

UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

- - - - - x
 :
 In the Matter of: :
 :
 LYLE E. CRAKER, Ph.D. : Docket No. 05-16
 :
 - - - - - x

VOLUME 7

Tuesday, December 13, 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
Washington, D.C. 20537

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:

MATTHEW STRAIT
Representative of the Government

RICHARD DOBLIN, Ph.D.
Representative of Respondent

C O N T E N T S

WITNESS

DIRECT CROSS REDIRECT RECROSS

Mahmoud El Sohly

(continued)

--	4	170	176
----	---	-----	-----

- - -

E X H I B I T S

EXHIBIT NOS.

MARKED

RECEIVED

RESPONDENT'S

No. 2

--

111

No. 53

139

140

GOVERNMENT'S

No. 79

--

73

No. 78

--

176

- - -

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

2 JUDGE BITTNER: I think we are resuming
3 with the cross-examination of Dr. El Sohly.

4 MS. CARPENTER: Thank you, Your Honor.

5 JUDGE BITTNER: And, doctor, of course,
6 you know you're still under oath.

7 THE WITNESS: Yes, ma'am.

8 Whereupon,

9 MAHMOUD EL SOHLY

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

13 CROSS-EXAMINATION (Resumed)

14 BY MS. CARPENTER:

15 Q Good morning, Dr. El Sohly.

16 A Good morning.

17 Q You testified yesterday about the
18 contracts under which you provide marijuana for
19 research purposes to NIDA. Do you recall that
20 testimony yesterday?

21 A Yes.

22 Q And those contracts--and we can get them

1 out if that would be helpful, but I don't think it
2 will be necessary for these questions. They
3 require two sort of separate kinds of activities.
4 One is cultivation and growing of marijuana, and
5 the other relates to testing and analyzing both the
6 marijuana you grow and other types of marijuana.
7 Is that a fair summary?

8 A Yes. Well, there is a lot of other
9 things, but these two items are in the contract,
10 yes.

11 Q So at least as for those two items of the
12 contract, someone who was not interested in or who
13 didn't have any expertise in testing or analysis,
14 would not be a likely candidate to win that
15 contract, would they?

16 A Well, not necessarily, because they could
17 subcontract that portion, just like we don't do the
18 cigarettes, so we subcontract that portion of the
19 contract. The contract--

20 Q But if someone--sorry, go ahead.

21 A The contract involves, as I indicated, it
22 goes all the way from, you know, the production to

1 the harvesting, to the storage, to the
2 manufacturing, to the analysis, to the
3 manufacturing of the cigarettes, and storing those,
4 and quality control and stability studies and all
5 of this, and the security of the garden for
6 example. So there are different segments of the
7 activities if you didn't have in place, you could
8 join effort with another organization that has that
9 capability, and that organization will be your
10 subcontractor.

11 Q So it would be possible to do that. But
12 someone who was interested in just being the
13 grower, the cultivator of the crops, then would
14 have to subcontract out all of those other pieces
15 of the contract, is that right?

16 A I would say if you don't have the
17 expertise to do all the other items, then you have
18 to find a way to do it to respond to that contract.

19 Q So if you wanted to respond to the
20 contract, you'd have to subcontract all of the--

21 A I would say that would be an avenue.

22 Q We talked a little bit yesterday about

1 some of the--well, let me just ask you this. Has
2 the University of Mississippi ever sent out a
3 survey or approached investigators in some other
4 way--and by investigators I mean medical marijuana
5 investigators, researchers--about what kind of
6 product they are interested in or they need to do
7 their research?

8 A No.

9 Q Have you approached any researcher--and
10 again I mean a medical marijuana researcher--about
11 whether they need or would like to have a product
12 with a different ratio of cannabinoids than ones
13 you currently offer?

14 A No.

15 Q In fact, have you approached any
16 researchers to ask them any questions about medical
17 marijuana research?

18 A No, I have not, not formally anyway.

19 Q Can you tell us what the level is of CBC
20 in the marijuana that you grow?

21 A It's approximately .3 percent, .2, .3
22 percent on the average.

1 Q And for the record, what is CBC?

2 A CBC is cannabichromene.

3 Q And is that--what is that?

4 A It's another cannabinoid that exists in
5 the plant material that does not have psychological
6 activity, but has some other pharmacological
7 activities of its own. Those activities might be
8 shared by Delta-9-THC, by the way.

9 Q And do you currently offer, you through
10 NIDA, offer medical marijuana for research with
11 varying ratios of CBC and THC--I'm sorry--CBD and
12 THC?

13 A The material that's currently in stock is
14 what's currently in stock, which has the same
15 composition as what's commonly available in the
16 U.S. market, which is high THC content, low CBD
17 content. There has not been any formal request for
18 any material of any other composition. And we do
19 have some other materials that have different
20 composition on smaller amounts that could be put
21 into small batches of cigarettes if there is a need
22 to.

1 As a matter of fact, there is a study that
2 we carried out with the group in Chicago, Dr.
3 DeWitt, that wanted to investigate the taking
4 different types of marijuanas that held different
5 composition of the different cannabinoids, and see
6 if the ratio of other cannabinoids has some effect
7 on the overall pharmacology of the plant. In other
8 words, if you have marijuana that's high in THC and
9 low CBD, and another marijuana that has high THC
10 and high CBD or a medium CBD, then would these two
11 types of marijuanas be different or have different
12 pharmacological activities on the subjects? And
13 those two were actually prepared, some cigarettes
14 were prepared along those lines, and the study was
15 carried out. So if there is a specific need for
16 some of these materials, this could be prepared.

17 Q And when you say "we" do you mean NIDA or
18 do you mean the institute?

19 A We, NIDA, the institute, because it has to
20 go through NIDA.

21 Q Okay. So it's the institute's research
22 through NIDA?

1 A Yes.

2 Q And so the marijuana that was used came
3 from the institute's source or--

4 A No, no, from the NIDA supply.

5 Q Just to be clear about what's in your
6 current inventory that's available to researchers--

7 A We have--

8 Q Let me just finish the question just so
9 the reporter can get it down. In terms of your
10 current inventory that's available to researchers,
11 you offer a product that has low CBC, high THC
12 ratio; is that correct?

13 A Well, all the cannabinoids exist of the
14 same type, but you have some materials that have,
15 might have relatively high CBC content, relative to
16 the average, some other materials that might have
17 higher CBD content relative to the average. You
18 might have some materials that have very low of
19 both of these, different ratios. We have probably,
20 Your Honor, maybe 100 different containers of
21 different plant materials, and depending on the
22 plants where those materials are harvested from,

1 you can have a different cannabinoid iteration, and
2 if you take all of these and blend them together,
3 you would end up with the average that I'm talking
4 about.

5 But you can take one particular container,
6 if you're interested in that composition of that
7 particular container, you can make cigarettes out
8 of that container that have this composition, or
9 take another container that has a different ratio
10 and make cigarettes out of that container. So
11 those different containers are available. It's
12 just a matter of what is needed, and we have to get
13 that request from the investigator first to NIDA,
14 and then NIDA approves it, and then we do it.

15 Q In terms of what you have available then,
16 what is the range of CBD content? I think you said
17 your generally was .3 percent, but now that there's
18 different containers that have different
19 percentages, what's the range of--

20 JUDGE BITTNER: Wait a minute. I got
21 lost.

22 MS. CARPENTER: Sorry.

1 JUDGE BITTNER: Because I thought
2 initially the .3 percent was referring to CBC.

3 MS. CARPENTER: You're correct, Your
4 Honor.

5 THE WITNESS: That's correct.

6 JUDGE BITTNER: And that's the--I can't
7 pronounce--

8 THE WITNESS: Cannabichromene.

9 JUDGE BITTNER: Cannabichromene. And CBD
10 is?

11 THE WITNESS: Cannabidiol.

12 JUDGE BITTNER: Okay. That's why I didn't
13 understand the question.

14 MS. CARPENTER: That's correct, Your
15 Honor. I apologize, that was my mistake.

16 BY MS. CARPENTER:

17 Q What is the range of CBD that is in the
18 various containers that you have?

19 A CBD would range from almost nothing or .1
20 percent, to probably about 2 percent.

21 JUDGE BITTNER: I'm sorry. To what, to .2
22 percent?

1 THE WITNESS: Two.

2 JUDGE BITTNER: 2 percent, no decimal
3 point.

4 THE WITNESS: Yes. It's about 10, 20
5 times range.

6 JUDGE BITTNER: Okay.

7 BY MS. CARPENTER:

8 Q And do you know what the--if you were to
9 mix all those materials, if you were just to send
10 materials to RTI, what would be the percentage of
11 CBD content and just a general, you know, your
12 standardized cigarette?

13 A It would be again in the range of .2
14 percent, .3 percent.

15 Q Thank you. Dr. El Sohly, when did you, at
16 University of Mississippi, start--when did you
17 first grow a potency of marijuana for research
18 purposes that was higher than 4 percent?

19 JUDGE BITTNER: THC you mean?

20 MS. CARPENTER: Yes, I'm sorry.

21 THE WITNESS: We have actually had
22 materials of higher than 4 percent for a long time,

1 certainly prior to 1999.

2 BY MS. CARPENTER:

3 Q And those were available to researchers?

4 A I mean it's in the inventory. Again, you
5 have to understand that the harvesting process, we
6 can do selective harvesting, and we have done
7 selective harvesting and had materials that are
8 purely leaves, have no, even before maturation of
9 the plant. If you pick the tops of the branches,
10 these are very small leaves that have high
11 concentration of the hairs, and you can pick those.
12 It's a severely labor intensive process, but you
13 can pick from the garden before they even flower,
14 and you can have materials around 6 percent.
15 That's totally just pure leaves. You are not going
16 to have 100 kilos or 200 kilos, but you'll have,
17 you know, two or three kilos of those tops. We
18 call them tops. And so we have had that for quite
19 a long time, prior to 1999.

20 Q Before 1999. How about in terms of what
21 has been available in the inventory of cigarettes?
22 Do you know when the first cigarettes were

1 available that had the potencies of higher than 4
2 percent?

3 A Actually, I have here a list of the
4 inventory, which has all these materials, but I
5 would say, you know, probably the higher content
6 was passed 2001.

7 Q Passed 2001?

8 A Yes.

9 Q Would it be helpful to look at your notes
10 to see?

11 A I can refine the inventory. I hope the
12 inventory, by the way, says when they were
13 prepared, but I'll look and see.

14 Q Okay.

15 [Pause.]

16 THE WITNESS: Unfortunately, the inventory
17 doesn't say when those were prepared, but it only
18 says it has the date of last analysis, but it
19 doesn't have when they were prepared. So I would,
20 just if you allow me to project a date, I would say
21 probably 2001.

22 BY MS. CARPENTER:

1 Q And that's for cigarettes higher than 4
2 percent?

3 A Yes. There might have been cigarettes at
4 the time when they were prepared prior to 2001 that
5 were maybe 4.3 or 4.2, around 4 percent, but if
6 you're talking about really getting higher than
7 that, you're talking about the current cigarettes
8 or the cigarettes that had been in the program that
9 are 6 percent, 7 percent, 8 percent. All these
10 were prepared past 2001.

