?

22 A Not really, because we're not talking

1 about a product that is--that is already on the
2 market that has a price on it and all of this.
3 We're talking about research material. We're
4 talking about material that's only available under
5 IND programs and only available for research, not a
6 commodity. So it's--I see the analogy that you're
7 trying to make, but really it's not applicable in
8 this case.

9 Q And isn't there competition in virtually
10 every other form of Schedule I substance available
11 for researchers?

12 A In most of the material for--you know,
13 available for research that's out there, it is
14 either coming out from NIDA. NIDA has a supply for
15 these materials.

16 JUDGE BITTNER: I think--no, I just want
17 to clarify. Ms. Carpenter's talking about Schedule
18 I substances other than marijuana or--

19 THE WITNESS: Yeah. I think there are
20 other materials that are available through
21 commercial suppliers.

22 BY MS. CARPENTER:

1 Q And those people would compete with each
2 other to provide better prices or better store
3 hours or better credit terms to the researchers who
4 want to use their products; isn't that right?

5 A That's correct.

6 MR. BAYLY: Your Honor, objection.

7 JUDGE BITTNER: I'm sorry. Ground.

8 MR. BAYLY: I have another objection to
9 the witness getting into these competition issues.

10 JUDGE BITTNER: Which is that he shouldn't
11 be getting into competition issues at all? Okay.

12 MR. BAYLY: Well, number one, is getting
13 into competition issues about other drugs. And
14 secondly, I guess even more importantly, it is
15 getting a witness to talk about what his
16 competition--

17 JUDGE BITTNER: I'm not trying to--I'm not
18 trying to rehash some other cases on competition,
19 at least I'd certainly rather not. But I think it
20 is relevant and the witness did say that he had
21 some familiarity with the requirements of Section
22 823(a). And so, again, if we're talking about

1 duplication of efforts with no benefit, I think
2 it's appropriate to inquire into exactly what that
3 meant, and competition is a factor. So I'll
4 overrule the objection. But I don't want to get
5 into, you know, Hirschmann-Herfindahl indices or
6 something.

7 MS. CARPENTER: I understand.

8 JUDGE BITTNER: Okay.

9 MR. BAYLY: Your Honor?

10 JUDGE BITTNER: Yes, sir?

11 MR. BAYLY: One other objection. If we're
12 going to talk about other Schedule I control
13 substances other than of course marijuana, then I
14 guess we've got a foundation argument as well.

15 JUDGE BITTNER: Well, let's get the
16 question if he knows.

17 MS. CARPENTER: Okay. Well, I think we've
18 already answered that question, or at least he's
19 already answered that question.

20 JUDGE BITTNER: I think he did, that there
21 were commercial--

22 I think you said that on some Schedule I

1 substances there were commercial supplies available
2 for research.

3 THE WITNESS: That's correct, there are.

4 MR. BAYLY: All right. I withdraw that
5 objection.

6 JUDGE BITTNER: Okay.

7 THE WITNESS: Your Honor, I can tell you--

8 JUDGE BITTNER: You have no question
9 pending, sorry.

10 BY MS. CARPENTER:

11 Q Let me ask you this question, Dr. El
12 Sohly. If an FDA approved researcher, someone with
13 an FDA approved protocol, wanted to do medical
14 research with marijuana, and NIDA and the
15 University of Mississippi both decided not to
16 provide it, but another grower who had a bulk
17 manufacturer's license would, having that other
18 source available would be of benefit to that
19 researcher, wouldn't it?

20 MR. BAYLY: Your Honor, this calls for the
21 witness to speculate on a totally hypothetical,
22 which I think is, number one, out of the scope, and

1 number two, beyond his competence to answer.

2 JUDGE BITTNER: Overruled.

3 THE WITNESS: Will you ask that question
4 again?

5 BY MS. CARPENTER:

6 Q Sure. If a researcher has an FDA approved
7 protocol to research with medical marijuana, and
8 both NIDA and the University of Mississippi refuse
9 to provide that researcher with marijuana to do
10 that research, having another source available from
11 another bulk manufacturer who could supply that
12 marijuana, would be a benefit to that researcher,
13 wouldn't it?

14 A I would say not necessarily.

15 Q And why would--

16 A First of all, the University of
17 Mississippi does not refuse anything. University
18 of Mississippi is not in a position to refuse or
19 approve.

20 Q I understand. You refuse because--

21 A So that's restricted to NIDA. If NIDA
22 doesn't approve it, then another supplier who has

1 material, would that be a benefit to the
2 researcher? I'm going to say not necessarily
3 because the process that that protocol goes through
4 through NIDA is a very important process in my
5 judgment because there could be some problems with
6 the protocol, and it could save the researcher a
7 lot of troubles in executing the research. The
8 fact that it's approved by the FDA, it doesn't
9 necessarily mean--it just has all the elements that
10 the FDA requires for you to have in place. Okay,
11 the elements. But not necessarily the--all the
12 other issues that NIDA and people that have the
13 experience with the drug reviewing that protocol,
14 approving that protocol.

15 Q So, but you would agree that the FDA does
16 approve protocols for clinical research and
17 studies, isn't that right?

18 A That's correct.

19 Q And for most substances other than
20 marijuana, that's all the researcher needs in order
21 to go ahead with the process; isn't that correct?

22 A With the testing in humans, that's

1 correct.

2 Q And so if a researcher didn't want the
3 additional benefit of NIDA's review, if they just
4 thought that wasn't a benefit, do you think it
5 would be a benefit to them to have a source of
6 marijuana available to them through another
7 licensed grower?

8 A You know, again, I'm just saying, not
9 necessarily. It could be, but not necessarily the
10 case in every case, because if a researcher wants
11 to take naive subjects and given them, you know, 10
12 percent marijuana to do because that's what they
13 want to do, and as I mentioned before, I think
14 that's--I don't think that will be appropriate to
15 do that. It would be too much for that subject to
16 tolerate.

17 Q But again, you're not a medical
18 researcher, are you, sir?

19 A But I'm familiar with the medical issues
20 related to marijuana and marijuana--

21 Q But are you a medical researcher, sir?

22 MR. BAYLY: Your Honor, I object. I mean,

1 you can't ask the witness questions and then object
2 to his competence to answer the questions after the
3 door has been opened.

4 MS. CARPENTER: Excuse me, Your Honor.
5 I'm not asking a question about the benefits of
6 medical research.

7 JUDGE BITTNER: All right. The witness
8 was answering the question posed about benefits.

9 MS. CARPENTER: Okay, I'll move on.

10 JUDGE BITTNER: Now, that--are you
11 finished with that answer, Dr. El Sohly?

12 THE WITNESS: Yes, I'm finished, Your
13 Honor. And I said that is not necessarily a
14 benefit.

15 JUDGE BITTNER: Got it, okay. I got the
16 answer. So did the court reporter. And so the
17 next question is?

18 BY MS. CARPENTER:

19 Q By not necessarily, you agree that it
20 could be, isn't that right?

21 A I mean there is a possibility, but--

22 Q Okay, thank you.

1 A --not necessarily the case.

2 Q Okay. Now, if another bulk manufacturer
3 could grow the materials that an FDA approved
4 researcher needed at a lower cost than a current
5 manufacturer, would you agree that would be a
6 benefit to the researcher?

7 A That could be a benefit, yes.

8 Q And if a different grower, who had a DEA
9 license to do so, grew a different strain of
10 marijuana than you grow, or a different ratio of
11 cannabinoids to THC, and had that product available
12 when a researcher wanted to do the research, and
13 another grower, for instance, yourself, didn't,
14 would that also be a benefit to a researcher?

15 A First of all, I want to, you know, tell
16 you that in order to be able to do that, you have
17 to have all the preclinical work done with material
18 of similar composition to really qualify even to do
19 that. All the material that's available that has
20 been requested, all the material that's on the
21 market, on the illicit market has the composition
22 that's currently available through the program.

1 There is no limitation in the program as far as
2 what kind of material is being produced. If that
3 was deemed necessary by the scientific or medical
4 community, that process is there. It's just like,
5 you know, Grower XYZ is going to produce material
6 that has this particular composition. We could
7 also grow the same composition. It's not a
8 problem. It's not a limitation that we have.

9 Q I understand. But my question is, if a
10 licensed grower had that available and you did not,
11 would that be a benefit to that researcher?

12 A It would be a benefit, yeah.

13 Q Thank you. And just to be clear, I think
14 you stated this earlier, but I just want to be
15 clear. The University of Mississippi, through the
16 institute license, cannot provide FDA approved
17 researchers with medical marijuana for research
18 purposes outside the NIDA program; is that right?