11 Q And when you say past 2001, you mean more
12 recently than 2001?

13 A 2001 is when we had the, you know, the
14 first bulk material that had in excess of 7, 8, 9
15 percent, so, you know, to make an 8 percent batch
16 or a 7 or 6 percent batch, you need those high
17 potency materials. And these were prepared in
18 2001, the bulk material.

19 Q And that would have been at NIDA's request
20 that you--

21 A Yes.

22 Q That you planted the crop that would

1 result in the higher potency bulk material?

2 A Yes, yes.

3 Q Do you know when you got that request?

4 A 2000, 2001.

5 Q It would have been before the growing
6 season?

7 A I'm sorry. It was part of the contract
8 requirement for the 1999 to 2004 RFP.

9 Q And then I believe you testified yesterday
10 that you installed a deseeding machine in 2001?

11 A That's correct.

12 Q And did NIDA ask you to do that?

13 A No.

14 Q Did NIDA pay--was it paid for through the
15 contract between you and NIDA?

16 A No.

17 Q Who paid for that?

18 A The university.

19 Q At present, Dr. El Sohly, you hold the
20 only two licenses, you, the University of
21 Mississippi, hold the only two license to bulk
22 manufacture marijuana in the United States; is that

1 right?

2 A It's--I really can't answer that because I
3 don't know who other manufacturers are.

4 Q Do you know of any other manufacturers?

5 A I don't know of other manufacturers, but--

6 Q Do you know of any other source for
7 marijuana in the United States?

8 A There are many investigators that have--not
9 manufacturer's license but registration--no, I
10 don't know of any manufacturer registrations for
11 marijuana. I don't know, but this probably a
12 question the DEA can answer better than I can.

13 JUDGE BITTNER: Could I just ask, I don't
14 know if it's on the record anywhere. The
15 University of Mississippi is a State university
16 supported with tax money, right?

17 THE WITNESS: That's correct, Your Honor.

18 JUDGE BITTNER: I just thought that should
19 be in there somewhere.

20 BY MS. CARPENTER:

21 Q So at least you don't know of anywhere
22 else in the United States that researchers, medical

1 marijuana researchers could go to get a supply of
2 medical marijuana for research; is that correct?

3 A That's correct.

4 Q Now, I want to talk a little bit about the
5 marijuana that you grow at the University of
6 Mississippi under those two license. So let's talk
7 first about what you grow under the NIDA license.

8 A Okay.

9 Q We understand what we mean by that, the
10 NIDA registration?

11 A Yes.

12 Q The last time--I think you said yesterday,
13 the last time that you grew a crop for NIDA was
14 2001-2002, is that right?

15 A That's correct.

16 Q And the potencies that you have grown for
17 NIDA are from zero up to 15 percent; is that
18 correct?

19 A 14 point fraction.

20 Q Okay. Now, since the new contract was
21 signed in March of 2005, has NIDA asked you to grow
22 any more marijuana?

1 A No.

2 Q Has there been any discussion about
3 whether you will or will not?

4 A A possibility for growing some this coming
5 season.

6 Q By this coming season would be next
7 spring?

8 A In the next spring, yes.

9 Q Any discussion about how much that might
10 be?

11 A No, not yet. Too early for that.

12 Q And so you don't have any currently
13 growing for NIDA; is that correct?

14 A No, because that's not a growing period
15 right now.

16 Q You could grow some indoors I think you
17 testified yesterday?

18 A That's correct, but we're not.

19 Q Have you ever grown indoors for NIDA?

20 A No.

21 Q Now, when you grow the marijuana for NIDA,
22 you use the 12-acre plot that we talked about

1 yesterday; is that right?

2 A That's correct.

3 Q And do you get the seeds from NIDA?

4 A I get--

5 Q The seeds to grow the marijuana from?

6 A I have the seeds.

7 Q Did you get those seeds from NIDA? I knew
8 there was some discussion yesterday about where
9 they came from. You said you worked with the DEA
10 and I'm just curious how that worked.

11 A That's historically, yeah, way back before
12 my time, the original seeds. And then I acquired
13 on my own seeds from different sources.

14 Q On your own through the NIDA license?

15 A Through the licenses in my name, not
16 through the manufacturer license. Through the
17 researcher license, through the collaborating
18 license--

19 Q At the institute or at El Sohly Labs?

20 A At the institute.

21 Q Okay. So you basically have a stock of
22 seeds dating from when UMiss first started growing

1 for NIDA, and then you've added to that through
2 your institute license; is that fair?

3 A That's correct.

4 Q So under the new contract that you signed
5 in March of 2005 or that was signed by the
6 University, University of Mississippi stands to
7 earn close to \$6 million over the five-year period,
8 assuming it grows no marijuana at all; is that a
9 fair characterization of the contract?

10 A Well, I think when you say earn, that's
11 the cost of the contract. It's a cost
12 reimbursement contract. It's nonprofit, in other
13 words. I just want to make sure that "earn"
14 doesn't mean they will net, take \$6 million.

15 Q They could net 6 million if they--

16 A No, they couldn't net.

17 Q Okay. They could be paid 6 million by the
18 Government if they incur costs up to that amount;
19 is that fair?

20 A That's fair.

21 Q And that's without growing any new crops?

22 A Whatever the amount in the contract is.

1 Q Okay.

2 A I'm not sure how much it is, but--

3 Q We'll turn to that in just a minute. You
4 can check.

5 Now, turning from the NIDA license to the
6 institute license, the institute license is
7 different.

8 A Yes.

9 Q Some of what you cultivate at the
10 University of Mississippi just goes to the
11 institute, isn't that right?

12 A Yes.

13 Q Some of the marijuana that you cultivate
14 there.

15 A Yes.

16 Q Why does the institute grow its own
17 marijuana rather than use NIDA's marijuana?

18 A Because this particular marijuana is grown
19 for a particular purpose, and that is to prepare
20 extracts that would be used for commercial
21 pharmaceutical development activities, not the
22 marijuana itself, but the extract. So it has to be

1 separate from NIDA because that's not a function
2 that NIDA is supporting or it's not a function
3 that--using the Government material to prepare
4 things that you would eventually have a commercial
5 product.

6 Q So if somebody wants to develop a
7 commercial product with marijuana, they could not
8 use the NIDA marijuana; is that fair?

9 A That's correct.

10 Q How much per year, if that's a good
11 estimate, how much per year marijuana do you grow?
12 That's awkwardly phrased. Let me rephrase that.
13 How much marijuana do you grow per year for the
14 institute?

15 A It depends on the quota.

16 Q Can you give me an estimate over the last
17 two or three years?

18 A Last two or three years, approximately
19 1,000 kilos.

20 Q Each year?

21 A Roughly.

22 Q Okay. Do you grow that marijuana in the

1 same 12-acre plot that you would grow the NIDA
2 marijuana in?

3 A That's correct.

4 Q And where do you get the seeds from this
5 marijuana?

6 A These are the seeds that the institute had
7 from those other activities that I indicated to you
8 from the analytical license and the researcher
9 license that preceded the manufacturer license.

10 Q Since you work with both of those
11 projects, do the seeds interchange between them,
12 that is, do you have NIDA seeds and--

13 A No, they are not.

14 Q Let me just finish the question. Do you
15 have NIDA seeds and institute seeds, or do use both
16 seeds for both projects?

17 A No. We have separate seeds. It's a
18 separate inventory.

19 Q Who decides under the institute license
20 how much marijuana will be grown each year?

21 A It depends on the need.

22 Q Well, who makes the decision about the

1 need? Is that you or is that somebody else at the
2 institute?

3 A It depends on how much extract we have to
4 produce, we need to produce, and that's based on
5 the requests that we receive from our
6 pharmaceutical partner.

7 Q And who's your pharmaceutical partner?

8 A Mallinckrodt.

9 Q So Mallinckrodt decides how much--well,
10 let me ask you this. This extract is used for the
11 suppositories that UMiss holds the patent for?

12 A Well, the extract is used to purify this
13 extract and produce pharmaceutical grade Delta-9-THC.

14 Q And what is that?

15 A The active ingredient.

16 Q Yes. And what is that THC then used for?

17 A And that THC would be used for products,
18 pharmaceutical products that are based on
19 naturally-occurring THC, could be THC itself, could
20 be THC derivative that will go into the
21 suppository, could be THC that will go into other

1 formulations. We are working on another
2 formulation right now that involves trends because
3 of delivery system, could go into any new
4 development of new products in the THC area.

5 Q So Mallinckrodt and the institute are
6 engaged in a partnership in terms of investigating
7 ways--pharmaceutical uses for THC; is that fair?

8 A That's not just the institute and
9 Mallinckrodt. We have other partners too.

10 Q Who are those other partners?

11 A Right now we have the suppository's been
12 licensed to a pharmaceutical company in Chicago
13 called Insys Pharmaceuticals.

14 Q Could you spell that?

15 A Insys, I-N-S-Y-S. Insys Therapeutics.

16 Q Are there any other partners?

17 A No. We're discussing with another partner
18 that I'm not at liberty of disclosing right now.

19 JUDGE BITTNER: Doctor, do you know which--how do
20 I phrase this? My understanding is that
21 Mallinckrodt is a rather complicated corporate
22 structure. Do you know which piece of Mallinckrodt

1 is your partner?

2 THE WITNESS: It must be the
3 pharmaceutical part of Mallinckrodt.

4 JUDGE BITTNER: But you don't know the
5 full name of it?

6 THE WITNESS: I should, but I don't recall
7 the name.

8 JUDGE BITTNER: I'd like to ask the
9 counsel to come up with a stipulation as to that,
10 because I know there are multiple Mallinckrodt. I
11 mean they're all connected. I'm not suggesting
12 they are different, separate entities, but there's
13 a Mallinckrodt owned by a Mallinckrodt, owned by a
14 Mallinckrodt, owned by somebody, owned by Tyco. So
15 I would just like to have the correct name.

16 Thank you.

17 BY MS. CARPENTER:

18 Q So, in terms of the institute, you contact
19 your various partners, you find out what they are
20 working on or developing or you're developing with
21 them, and together you come up with an estimate of
22 how much extract you'll need for a particular year.

1 Is that fair?

2 A Those partners that need these materials
3 will have to have what we call a procurement quota
4 from the DEA.

5 Q Okay.

6 A Based on their--you know, they have to
7 obviously provide DEA with the supporting evidence
8 that they actually need that much material. Once
9 they have that procurement quota, then they can let
10 us know that they're going to need, you know, so
11 much material, and we have to estimate how much
12 marijuana we have to grow to produce that much
13 material, and we then have to get our quota for
14 that amount of marijuana and that amount of
15 extract.

16 Q Okay.

17 A So it's not just a simple decision, yeah,
18 we need so much, we need so much, and--

19 Q Okay. And how long does that process take
20 to get the quotas for the particular companies and
21 then for you to get your quota; that is, how far in
22 advance before the growing season would that

1 process have to start, roughly?

2 A The request for quotas has to--let's say
3 for 2006, the request for quotas is already in
4 place. You know, you're supposed to ask for your
5 quota by April or May of the year before.

6 Q Okay.

7 A And so you can have, you know, this quota
8 on time for the new year.

9 Q Okay. And who at the institute decides
10 what potency THC marijuana you will grow for the
11 institute's product development?

12 A I do.

13 Q You do? And what is that based on?

14 A It's based on economics. The higher the
15 potency is, the easier it is to extract it, the
16 more extract you can get. So it just makes sense,
17 you know, to shoot for the highest possible level.
18 But also another consideration is what the
19 cannabinoid profile is for the material that you
20 produce. And I make that decision.

21 Q Okay. And based on those economics that
22 you just talked about, what's the highest potency

1 of material that you have grown for the institute's
2 research purposes?

3 A Well, another consideration that I need to
4 apprise you of is that we--because this material
5 will be extracted, it doesn't really matter whether
6 it has leaves or has, you know, buds or whatever.
7 What matters is the average; when you put all the
8 material together, what the average is. So we
9 don't really try to segregate the leaves out of the
10 buds and so on. We can produce, again, just like
11 we can produce for NIDA, as high as possible. The
12 amount of biomass is also important, you know, for
13 the production of the extract.

14 So we have produced individual barrels, if
15 you will, that were in excess of 14, 15, 16--actually, I
16 have a barrel right now that has 23
17 percent THC. But when you put it all together, if
18 I take all my thousand kilos that I have and put it
19 together, the average would probably be about 7 or
20 8 percent. But the range is somewhere between 4
21 percent to, let's say, 23 percent, which is the
22 highest I have.

1 Q And when you say barrel, you're referring
2 to the bulk product?

3 A I'm sorry?

4 Q When you say you have a barrel of 23
5 percent potency THC, that's the bulk product, not a
6 barrel of extract?

7 A No. Bulk product. The extract is a much
8 higher percent than that.

9 JUDGE BITTNER: What form does the--now,
10 when you're talking about the extract, you're
11 talking about THC from this bulk product, right?

12 THE WITNESS: Well, the bulk product is
13 extracted with an organic solvent. Then you take
14 that extract, just like in the example I used, you
15 know, making coffee, and then you take that
16 extract, which is a huge amount of liquid that
17 contains all the components of the plant material,
18 then you subject it to a distillation process where
19 the solvent is distilled off and what you have is
20 the residue. And that residue is very thick, oily,
21 more or less like a tar preparation. That's the
22 extract. And then that very junky-looking material

1 is what you use then in the subsequent process to
2 purify THC out of that.

3 JUDGE BITTNER: What color is it?

4 THE WITNESS: The extract?

5 JUDGE BITTNER: Yes, the gummy--

6 THE WITNESS: Extract is dark, very, very
7 dark brown-green.

8 JUDGE BITTNER: Thank you.

9 BY MS. CARPENTER:

10 Q Now, do you store plant material from year
11 to year for the institute?

12 A Yes.

13 Q Do you keep some of that in storage?

14 A Yes.

15 Q How much would you say you have in storage
16 now?

17 A Right now how much we have?

18 Q Right.

19 A It's about a thousand kilos or so.

20 Q Okay. And is that stored in the same
21 place where you store the NIDA marijuana?

22 A No. They are separate storage, yes.

1 Q Is it a separate vault or is it all--

2 A We have two vaults, yes.

3 JUDGE BITTNER: Are the two vaults, one
4 for the institute and one for NIDA, or are they
5 different temperatures or--

6 THE WITNESS: They are--they are--we have
7 the two vaults. The majority of NIDA's is in one
8 vault, but we have some of the material from NIDA's
9 supply stored in the freezer that is in the second
10 vault simply because it's high THC content and we
11 need to keep it in the freezer because the chance
12 is that will stay in that storage a lot longer than
13 the institute material. The institute material is
14 presumably extracted more or less as it's produced.

15 JUDGE BITTNER: Okay.

16 BY MS. CARPENTER:

17 Q When the institute built those vaults, was
18 some or part of the cost covered by NIDA?

19 A Yes.

20 Q Okay. How much of that cost was covered
21 by NIDA?

22 A Half.

1 Q So the extracts that the institute makes
2 from THC, those are used with your business
3 partners. Are they used for any other purposes?

4 A No.

5 Q Okay. Does El Sohly Labs obtain any of
6 that extract?

7 A No.

8 Q Okay. And some of that THC extract is
9 used in the suppositories that you patented; is
10 that correct?

11 A Not yet.

12 Q Okay. It's used in research on those--

13 A Hopefully it will be.

14 Q Okay.

15 A Because what we have, we have taken the
16 suppository patent and the suppository formulation
17 all the way to Phase I clinical trial. So it's
18 really at the stage now, you know, beyond the
19 preclinical toxicology and all of that stuff that
20 needs material that is possible to be not GMP
21 material. So right now we have to have GMP
22 material to do that, and so we're waiting for the

1 supply of THC, of the bulk active THC to make the
2 product, the THC hemisuccinate, that will then be
3 used to make the suppositories that will then be
4 used for the Phase II and so on trials. So it's a
5 process in progress.

6 Q So let me just go back and break that down
7 a little bit. Why is the material that you have in
8 stock not available under GMP, under good
9 manufacturing processes, to be turned into
10 suppositories?

11 A It's not to that stage yet. The extract
12 is prepared GMP; the marijuana is grown GMP. But
13 it has to be purified under GMP and have a supply
14 of the bulk active THC that's GMP, which will be
15 done at Mallinckrodt. To have this material as the
16 starting material to make the hemisuccinate, which
17 is the product that will then be put into
18 formulation for the suppositories. So it--

19 Q Okay. I'll be showing my ignorance here,
20 but what is the difference--what additional
21 practices will need to be added to make the product
22 usable under GMP practices?

1 A Well, the product that we have right now
2 is just an extract. That's a very--

3 Q Let me just break that--but the extract
4 was created from marijuana that was grown under
5 GMP; is that correct?

6 A Yes.

7 Q And the process that was used to create
8 that extract was done with GMP?

9 A That's correct.

10 Q Okay. And so the extract needs to then go
11 into another--what?

12 A Process.

13 Q Okay, to be purified?

14 A A very elaborate process to be purified,
15 to get the THC out.

16 Q Okay. And who does that process?

17 A Mallinckrodt.

18 Q Mallinckrodt does that--

19 A Yes.

20 Q --purification process?

21 A That's correct.

22 Q Okay. And has it done that for any of the

1 materials that will be used in the suppository?

2 A Yes, it has, but it has not done enough to
3 start giving materials to other companies.

4 Q Researchers.

5 A They are doing--they're filing their
6 paperwork with the FDA.

7 Q Okay. So the FDA hasn't approved the GMP
8 steps for the next purification process?

9 A That's correct, yes.

10 Q Okay. I understand.

11 Now, I thought you said earlier that
12 Mallinckrodt was not doing the suppositories, that
13 Isis (ph), was it--

14 A Insys.

15 Q Insys had that license?

16 A Yes.

17 Q Okay. So why would Mallinckrodt be doing
18 this purification process for those suppositories?

19 A Well, I didn't say that it was just doing
20 it for the suppositories.

21 Q Oh.

22 A I'm saying that Mallinckrodt will be

1 preparing bulk active Delta-9-THC as a
2 pharmaceutical active ingredient that could be used
3 by Mallinckrodt for some of their own product
4 developments, and it could also have it as a bulk
5 active GMP chemical to provide to others who would
6 want some GMP Delta-9-THC, which is currently not
7 available in the U.S.

8 Q Okay. So Insys, that has the patent for
9 the suppositories that you created, currently--

10 JUDGE BITTNER: Has a license, not--

11 THE WITNESS: Yes, they have a license.

12 BY MS. CARPENTER:

13 Q A license, right, to use the patent that
14 you created, currently doesn't have access to the
15 kind of purified THC that it would need to
16 manufacture those suppositories?

17 A That's correct.

18 Q And is there any other place they could
19 get that other than Mallinckrodt, assuming that
20 they get the--

21 A Not at this time. Not at this time.

22 Q Okay.

1 A There are--you know, certainly because of
2 the delay in getting this material, they are
3 investigating other avenues of trying to get some
4 material because it's been taking a long time.

5 Q How long has it taken--

6 JUDGE BITTNER: Insys is looking at other
7 avenues, not Mallinckrodt.

8 THE WITNESS: Yes, ma'am. Insys is
9 looking at other avenues.

10 BY MS. CARPENTER:

11 Q Other avenues to obtain--

12 A To obtain--

13 Q --purified THC?

14 A Yes.

15 Q Okay. What are those other avenues it's
16 looking at?

17 A You know, one of the avenues is actual
18 chemical synthesis, so going back to synthetic THC.

19 Q Okay. So creating synthetic THC rather
20 than extracting it from a plant.

21 A That's correct.

22 Q Okay. And would that be more expensive

1 than getting it from the plant?

2 A It might be. It might not be. I don't
3 know.

4 Q Okay.

5 JUDGE BITTNER: Dr. El Sohly, when you say
6 "synthetic," could you tell me what you mean?

7 THE WITNESS: Delta-9-THC, Your Honor, is
8 a chemical that has a particular chemical
9 structure. You can get that chemical from the
10 plant material, marijuana; you can extract it out;
11 or you can make it in the laboratory from much
12 simpler chemical starting materials. You can take--it's
13 like building blocks. You can take those
14 building blocks, put them together, end up with the
15 final structure that is Delta-9-THC, which would be
16 the exact same thing as the natural material. If
17 you have them side by side, you couldn't tell which
18 is which. It's the same chemical, same everything.

19 JUDGE BITTNER: So synthetic means
20 chemically produced. It doesn't necessarily mean
21 fake.

22 THE WITNESS: That's correct.

1 JUDGE BITTNER: Okay.

2 THE WITNESS: Yes.

3 BY MS. CARPENTER:

4 Q And if THC can be synthetically produced,
5 then why is the institute interested in pursuing
6 extracts?

7 A Well, the idea, first of all, there was no
8 manufacturer--there's only one manufacturer of
9 synthetic Delta-9-THC, which I believe the company
10 name is Norac, N-o-r-a-c, that is--and maybe it's
11 bought now by another company or something, but it
12 used to be called Norac. But, anyways, that
13 company that has had the process for making THC for
14 a long time, ever since Marinol was put on the
15 market back 10, 12 years ago, but Norac has an
16 exclusive license with the company that
17 manufactures Marinol or that markets Marinol, so
18 they can only provide materials to--it used to be
19 Unimed, and I think now it's Solvay or something
20 like that. So they have an exclusive license. It
21 means they cannot produce for anybody else. They
22 have to produce only for this company. And that's

1 a single source. So there is no other--you have to
2 develop a new process. You have to put the
3 manufacturing facility in place. I mean, it would
4 be a very difficult thing for somebody just to
5 start up and do this.

6 Q Okay.

7 A So that's the reason--that's--a good
8 alternative is to go to the plant material, make
9 the extract, and then take that extract through a
10 purification process, which we have a patent for
11 that, and then get the natural THC out and have THC
12 available for pharmaceutical development of any of
13 the formulations or new products or whatever the
14 case might be.

15 Q Okay. So the THC extract was necessary
16 because there was only one source for the
17 synthetic; is that a fair statement?

18 A That's correct.

19 Q Okay. And nobody else could get the
20 synthetic even if they wanted to use it for a
21 different medical research purpose?

22 A Unless you start your own process

1 development.

2 Q Okay. Now, I think you just indicated
3 that the suppositories that you have patented have
4 been through Phase I preclinical studies; is that
5 right?

6 A That's correct.

7 Q Okay. Was any of that research--did that
8 go through the NIDA, NIH, Public Health Service
9 Committee approval process?