19 A That's my understanding.

20 [Pause.]

21 BY MS. CARPENTER:

22 Q If I can just ask you to turn to page--and

1 this is the last. We can stop after this one, Your
2 Honor, if that makes sense. Page 2 of that
3 exhibit, Respondent's Exhibit 7, and again, that's
4 the bottom of the page with the paragraph, the half
5 of paragraph that's been X'd out of there's a line
6 through it. And the sentence begins, "Proponents
7 of marijuana legalization criticized that NIDA
8 provided cigarettes for the presence of this
9 material"--and I presume by "this material" you
10 mean small seed and stem particles--"as well as for
11 the potency of THC." Who were you referring to
12 there when you said proponents of marijuana
13 legalization?

14 A NORML.

15 Q NORML. Anybody else?

16 A I'm sorry?

17 Q Anyone else?

18 A No.

19 Q So you're not referring to any researchers
20 who criticize--who criticize NIDA marijuana?

21 A Not in this.

22 MS. CARPENTER: I think if I just do the

1 last two exhibits, which will be short, we'll be at
2 a good stopping point.

3 JUDGE BITTNER: Okay.

4 BY MS. CARPENTER:

5 Q If I could ask you to turn, please, to
6 Respondent's Exhibit 9? And I'll just actually
7 give you 8 and 9 at the same time. If you would
8 just look at Exhibits 8 and 9, and start with
9 Exhibit 8 when you get ready.

10 A Okay.

11 Q Have you seen that exhibit before? It
12 consists of an e-mail dated September the 9th from
13 Dr. El Sohly to Walt Chambliss and others?

14 A Yes.

15 Q And the second page there is entitled
16 "final draft" dated September 9th, 2003?

17 A Yes.

18 Q Did you send that e-mail?

19 A Yes, I did.

20 Q And did it have that draft attached to it?

21 A Yes.

22 Q I would move the admission of Respondent's

1 Exhibit 8.

2 JUDGE BITTNER: Mr. Bayly?

3 MR. BAYLY: No objection.

4 JUDGE BITTNER: Received.

5 [Respondent's Exhibit No. 8
6 received in evidence.]

7 BY MS. CARPENTER:

8 Q And then if you would turn over to
9 Respondent's Exhibit 9, which is a draft entitled
10 "Draft 3." It's, again, a draft of that same
11 letter dated September 9, 2003.

12 A I do believe that this is the same.

13 Q The same letter?

14 A I believe it's the same letter.

15 Q Okay.

16 A I'm not 100 percent positive, but I think
17 it's the same letter because it went out the same
18 day.

19 Q Okay. So this was just Draft 3, and then
20 you turned it into the final; is that what
21 happened?

22 A Yes, I believe so.

1 Q Do you know if there were any other phone
2 calls or conversations about it after it went out
3 that last time?

4 A I don't think so.

5 MS. CARPENTER: Your Honor, I'm at a good
6 stopping point if that makes sense, or I'll push
7 on.

8 JUDGE BITTNER: Well, do you want to offer
9 Respondent 9?

10 MS. CARPENTER: I do, thank you.

11 JUDGE BITTNER: Mr. Bayly, do you have an
12 objection to Respondent's Exhibit 9?

13 MR. BAYLY: No. Could we go off the
14 record though, just to talk briefly about--

15 JUDGE BITTNER: Yes, but let me just
16 receive that.

17 MR. BAYLY: No, no objection.

18 JUDGE BITTNER: All right, 8 and 9 are
19 received.

20 [Respondent's Exhibit No. 9
21 was received in evidence.]

22 MS. CARPENTER: And can I just be clear

1 that Exhibit 7 is also received? I don't have it
2 circled.

3 JUDGE BITTNER: Yes.

4 MS. CARPENTER: Okay, thank you.

5 [Discussion off the record.]

6 JUDGE BITTNER: Let's of on the record to
7 say that we will go off the record now, and we will
8 resume at 9:00 o'clock here, and remember, please,
9 that there are some glitches with getting you all
10 in. And remember your numbers. Off the record.

11 [Whereupon, at 5:59 p.m., the hearing was
12 adjourned, to reconvene at 9:00 a.m., December 13,
13 2005.]

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