10 A The material that was used for that did
11 not come from the NIDA program. That material was
12 actually synthesized in--or, I should say, prepared
13 because I believe the THC that was used to
14 manufacture the clinical supply for the
15 suppositories that were used in the Phase I
16 clinical trial was prepared from natural THC, but
17 not in the U.S. It was prepared in the U.K.

18 Q Okay.

19 A And it was prepared by a company in
20 England, and the suppositories were manufactured in
21 England, and the clinical trial was actually done
22 in England. But it was done under the same rules

1 and regulations as applied to the FDA. These are
2 all FDA-approved facilities that carried out those
3 activities in the U.K.

4 Q Okay. And what company was that in the
5 U.K. that manufactured the suppositories?

6 A The company that manufactured the THC is
7 Macfarlan Smith--that manufactured the THC is
8 Macfarlan Smith.

9 Q And, again, that was a natural extract,
10 not a synthetic?

11 A I do believe that it was natural THC.

12 Q Okay.

13 A Natural THC, yes.

14 Q Okay. And is that also who manufactured
15 the suppositories?

16 A No. The suppositories were manufactured
17 by another company, a pharmaceutical company that
18 does formulations. The name is escaping me right
19 now. I believe maybe Panlabs in the U.K. Panlabs.

20 Q Panlabs.

21 A But don't hold me to this name, but it
22 sounds--Panlabs.

1 Q Do you know if there are other producers
2 of natural THC extract in England other than
3 Macfarlan Smith?

4 A I know there are several companies that
5 manufacture natural THC in Europe, but I'm not sure
6 if I know a particular one in England. I know GW
7 Pharmaceuticals have a supply of plant material and
8 extracts and so on, but I don't know if they
9 carried it all the way to having THC, you know,
10 natural THC as a pure chemical entity or not. I
11 don't know that.

12 Q Okay.

13 A But I know in Europe, in general, I know
14 there is one or two in Germany; there may be one in
15 the Netherlands. There are several companies that
16 at least claim that they have, you know, natural
17 THC that is maybe GMP. But I don't know that for
18 sure.

19 Q And was it Unisys that sponsored this
20 research in England with the Phase I--

21 A You mean Insys?

22 Q Insys. I'm sorry.

1 A No, it was not Insys.

2 Q Who sponsored that research?

3 A It was the predecessor of Insys. There
4 was another company that had the first license to
5 the suppository. That company was called Oxford
6 Natural Products. It was a British company that
7 went all the way to the Phase I. They could not
8 raise enough money to proceed with the development
9 of the product, so under the contract that we had
10 with the company, we pulled the product away from
11 them, and we relicensed to Insys.

12 Q Okay.

13 A But, nonetheless, because of the
14 contractual obligation, the data that was generated
15 belongs to the institute, belongs to us.

16 Q Okay. And why was that--why were those
17 Phase I studies done in England and not in the
18 United States?

19 A That was not our decision. This is a
20 decision of the company that had the license. It
21 was a U.K. company, and so it probably was a lot
22 more convenient for them to do it there.

1 Q Okay. Also, was it possible to get THC
2 extract that could be used in preclinical studies
3 in the United States at that time?

4 A Extract or TCH? I'm--

5 Q THC. I'm sorry.

6 A That probably preceded our preparation of
7 the extract. It's been a long time.

8 Q So the answer is no, there was nowhere to
9 get it in the United States at that time?

10 A At that time it was not available yet.

11 Q Okay. Let me just take you back to the
12 research that the institute conducted when you were
13 developing the suppositories.

14 A Okay, yes.

15 Q So apart from the marketing process, but
16 leading up to it, was any of that research reviewed
17 or approved by NIDA, NIH, or the PHS committee?

18 A The original work on the suppositories,
19 Your Honor was funded under an SBIR grant. It was
20 actually done in my private lab.

21 Q What is S-P--

22 A S-B-I-R, Small Business Innovative

1 Research program, S-B-I-R. And under this program,
2 small companies have the opportunity to put
3 together proposals to develop products, services,
4 processes, and so on that have the potential of
5 being marketed, being put--to put products on the
6 market. This program has money that is set aside
7 for the small businesses that could not be competed
8 for by anyone else but small businesses.

9 I put a proposal together to develop this
10 particular formulation, I believe back in 1990-something. I
11 don't remember the date, but, you
12 know, either 1990 or before or thereafter. That
13 program has a Phase I which allowed you to do work
14 with a small amount of money to prove the concept,
15 that this is something that will work or has a
16 potential of working.

17 If the Phase I is successful, then you are
18 eligible for a Phase II proposal, and I did the
19 Phase I and we had very good data, so we put a
20 Phase II. That gives you a lot more money to do a
21 lot of the other activities that will allow you to
22 bring this product closer to finalizing the concept

1 and know that you have something that is worth
2 pursuing by, let's say, a pharmaceutical company.
3 So this work was actually supported by NIH. The
4 whole entire initial work on the suppository was
5 supported by NIH.

6 Q Okay, but that's not my question. Was the
7 research that you did reviewed for scientific merit
8 by--

9 A Of course. It went through a grant.

10 Q Let me just finish my question--

11 JUDGE BITTNER: By whom?

12 BY MS. CARPENTER:

13 Q By the PHS committee or someone at NIDA?

14 A I don't know who reviews, but this was
15 actually federally funded. So it has gone through
16 the review process by a body of experts that review
17 this proposal and say, hey, this is something
18 really worth doing, to the point that they're
19 actually giving money to be done.

20 Q Okay. And SBIR is funded by--

21 A Small Business--

22 Q --NIH?

1 A --Innovative Research program.

2 Q Okay. And is that an agency of NIH?

3 A No. It's a program that is--it's not just
4 NIH that has this program. All federal agencies
5 that have research--a budget in excess of a certain
6 amount--and I don't know the exact amount--will
7 have to set aside a certain percentage of that
8 research budget for small businesses under this
9 program. And only small businesses can compete for
10 that little bit of money that's set aside for SBIR
11 program.

12 JUDGE BITTNER: So different agencies
13 might be--okay. I'm trying to get my brain around
14 this. So an SBIR grant could be made by, say,
15 Department of Defense or--

16 THE WITNESS: That's correct.

17 JUDGE BITTNER: Or by anybody--

18 THE WITNESS: Department of Agriculture,
19 Department of Interior--

20 JUDGE BITTNER: Anybody who's got research
21 money.

22 THE WITNESS: Any department in the

1 Federal Government that has a research budget in
2 excess of a certain amount of money will have to
3 set aside some of that money for the SBIR program.
4 And each agency that has that SBIR budget would
5 actually put out more or less like an advertisement
6 that we have this SBIR money and these are areas
7 that we are interested in that you can submit--as a
8 small business you can submit a proposal. But
9 you're not limited to those areas. If you have
10 another idea, you still submit, and if they say,
11 hey, this was not one of the points that we wanted
12 to do but it's worth doing, they can still support
13 it, they can still fund it.

14 JUDGE BITTNER: And so in this instance,
15 El Sohly Labs--this had nothing to do with the
16 University of Mississippi, right?

17 THE WITNESS: Well, the University of
18 Mississippi was a subcontractor because there is
19 some work that I had in that SBIR that I don't have
20 the facility to do it, such as animal work.

21 JUDGE BITTNER: But the applicant was El
22 Sohly Labs?

1 THE WITNESS: The applicant was El Sohly
2 Labs. The budget comes to El Sohly Labs. And the
3 university has like a subcontract to do that
4 portion that has the animal work, and it has its
5 own budget, but they don't bill NIH. They bill El
6 Sohly Labs. I bill NIH. When I get the money, I
7 pay the university.

8 JUDGE BITTNER: And so you were funded by
9 NIH, big NIH, not NIDA?

10 THE WITNESS: That's correct.

11 JUDGE BITTNER: Okay

12 BY MS. CARPENTER:

13 Q And was marijuana used in this research
14 developing the suppositories?

15 A No.

16 Q Was there THC used in this--

17 A Yes.

18 Q Okay. And where did that THC come from?

19 A It came from NIDA.

20 Q From NIDA.

21 A It's a--anytime you have a federally
22 funded grant that requires materials, you get this

1 material free of charge from NIDA or whatever the
2 source is.

3 Q And when you say it came from NIDA, does
4 that mean it came from you?

5 A Not necessarily.

6 Q Was there anybody else creating THC at the
7 time?

8 A Well, I think NIDA had a supply of THC, if
9 I can use this term again, synthetic THC in their
10 supply program before this--before they started
11 getting some of the natural THC.

12 Q And did you use the synthetic THC?

13 A That's correct, yes. In the initial
14 developmental work.

15 Q Okay. So that deals with the suppositories.
16 There were also a few patents yesterday
17 that had to do with the extraction process. Do you
18 recall those?

19 A Yes.

20 Q And in your research leading up to those
21 or research relating to the extraction process, was
22 any of that research--did any of that research go

1 through NIH or NIDA or PHC committee review?

2 A Yes.

3 Q And why was that?

4 A Because it was also funded by an SBIR
5 grant.

6 Q Okay.

7 A Same process that I just described for the
8 suppositories was the same process for the process
9 of extraction.

10 Q Okay. And did the marijuana that was
11 necessary to create the THC extract, did that come
12 from NIDA?

13 A It has to.

14 Q It didn't come from the institute?

15 A It had to come from NIDA.

16 Q Okay. At what point did the institute
17 start growing its own marijuana?

18 A Maybe in 1999, maybe 2000. Something like
19 that.

20 Q And is that after--I didn't look at the
21 dates of those patents yesterday, but what was the
22 date of the patent on the suppository, do you

1 recall?

2 A The date on the patent of the suppository
3 was 1992, I believe.

4 Q So the research--would you say that the
5 research that you had done on the suppository that
6 involved any use of marijuana or THC predated the
7 institute's growing of its own THC--marijuana to
8 make THC?

9 A Yes, first of all, the work on the
10 suppository did not use any marijuana. I just want
11 to clarify that.

12 Q Okay. But it did use THC.

13 A Second--yes, it used THC, and that THC
14 came directly from NIDA, and I believe at that time
15 all the THC that NIDA had in their supply program
16 was synthetic THC.

17 But to answer your question regarding the
18 dates, the development of the suppository way
19 preceded the acquisition of the manufacture license
20 for the institute to grow marijuana and prepare
21 extracts.

22 Q Okay. Now, with regard to the marijuana

1 that is currently grown by the institute, is all of
2 that used to create extracts?

3 A That's correct.

4 Q Okay. And do those extracts only go to
5 product development that you talked about earlier
6 with your partners?

7 A That's correct.

8 Q Okay. So the institute doesn't do any
9 research at the institute using those extracts?

10 A Well, the institute can do research.
11 Remember, we have also a manufacture license--another
12 manufacturer by the researcher license and
13 analytical license that we can produce some
14 material to do research with.

15 Q That's my question. Do you do any
16 research with the extracts that you create at the
17 institute?

18 A Yes.

19 Q You do? Okay. What research is that?

20 A Well, we do--you know, doing improvement
21 on that extraction process that's done, preparing
22 some--purifying some non-GMP material to create

1 some THC that could be used for developing new
2 formulations, new products. They're all non-GMP,
3 so it doesn't--the material doesn't have to be GMP,
4 so we don't have to get it from Mallinckrodt or
5 some other company that manufactures GMP or
6 preliminary research does not require GMP material.
7 So we can use extract for doing that.

8 Q And does that research for which you use
9 the extract that you've created, does any of that
10 research go through an approval process with NIDA
11 or NIH or the PHS committee?

12 A Well, see, you have to remember that the
13 research that I'm talking about is non-clinical
14 research.

15 Q I understand, but my question is--

16 A The review process--let me finish. The
17 Public Health Service, or whatever that committee
18 and all this process that you're talking about, is
19 because this is material that's going into humans.
20 It's clinical trials, and that's different than if
21 you just want to look at the chemistry of the
22 plant. If you want to see what the components in

1 there are, if you can do analytical work, if you do
2 formulation work, this is not clinical stuff. So--

3 JUDGE BITTNER: So the answer is no.

4 THE WITNESS: The answer, Your Honor, is
5 it doesn't require--it's a totally different
6 process, and we don't want to mix both together.

7 BY MS. CARPENTER:

8 Q So the answer is no.

9 A Yes.

10 Q Thank you. So is it your testimony that
11 that NIDA review or NIH review or PHS committee
12 review is only necessary for research when the
13 material--the research is going to be used in
14 humans?

15 A If you are asking NIDA for material in--you put a
16 grant--you can put a grant proposal that
17 doesn't have a clinical aspect to it. It will
18 still have to go through a review process.

19 Q Okay. What if you're willing to pay for
20 it yourself, take it outside of the grant proposal,
21 is it your testimony that any researcher who wanted
22 to research medical marijuana but did not want to

1 use that product in humans would not have to go
2 through the NIDA, NIH, or PHS committee review
3 process?

4 A I don't know that. You need to ask
5 someone from NIDA on that.

6 Q Okay. So when you stated previously that
7 it wasn't required for your research because that
8 wasn't used in humans, you don't really know
9 whether that's true or not, do you?

10 A The requirement--I'm just saying the
11 difference between what I know has been going
12 through with the request that came for the medical
13 marijuana process is for clinical trials.

14 Q I understand that, but that's not my
15 question. My question is: When you stated earlier
16 that it wasn't necessary for your research to go
17 through NIDA or NIH or PHS committee review because
18 it wasn't going to be used in humans, you don't
19 really know--

20 A Not only that, but I--

21 Q --whether that's true or not, do you?

22 A Not only that, but I was not using NIDA

1 material to start with. You can have a researcher
2 license, a researcher registration with the DEA to
3 do work that is non-clinical, that will allow you
4 to--you can make some materials, you can prepare
5 materials in the lab, you can grow some, you know,
6 marijuana if that is needed and use that for non-clinical
7 work.

8 If you start using these materials for
9 clinical--any work that is done with clinical
10 material for the clinic, for human use, has to be
11 under a manufacturer license.

12 Q Okay.

13 A But I'm not the only one registered as a
14 researcher with a Schedule I license to grow
15 marijuana as a researcher. There are several
16 researchers that have a Schedule I license that are
17 growing marijuana for research, for their own
18 research.

19 Q Okay.

20 JUDGE BITTNER: If I understand correctly,
21 everybody agrees that if you're going to do work
22 with humans, you have to get the material from NIDA

1 and you have to go through the whole NIDA process,
2 right? In terms of--oh, dear, I made it worse,
3 didn't I?

4 I guess the confusion is what are the
5 various pieces of when you need NIDA--this whole
6 review process with the PHS committee and so on,
7 when do you have to go through that and when do you
8 not need to, if you know?

9 THE WITNESS: Okay. I'll try to explain
10 to Your Honor the process and the difference
11 between the different registrations, the different
12 things that you can do with any one of those
13 registrations, and how these differences play into
14 the NIDA situation and acquisition of materials.

15 JUDGE BITTNER: Okay.

16 THE WITNESS: If you need some marijuana
17 to do research and you do not have the capability
18 of producing that marijuana in your own facility,
19 you have to get that from NIDA. There is no other
20 place to get it but NIDA because NIDA or the
21 government has the supply of marijuana that could
22 be distributed. So if you don't have the

1 capability of producing, you have no alternative
2 but to go to NIDA.

3 Now, if you have the capability of
4 producing marijuana, you have the proper
5 registration with the DEA as a researcher or as an
6 analytical laboratory, you can produce marijuana.
7 You have to--when you send that registration
8 request to the DEA, you have to tell them what you
9 want that registration for. And if you tell them,
10 well, I want that registration so I can grow some
11 marijuana, so I can take this marijuana and look at
12 the leaf structure or look at the components in
13 there, or look at this, look at that, whatever you
14 give them, the protocol of what you want to do, and
15 they approve your registration, then you can grow
16 that marijuana.

17 But the work that you can do with that
18 marijuana under that researcher license or
19 analytical laboratory license could only be non-clinical
20 work. Once you start putting things into
21 humans, with a controlled substance it has to be
22 under a manufacturer license. So any clinical

1 studies have to be done under a manufacturer
2 license.

3 JUDGE BITTNER: Oh, I see. So it's not
4 just that the manufacturer license is necessary for
5 commercial development. It's even if you're
6 nowhere near that point, if you just--okay. Let me
7 ask you--if somebody objects, I'll probably sustain
8 the objection, but if you're doing--if you're
9 simply doing research on what happens when a person
10 ingests a controlled substance, you don't
11 necessarily need a manufacturer license, right?

12 THE WITNESS: Well, it depends--

13 JUDGE BITTNER: If you're not trying to
14 develop a product.

15 THE WITNESS: That's correct. But if
16 you're going to give that substance to a human
17 being to see what it does to that subject, that's a
18 clinical trial.

19 JUDGE BITTNER: Well, I'm trying to get--but
20 doesn't clinical trial assume some sort of
21 development--in other words, if a--I'm thinking of
22 a case I had where a psychology department was,

1 say, testing the effects of cocaine on someone, on
2 people, they wouldn't have to have a manufacturer's
3 license, would they? A psychology department of a
4 university, wouldn't it just have a researcher
5 license? If you know.

6 THE WITNESS: They can have only a
7 manufacturer--I mean a researcher license, but the
8 producer of that cocaine would have to have a
9 manufacturer license.

10 JUDGE BITTNER: Okay.

11 THE WITNESS: Not the investigator.

12 JUDGE BITTNER: So the instance that you
13 gave of somebody producing his own marijuana in
14 order to put it into people in some fashion--

15 THE WITNESS: They cannot do it.

16 JUDGE BITTNER: --would have to have a
17 manufacturer license.

18 THE WITNESS: That's correct.

19 JUDGE BITTNER: And if I were a researcher
20 at the University of Chicago, in order to use
21 marijuana for any kind of research that involved
22 people, I would have to get the marijuana from

1 somebody who had a DEA manufacturer's license.

2 THE WITNESS: That's correct.

3 JUDGE BITTNER: Okay.

4 THE WITNESS: But at this point in time,
5 what I'm saying--and that one has to be NIDA, not--

6 JUDGE BITTNER: Right now.

7 THE WITNESS: That's correct.

8 JUDGE BITTNER: Okay.

9 BY MS. CARPENTER:

10 Q Because you're the only one who holds a
11 manufacturer's license and you have a contract with
12 NIDA; is that right?

13 A Well, that's part of it, but the main
14 reason is that NIDA is a representative of the
15 government that can distribute marijuana.

16 Q And where does that come from? Or how do
17 you know that?

18 A What do you mean how I know that?

19 Q How do you know that--well, let me ask you
20 this: Is it true that only NIDA can be authorized
21 to distribute in the United States?

22 A That's my understanding.

1 Q And what's your understanding based on?

2 A Based on the Single Convention.

3 Q Okay. We'll talk about that in a few
4 minutes.

5 Okay. Let me just ask you one other
6 question about the marijuana that you grow at the
7 institute. The marijuana that you grow at the
8 institute is, in part at least, going to be
9 extracted, and that extract will be provided to
10 Mallinckrodt; is that correct?

11 A That's correct.

12 Q Okay. And Mallinckrodt will then,
13 assuming all goes well, that it gets its GMP
14 approvals and all that, will be producing a product
15 that will then be put into materials that will be
16 put into humans; isn't that correct?

17 A That's correct.

18 Q Okay. And that marijuana does not come
19 from NIDA; isn't that correct?

20 A That's correct.

21 Q Okay.

22 A But I have to--

1 Q Let me just be clear. That process is not
2 under NIDA supervision at all, is it?

3 A No, it's not.

4 Q Okay.

5 A But the product that's produced--that is
6 distributed is not marijuana.

7 Q I understand that.

8 A We have not distributed any marijuana at
9 all.

10 Q I understand that.

11 A That's a big distinction between what we
12 are doing and what you're proposing to do.

13 Q But the growing of it you do. You do grow
14 the marijuana in order to--

15 A Yeah, you can--

16 Q --develop the extract.

17 A --grow it, you can do whatever you want to
18 do with it, but you cannot distribute it.

19 Q That's all I want to know.

20 All right. Now, let's talk a little bit
21 about the Mallinckrodt plans. Do you plan to grow
22 any marijuana this year which would then be

1 extracted to fulfill the needs of any private drug
2 developers?

3 JUDGE BITTNER: What do you mean by "this
4 year"?

5 MS. CARPENTER: That's a good question
6 because I guess we are--

7 BY MS. CARPENTER:

8 Q Do you have any currently growing?

9 A No.

10 Q Okay. Do you plan to grow any next year?

11 A If I get the proper quota and the proper
12 request, I will, and I hope I will.

13 Q Okay. Did you seek a quota--

14 JUDGE BITTNER: And this is for the
15 institute, correct?

16 THE WITNESS: That's correct, Your Honor.

17 JUDGE BITTNER: Okay.

18 BY MS. CARPENTER:

19 Q And when we say "next year," I guess I'm
20 referring to the next growing year, which would--

21 A Two thousand--

22 Q --be 2006-2007---

1 A That's correct.

2 JUDGE BITTNER: I'm sorry. I got confused
3 again.

4 MS. CARPENTER: When I say "next year," I
5 mean the next growing season, which would be--

6 JUDGE BITTNER: Yes, because I'm trying to
7 remember, is any of the institute marijuana grown
8 outdoors?

9 THE WITNESS: It's all grown outdoors--most of
10 it's grown outdoors.

11 JUDGE BITTNER: Okay. So you're talking
12 about next April--

13 THE WITNESS: That's correct.

14 JUDGE BITTNER: --institute marijuana
15 season.

16 THE WITNESS: Yes, Your Honor.

17 JUDGE BITTNER: Okay.

18 BY MS. CARPENTER:

19 Q And it's grown in the same 12-acre plot
20 as--

21 A That's correct.

22 Q --the NIDA marijuana, okay.

1 A Yes.

2 Q And is the--okay. Did you seek an
3 increase in your quota for this year to grow
4 marijuana which would be turned into extract for
5 private drug development?

6 A I have a quota request, that's correct.

7 MS. CARPENTER: Okay. I'd ask that the
8 witness be shown Government's Exhibit 79. Let me
9 just check on that number.

10 [Pause.]

11 MR. BAYLY: Your Honor, may I give the
12 exhibit to the witness?

13 JUDGE BITTNER: Yes.

14 MR. BAYLY: It's marked Government Exhibit
15 79, but it is not an exhibit that's been admitted.

16 BY MS. CARPENTER:

17 Q Dr. El Sohly, I'll ask you to take a look
18 at that and ask you whether you've seen that
19 before.

20 A Yes, I have.

21 Q Okay. Can you tell us what it is?

22 A This is a letter from the Deputy Assistant

1 Administrator--I believe that's the correct title,
2 Deputy Assistant Administrator--to Dr. Alice Clark,
3 who is the Vice Chancellor for Research and
4 Sponsored Programs.

5 Q And the date on that is June 15, 1005?

6 A That's correct.

7 Q Okay. And if you could turn to the last
8 page, is that document signed--I guess by--the last
9 two pages.

10 A Yes.

11 Q And is the letter signed by William Walker
12 from the Office of Diversion Control?

13 A Mm-hmm.

14 Q Okay. And then there's a signature on the
15 next page, which appears to be Alice Clark, dated
16 June 16, 2005?

17 A Yes.

18 Q Okay. And do you know generally what this
19 letter is about?

20 A Yes, I do.

21 MS. CARPENTER: Okay. At this time I
22 would move admission of Government's Exhibit 79

1 into evidence. I don't know if you want to make it
2 respondent's exhibit or what the government's
3 preference is there.

4 JUDGE BITTNER: Mr. Bayly?

5 MR. BAYLY: I understand, Judge Bittner,
6 that your practice is that if one party has an
7 exhibit which they don't put into evidence
8 themselves but the other party wants to put it in,
9 that you do allow that.

10 JUDGE BITTNER: I do. I think re-numbering it--
11 once it's in evidence, it doesn't
12 generally--there may be some exceptions--matter
13 whose exhibit it is.

14 MR. BAYLY: Well, in lieu of making a
15 futile objection, I'll have no objection.

16 JUDGE BITTNER: I think that's easier
17 since we already have the list, but if for some
18 reason it comes up, someone could note who offered
19 it, but okay, Government's 79 is received.

20 MS. CARPENTER: Okay.

21 [Government Exhibit No. 79
22 received in evidence.]

1 MR. BAYLY: But for the record, it's
2 admitted through the respondent.

3 JUDGE BITTNER: Correct. I don't know if
4 that would ever become relevant or not.

5 MR. BAYLY: Leave it as Government Exhibit
6 79?

7 JUDGE BITTNER: Yes, please.

8 MR. BAYLY: Okay.

9 BY MS. CARPENTER:

10 Q Dr. El Sohly, this is a letter from the
11 DEA about increasing the quota, the 2005 individual
12 manufacturing quota, for the University of
13 Mississippi; isn't that right?

14 A That's correct.

15 Q Okay. And the letter indicates on the
16 fourth line there that the quota would increase
17 from 913 kilograms to 4,500 kilograms. Is that
18 correct?

19 A That was the hope, yes.

20 Q Okay. And this letter indicates that DEA
21 will take the appropriate steps to raise the
22 aggregate quota as necessary. Is that correct?

1 A That's correct.

2 Q Okay. Has your quota been raised for
3 2005?

4 A Not my quota, but the aggregate quota has
5 been raised.

6 Q And when you say "not my quota," what do
7 you mean?

8 A Well, you have the--are you familiar with
9 what the aggregate quota is?

10 Q I'd like you to explain for the record.

11 A Okay. The aggregate quota, Your Honor, is
12 each individual manufacturer would request a quota
13 from the DEA for a particular substance or whatever
14 the product might be. And the combination of all
15 the requests from all the different manufacturers
16 around the country, when you put all these
17 together, that's the aggregate quota.

18 The DEA has to get that aggregate quota
19 through the UN process approved and so on that this
20 is the aggregate quota for this product for the
21 U.S. And then from that aggregate quota, it would
22 be split into this manufacturer has so much, this

1 one has so much, this one has so much.

2 If at any point in time the requests for
3 the DEA--the quota requests from different
4 manufacturers exceeds what the DEA has in the
5 aggregate quota, the DEA has to request an increase
6 in the aggregate quota through the UN. And then
7 once the DEA gets that aggregate quota increase
8 established in place, then they could give to the
9 manufacturers their shares, if you will, of that
10 aggregate quota.

11 So at the time when I put my request for
12 the 4,500 kilos quota for 2005, DEA had only
13 aggregate quota for 913, or something like that,
14 kilos. So the DEA had to revise the aggregate
15 quota to the level that will allow them to give me
16 my request of 4,500 if they approved. Okay, so--

17 Q Okay. Let me ask you, you indicate that
18 all the individual manufacturers from all over the
19 country would put in the request, but you're the
20 only manufacturer in the United States; isn't that
21 right?

22 A But I don't know that. Or I know--

1 Q Do you know of any other source that you
2 can get marijuana in the United States as a
3 manufacturer?

4 A Yeah, but I don't know if there is any
5 other manufacturer. I don't know that.

6 Q I thought you indicated earlier that you
7 did not believe there was any other source of
8 marijuana in the United States and that NIDA was
9 the only source.

10 A That's my understanding, but I don't know
11 that for sure. I mean, the DEA knows who has a
12 manufacturer for marijuana.

13 Q Okay. And you've been doing this for 30
14 years?

15 A Yes, I've been doing this for 30 years.

16 Q Have you ever heard of any other
17 manufacturer of marijuana?

18 A No, I haven't.

19 Q All right. And so you just indicated that
20 the DEA aggregate for that at the time the letter
21 was written was 913 kilograms?

22 A That's correct. Roughly about that much.

1 Q Okay. And in this letter, it says that
2 the University of Mississippi is requesting an
3 increase in its 2005 individual manufacturing quota
4 for marijuana from 913 kilograms to 4,500
5 kilograms.

6 A That's correct.

7 Q So your individual manufacturing quota was
8 913 kilograms?

9 A Yes.

10 Q Okay. And that's the same as the DEA
11 aggregate?

12 A That's correct.

13 Q Okay. Thank you.

14 Now, has the DEA increased your quota for
15 2005?

16 A No.

17 Q It has not.

18 A Not yet. It's still pending.

19 Q Okay. So they haven't denied it. It's
20 still pending.

21 A It's still pending.

22 Q Okay.

1 A The aggregate quota, however, has been
2 revised.

3 Q And what has it been revised to, do you
4 know?

5 A I don't remember.

6 Q Okay. Is it something like 4,500 pounds--or
7 kilograms?

8 A Around that figure, yes.

9 Q I'm sorry?

10 A Around that figure, yes.

11 Q Around that figure.

12 A But I'm not sure that it's exactly that
13 or--I think at some point there was, like, 20 grams
14 more in the requests--in the aggregate quota than I
15 requested.

16 Q Twenty grams more?

17 A Twenty grams more.

18 Q Okay.

19 A So at some point--I don't remember, but
20 that's why I was saying I don't know whether there
21 is another manufacturer, because at some point the
22 aggregate quota for marijuana had more than I had.

1 Q Okay. Now, the increase from 913
2 kilograms to 4,500 kilograms, over four times that--so
3 you're asking for an increase four times your
4 previous amount, right? A little more than that?

5 A Yes.

6 Q Okay. And what would be the purpose of
7 that increase?

8 A Well, with Mallinckrodt, we were looking
9 at really moving--and that's the purpose of this
10 whole--or at least part of this whole letter and
11 all of this, you know, procedure that went through
12 to that point, is that we were--or at least
13 Mallinckrodt was anticipating going from the
14 development stage of the product to a launching
15 stage. And, therefore, for launch, you're going to
16 need a lot more material. So that was the
17 anticipation.

18 Things got delayed and so on, so that's
19 where we are.

20 Q Okay.

21 JUDGE BITTNER: I'm sorry. I got
22 confused--for a change.

1 Does this letter, Government Exhibit 79,
2 increase the institute, right? That's what we've
3 been using as shorthand for the University of
4 Mississippi National Center for Natural Products
5 Research, right?

6 THE WITNESS: Yes, Your Honor.

7 JUDGE BITTNER: Okay. Does this letter by
8 its terms increase the institute's manufacturing
9 quota for 2005 to 4,500 kilograms?

10 THE WITNESS: No, Your Honor, it does not.
11 The only--

12 JUDGE BITTNER: I see.

13 THE WITNESS: It does two things.

14 JUDGE BITTNER: Okay.

15 THE WITNESS: Initially, what we had, we
16 had requested an upgrade or an increase of our
17 quota from the 913 to 4,500 kilos. The reason for
18 that is we're anticipating that Mallinckrodt would
19 be launching a product in 2006 and, therefore,
20 they're going to need a lot of material to prepare
21 for that launch. You're now going from the
22 research and development activity or from

1 developing a product and doing the initial clinical
2 trial and so on, getting to a stage where you're
3 going to actually be sending--putting product on
4 the market. So you're going to need a lot more
5 material then, and that's the jump from 913 to
6 4,500 kilos.

7 Now, because that was the purpose stated
8 for needing that quota, the DEA indicated that,
9 well, that's a different--you're going into a new
10 era of production, you're going into launch instead
11 of just development, and so we have to look at that
12 again. You have to apply for another license or
13 another registration that explicitly says that you
14 will be launching pharmaceutical products. And
15 that's the purpose of this.

16 So we said, okay, we don't have a problem
17 doing that, except that if we wait until we put in
18 and get a new manufacturer license--registration, I
19 should say, then it will be too late to grow.
20 Would you please allow us to grow and let us have
21 the material in place, it will be quarantined, if
22 at the final analysis everything is denied and it's

1 not going to go through, then we lost a season, we
2 lost the material. But if it's going to through,
3 then at least we have the material.

4 So these were the stipulations that were
5 outline in this letter.

6 JUDGE BITTNER: I see. So even though the
7 first paragraph says DEA is willing to grant this
8 request because of all the provisos, it hasn't
9 happened yet?

10 THE WITNESS: It hasn't happened yet. We
11 are still waiting for that.

12 JUDGE BITTNER: Okay. Thank you.

13 BY MS. CARPENTER:

14 Q Dr. El Sohly, if you look at paragraph 3,
15 the letter says, "Unless DEA issues a corresponding
16 individual manufacturing quota authorizing the
17 UMiss Center to convert such marijuana," is there a
18 separate quota for--

19 A The extracts--

20 Q --extracts?

21 A Yes, ma'am.

22 Q Okay.

1 A But I just want to, you know, clarify to
2 you so you don't say, well, but it's not in the
3 Federal Register that you have a quota for extract.
4 The extract and marijuana are the same--are
5 considered as the same code number, and, therefore,
6 there is no difference between marijuana and
7 extract. So it's only--

8 Q But is the quota different?

9 A It's a quota in terms of the DEA--from the
10 DEA side internally, but it's not--it doesn't
11 appear in the aggregate quota because it's the
12 same, you know, drug code, 73--

13 Q So in terms of the UN Convention, there
14 would not be a separate quota for extracts?

15 A We have a separate quota for extract.

16 Q In terms of the United Nations?

17 A No, not the United Nations. United
18 Nations--

19 Q DEA internal provisions?

20 A It's only for internal use at the DEA and
21 for us. We cannot prepare any more extract than we
22 have in the extract quota even though we have the

1 plant material.

2 Q And where does that limitation come from?
3 Is that a limitation on your license?

4 A It's a limitation that the DEA has. We
5 have to tell DEA what we want to do with this plant
6 material, and so we have to keep track of how much
7 extract is prepared and so on. Just having the
8 quota for the plant material doesn't mean you can
9 do what you want to do with it. You have to say
10 what you are going to do with this plant material.

11 Q Right. And when you say what you want to
12 do with this plant material, the DEA says that you
13 can only make X amount of extract?

14 A They don't say you have to make X amount.
15 I say how much extract I want to make, and I
16 project that to make that amount of extract I need
17 X amount of plant material.

18 Q Okay.

19 A Now, sometimes this X amount of plant
20 material might fall short of providing me of the
21 amount of extract that I need, and sometimes it
22 might have actual overage, and that overage just

1 remains in the inventory until the next year.

2 Q Okay. So there's not a quota in terms of
3 how much extract you can get from the marijuana?
4 That's my question. There's no separate DEA quota.

5 A There is a separate DEA quota for how much
6 extract you can prepare, not that you can get. You
7 don't know how much you're going to get because the
8 plant material is different every season. Every
9 time, every barrel, every batch is going to maybe
10 give you a little bit more or a little bit less
11 extract depending on the THC content, the other
12 components that might be in the plant material. So
13 you're limited by how much you can prepare.

14 Q What is the current--well, let me ask
15 first: Does Insys have a contract with
16 Mallinckrodt to provide THC extract?

17 A Yes.

18 Q Okay. And what are the terms of that
19 contract?

20 A Just to--

21 Q In terms of price and timing.

22 A Well, the timing is, you know, you provide

1 the extract when they need it, and the price is
2 based on, you know, the THC content of the plant
3 material and cost and so on.

4 Q All right. And when you say you'll
5 provide the extract when they need it, do they need
6 it now?

7 A They have actually to request it. The
8 quota for 2005, I'm not sure they have all that
9 approved or not. I'm not really sure. But at this
10 point in time, I don't have a request from
11 Mallinckrodt to provide them with some extract for
12 the remainder of this year.

13 Q Okay. And have you already provided
14 Mallinckrodt with some extracts?

15 A Yes, I have.

16 Q And is that extracted from the marijuana
17 that you grew under the institute license?

18 A That's correct.

19 Q Okay. And did they pay for that extract?

20 A Yes, they have.

21 Q Okay. And who set the price for that?

22 A It's between the institute and

1 Mallinckrodt.

2 Q Okay. And does the institute profit at
3 all from that?

4 A Not profit per se.

5 Q Does it make any profit at all?

6 A It's not a profit.

7 Q So the institute creates an extract and
8 sells it to Mallinckrodt for no profit whatsoever?

9 A For, you know, getting money back for this
10 material that was provided to Mallinckrodt.

11 Q So it's simply at cost?

12 A Well, I don't know that it's at cost.

13 Q So if it's not cost, there might be
14 profit? It's got to be either cost or profit or
15 below cost, right?

16 A Well, you know, the cost is one thing.
17 The cost could be--if you calculate the cost that
18 includes all the time and effort that you have put
19 in in coming up with all these different things,
20 that's what's covered. There is no profit per se.

21 Q So there's no provision for profit in that
22 contract?

1 A Not to my knowledge.

2 Q Okay. Have you seen the contract?

3 A Yeah, I have seen the contract.

4 Q And who negotiated the price? Was that
5 you?

6 A The Office of Research.

7 Q Okay. Were you involved in that
8 negotiation?

9 A To some extent, yes.

10 Q To what extent?

11 A I was there.

12 Q So you were there during the negotiation?

13 A Yes.

14 Q Okay. And in terms of how the University
15 of Mississippi came up with its price, did it just
16 gather together all of its costs, all of its direct
17 costs?

18 A All the costs, the overhead, the research
19 and development activities, and all of that, yes.

20 Q So there's a research and development
21 component of that?

22 A That's correct.

1 Q Okay. To sort of cover the cost of the
2 research and development that had been done to get
3 to the point where you could provide an extract?

4 A Yeah.

5 Q Okay. And that research had been funded
6 through NIDA, I think you said, or through Small
7 Business--

8 A Well, some of that research, yes.

9 Q Okay. So you had already been paid for
10 some of that research?

11 A That's correct.

12 Q Okay. So Mallinckrodt's paying for that
13 research again?

14 A Well, there is also, you know, development
15 activities that you are putting things in place,
16 extra things that you put in place to be able to
17 produce, you know, cost of equipment.

18 Q Now, Mallinckrodt--the marijuana that
19 you'll be growing for Mallinckrodt--and I
20 understand you have to make the extract that
21 Mallinckrodt will receive. Where do you get the
22 seeds for that marijuana?

1 A I have a seed supply.

2 Q That would be the institute seed supply?

3 A That's correct.

4 Q Okay. And, again, is that grown in the
5 same 12-acre plot that you grow the NIDA marijuana
6 and--

7 A Yes.

8 Q --the institute's research marijuana?

9 A Yes.

10 Q Okay. And does Mallinckrodt require you
11 to grow or ask you to grow a certain potency of
12 marijuana to develop--

13 A No.

14 Q Okay. Is that decision up to you?

15 A Yes.

16 Q Okay. Are they requiring a certain--does
17 THC extract, the extract that you'll be sending,
18 does that come in different potencies?

19 A Yes.

20 Q Okay. And have they set a potency that
21 they--

22 A Yes, they have.

1 Q --would like? And what potency level is
2 that?

3 A Forty percent.

4 Q Forty percent?

5 A Yes.

6 Q Okay. Do you plan on growing some of that
7 material indoors?

8 A Not for production. It's to--it's not
9 possible to have that much material produced
10 indoors.

11 Q Okay.

12 A You know, at least with the current
13 facility, unless you expend a tremendous amount of
14 money in infrastructure.

15 Q Okay. Does the institute have any
16 arrangements with Mallinckrodt in terms of bonuses
17 or any other way in which Mallinckrodt would pay
18 the institute for the extracts? For example--let
19 me just give you an example--if after a product
20 launch the product sold 2,000 or 20,000 units, is
21 there any provision in the contract that allows the
22 institute to make more money if--

1 A Yes.

2 Q --if the--

3 A Yes, there is.

4 Q --if the product succeeds?

5 A Yes.

6 Q Would you describe that provision?

7 A It's a royalty.

8 Q A royalty.

9 A Yes.

10 Q Okay. So in addition to those royalties,
11 does Mallinckrodt pay a set fee for the extracts it
12 receives from you?

13 A Like I said, depends on the THC content.

14 Q But depending on the THC content, does it
15 pay for the extracts from you a set fee?

16 A Yes, it does.

17 Q So for a particular percentage it would be
18 X amount of dollars, and for another percentage it
19 would be X plus dollars?

20 A Yes.

21 Q And then the royalties would be in
22 addition to that?

1 A Yes, that comes after launch.

2 Q Okay. Now, as far as you know, there's
3 not another grower in the United States
4 Mallinckrodt could have gone to to get the natural
5 THC extract, is there?

6 A No, I don't.

7 Q Have you seen any economic models
8 forecasting revenue that University of Mississippi
9 expects from this arrangement with Mallinckrodt?

10 A No.

11 Q Do you know who will receive the royalties
12 that you mentioned; would that be the institute or
13 the university?

14 A Well, it's the same thing. The royalty
15 would come to the university, but the university
16 has a policy as far as distribution of royalty
17 between the central administration, research, and
18 sponsor programs, activities, the unit creating the
19 research that resulted in that royalty, and also
20 with the inventors.

21 Q Okay. Now, the license agreement that you
22 have with--and I know I'm going to get this wrong--Insys,

1 not Unisys--Insys relating to the
2 suppositories.

3 A Yes.

4 Q Is there a similar arrangement for you to
5 provide THC extract to them, or would that extract
6 that they need come from Mallinckrodt?

7 A No. There is no provision in the
8 agreement that we have with Insys for us to provide
9 them with raw materials.

10 Q Okay.

11 A They just have a license to the product,
12 and it's up to them to acquire the THC from
13 whatever supply they can get it, and obviously,
14 Mallinckrodt would be a good starting point. Had
15 they had the material ready by now, this would have
16 really helped our suppository project tremendously,
17 but it's not, so.

18 Q Okay. Dr. El Sohly, do you use pesticides
19 in your growing of marijuana?

20 A No.

21 Q Herbicides?

22 A No.

1 Q Any growth hormones?

2 A No.

3 Q Okay. Are you familiar with organic
4 growing processes?

5 A Only on general terms.

6 Q Would you say that your product is an
7 organic one, organically produced?

8 A I think the only confusing thing to me as
9 far as organically produced is whether the use of
10 chemical fertilizers is considered as you're not
11 doing it organically or not.

12 Q Okay.

13 A And we do use fertilizers.

14 Q Chemical fertilizers.

15 A Fertilizers, triple 13 or 6-0-5 or
16 whatever those kinds of fertilizers are. So we
17 use--only thing we use are fertilizers, but we
18 don't use herbicides, pesticides, rodenticides, any
19 of that stuff.

20 Q Okay. Now, you indicated yesterday that
21 NIDA holds the drug manufacturer file for the
22 marijuana that you grow for the NIDA contract; is

1 that right?

2 A You mean the drug master file.

3 Q I'm sorry. Did I say something different?

4 A You said the drug manufacturing file.

5 Q Sorry. The drug master file, correct?

6 A Yes. Well, it's not NIDA actually. The
7 drug master file is filed with the FDA, but it's
8 owned by NIDA.

9 Q Right. It's filed with the FDA but NIDA
10 owns it?

11 A That's correct.

12 Q Now, do you have a separate drug master
13 file for the marijuana that you grow for the
14 institute to support Mallinckrodt?

15 A Yes, yes, I do.

16 Q You do?

17 A Yes.

18 Q Okay. Is part of your deal with
19 Mallinckrodt that they can rely on that drug master
20 file to--

21 A At this point in time they're the only
22 organization that's allowed to reference that drug

1 master file.

2 Q Okay. And does your contract provide that
3 they're the only one who will be allowed? That is,
4 is it an exclusive contract?

5 A No, I don't think that actually was part
6 of the contract agreement, but I think if we are to
7 provide extract for another company that will use
8 that extract for whatever, if there's another
9 company that wants to make another product similar
10 to Sativex, let's say, they can get extracts from
11 our process, and they would be allowed to reference
12 that drug master file because that has--the drug
13 master file that we have is more--has a lot more
14 information in it than the NIDA drug master file
15 because it goes also into the process of making the
16 extract and providing all the way from the growing
17 the plant material all the way to providing the
18 extract. So if it is another company that is
19 interested in getting some extracts from us, and
20 they would use that extract to do some clinical
21 development or new product or something like that,
22 then we would write the FDA and tell them that this

1 company XYZ can--has the right to reference our
2 DMF.

3 Q Okay.

4 JUDGE BITTNER: And it's the institute
5 that owns this DMF?

6 THE WITNESS: That's correct.

7 BY MS. CARPENTER:

8 Q The product launch that you and
9 Mallinckrodt have a contact about, Mallinckrodt, as
10 I understand it, is seeking to launch a generic
11 Marinol at the expiration of the Marinol patent?

12 A That's correct, yes.

13 Q So if there was another company that also
14 wanted to manufacture generic Marinol, would you
15 allow that company to buy your extract for those
16 purposes?

17 A That's correct.

18 Q So there's nothing in your contract with
19 Mallinckrodt that would--

20 A No. The contract we have with
21 Mallinckrodt, as far as providing the extract, is
22 nonexclusive. Now, the process of purifying the

1 extract through the THC for the purpose of getting
2 the THC out is exclusive. So another company that
3 can buy the extract, they have to have their own
4 process for taking from that point on, but there's
5 nothing in our contract with Mallinckrodt that will
6 prevent us from selling extract to other companies.

7 Q Okay. And do you know the current status
8 of the Mallinckrodt product?

9 A I know that they have submitted their
10 information to the FDA.

11 Q That's an ANDA?

12 A The ANDA, and they had some questions that
13 had to be addressed, and they are preparing those
14 questions. So it's in the DMF stage right now.

15 Q And is there a process that Mallinckrodt
16 has to go through with the DEA as well involving
17 rescheduling?

18 A I'm sure the product that they will have--because
19 they would have the same material basically
20 like Marinol. It's a generic product of Marinol.
21 And I'm sure that Mallinckrodt, if they haven't
22 already done that, and I believe they have a

1 request in place for the DEA to reclassify their
2 product. But, of course, that reclassification,
3 not reclassifying, you know, changing the schedule
4 from being a Schedule I, which is all the raw
5 material leading to the final product is Schedule
6 I, and until they have an explicit rescheduling of
7 their own product to a Schedule III, just like
8 Marinol, then it's still Schedule I, and part of
9 that rescheduling of course is pending on the FDA
10 approving their ANDA, so it's a process the all has
11 to happen, you know, one after the other. So--but
12 I'm sure they already have some requests or at
13 least alerting the DEA to the fact that they are
14 going to need that reclassification.

15 Q But you don't know whether that's been
16 granted or not?

17 A I don't believe it's been granted or could
18 be granted because the FDA hasn't granted that, you
19 know, hasn't approved that product yet. So it's
20 part of the process.

21 Q Right. Do you know if Mallinckrodt tried
22 to obtain marijuana from NIDA, which it would then

1 extract and turn into the THC it wants to produce?

2 A I don't believe they have, but I don't
3 know that for sure.

4 Q Okay. Now, if there were another grower
5 in the United States with the bulk manufacturing
6 for marijuana license, at the time--let me step
7 back and ask you this. How long does the contract
8 last that you have with Mallinckrodt to provide the
9 THC extract?

10 A I don't remember, but if I remember
11 correctly, it's 10 years.

12 Q Ten years.

13 A Yes.

14 Q So if in another 10 years the product was
15 going well and Mallinckrodt wanted to renew its
16 contract or wanted to at least keep producing this
17 Marinol generic substitute, and there were another
18 grower licensed in the United States to grow
19 marijuana from which an extract could be produced,
20 then Mallinckrodt could go to that other grower,
21 couldn't they?

22 A Yeah, they could, but that grower have

1 also to produce the extract. They can't ship the
2 material to Mallinckrodt or to another company to
3 do that process.

4 Q All right. So then University of
5 Mississippi would have some competition with
6 whoever that other grower is, assuming they could
7 produce the extract, for that Mallinckrodt renewal
8 contract, wouldn't it?

9 A I would say yes.

10 Q So University of Mississippi has a
11 financial interest in being the only grower of
12 marijuana from which an extract can be produced, at
13 least at this point in time, doesn't it?

14 A I would say yes.

15 Q Turning your attention, Dr. El Sohly, to
16 the suppository product that you have developed, do
17 you know whether the company that has the license
18 for that product--and let me just step back. If
19 they do produce that product and sell it, I presume
20 UMiss would be entitled to royalties as well?

21 A That's correct.

22 Q Okay. Have they filed anything with the

1 FDA to develop that product, the suppositories?

2 A No.

3 Q Not yet?

4 A Not yet.

5 Q So there's no IND pending?

6 A No. They're working on trying to get the
7 supply first.

8 JUDGE BITTNER: Could I just ask? Doctor,
9 you said that your contract with Mallinckrodt, the
10 institute's contract with Mallinckrodt, isn't
11 exclusive insofar as the institute could provide
12 extract to other companies.

13 THE WITNESS: That's correct, Your Honor.

14 JUDGE BITTNER: Does the contract provide
15 by its terms, leaving aside DEA requirements and so
16 on, that Mallinckrodt can't buy extract from anyone
17 else? I mean, recognizing that there's nobody else
18 who can supply it right now, but if there were,
19 could Mallinckrodt buy it from them?

20 THE WITNESS: I don't--Your Honor, I'm
21 sorry, I don't know. I don't know if it prevents
22 them from or--I think they have to buy a minimum

1 amount. And if I remember correctly, that minimum
2 amount really is not that much, is like 10 kilos or
3 something, which is not enough to make a difference
4 really in the--but if there is, they could.

5 BY MS. CARPENTER:

6 Q With regard to the patent that you hold,
7 did you assign that to the University of
8 Mississippi?

9 A Yes.

10 Q So the royalties that would come from any
11 production of that suppository product would come
12 back to the University of Mississippi, and would be
13 divided up along the lines you discussed earlier?

14 A That's correct.

15 Q And as an inventor, you would be entitled
16 to some of those?

17 A That's correct.

18 Q You personally?

19 A Yes.

20 JUDGE BITTNER: Is that true with all of
21 the patents?

22 THE WITNESS: That's true with all the

1 patents, Your Honor.

2 BY MS. CARPENTER:

3 Q With regard to the research that
4 Mallinckrodt has done with developing the extract
5 purification process, do you know whether any of
6 those protocols for its research were submitted to
7 review by NIDA or NIH or the PHS review committee,
8 or PHS committee, rather?

9 A I don't think so because they--first, they
10 are not asking anything from NIDA or--no, it's not
11 required.

12 Q So it wasn't necessary because they're
13 getting the extract directly from the institute and
14 not from NIDA; is that correct?

15 A Plus any of the clinical trials they are
16 doing, they are not doing with the extracts anyway.
17 They're doing with a purified single-entity
18 chemical compound.

19 Q Now, if other delivery forms of marijuana
20 or THC as medicine were to be approved by the FDA,
21 those forms would compete with your suppository,
22 wouldn't they, on some broad level anyway?

1 A I don't really like to lump marijuana with
2 THC in that context.

3 Q Well, I think you testified earlier that
4 the main active ingredient of marijuana was THC.

5 A Yes, but you don't say marijuana or THC.
6 These are two different, quite different things.

7 Q So you don't think that if some form of
8 marijuana as a plant were approved as medicine,
9 that that particular FDA approved prescription
10 medicine would compete with Marinol, for example,
11 or with your suppository--

12 MR. BAYLY: Objection. Excuse me, Dr. El
13 Sohly. This is getting out of the scope of the
14 direct. It's also getting into medical issues, and
15 in fact, I believe respondent's counsel yesterday
16 indicated that the witness was not qualified to get
17 into medical issues here, and that's exactly what
18 this questioning or this line of questioning seems
19 to be getting into.

20 MS. CARPENTER: May I respond, Your Honor?

21 JUDGE BITTNER: Yes.

22 MS. CARPENTER: What I'm asking is not

1 about his medical testimony, but he's outlined that
2 he has several business interests and financial
3 interests in developing these particular medicines
4 or medications, and I'm asking what the competition
5 for those medications would be, if he knows as part
6 of his development, as--

7 JUDGE BITTNER: Why don't you ask that?

8 MS. CARPENTER: Okay. I thought I did.

9 JUDGE BITTNER: Which isn't quite what you
10 asked before.

11 BY MS. CARPENTER:

12 Q The suppository that you have invented and
13 patented, and now which has been licensed to a drug
14 developer, are there other medications that have
15 currently been approved that would compete with
16 your suppository, that people would use for
17 generally the same purposes?

18 A The only product that I know right now is
19 Marinol.

20 Q Okay. And if there were a form of
21 marijuana as whole plant medicine, either smoked,
22 or vaporized or some other delivery form that

1 involved the whole plant, do you think that
2 particular prescription drug, if it were approved
3 by the FDA, would also compete with Marinol or with
4 your suppository product?

5 A Well, any product that you put on the
6 market for the same indication, regardless what it
7 is, if it's for the same indication, these are
8 competing products.

9 JUDGE BITTNER: What is the indication for
10 the--

11 THE WITNESS: Right now, THC has been
12 approved by the FDA for nausea and vomiting caused
13 by chemotherapy in cancer patients, and it's also
14 been approved for --as an appetite stimulant for
15 AIDS patients that are suffering from the wasting
16 syndrome. So it's as anti-nausea and appetite
17 stimulant. These are the two current indications
18 for which THC is approved.

19 JUDGE BITTNER: Not pain relief?

20 THE WITNESS: Not yet.

21 MS. CARPENTER: I'm sorry. Not what, Your
22 Honor?

1 JUDGE BITTNER: Pain relief.

2 BY MS. CARPENTER:

3 Q I'll ask that the witness be shown
4 Respondent's Exhibit 2. I'll ask you to take a
5 look at that Dr. El Sohly. And I'll represent for
6 the record that Respondent's Exhibit 2 is entitled
7 Single Convention on Narcotic Drugs, 1961.

8 A Yeah.

9 Q You referred several times earlier in your
10 testimony to the Single Convention. Is this the
11 Single Convention you were referring to?

12 A Yes.

13 Q I'd ask that Respondent's Exhibit 2 be
14 entered into evidence.

15 JUDGE BITTNER: Mr. Bayly?

16 MR. BAYLY: Your Honor, I thought this was
17 already entered. We have no objection to the
18 exhibit being admitted.

19 MS. CARPENTER: I don't think it was
20 entered previously, but I could be mistaken.

21 JUDGE BITTNER: Well, even if it is, I
22 have found that sometimes what happens is if I have

1 duplicate exhibits from duplicate parties, there's
2 already stuff in the record that refer to each
3 number. So if I take one out, we end up not
4 knowing what the reference is.

5 Respondent 2 is received.

6 [Respondent's Exhibit No. 2
7 received in evidence.]

8 BY MS. CARPENTER:

9 Q You testified earlier that you were
10 familiar with the Single Convention; isn't that
11 correct, Dr. El Sohly?

12 A In general terms, yes.

13 Q If I could ask you to turn--there's two
14 page numbers in these. I want to make sure I give
15 you the right one. If you'll look at the Bates
16 numbers in the right-hand corner of the bottom of
17 each page, if you turn to page 26.

18 A Okay.

19 Q And if you look at Article 23 there,
20 entitled National Opium Agencies.

21 A Yes.

22 Q And is it your understanding that the

1 Single Convention in another area says that
2 cannabis is to be treated as Article 23 sets
3 forward with regard to opium?

4 A Yes.

5 MR. BAYLY: Objection, Your Honor. Could
6 we strike this answer just until the objection is
7 heard and ruled on?

8 JUDGE BITTNER: Sure.

9 MR. BAYLY: All right, thank you. There's
10 no foundation. Yes, the witness tangentially
11 mentioned the Single Convention during cross-examination.
12 However, that does not qualify the
13 witness to testify as a legal expert on the Single
14 Convention, and indeed, there was not direct on
15 that, indeed there was no proffer in any of the
16 prehearing statements, both issued or filed by the
17 government and respondent, that this witness will
18 be testifying or interpreting the Single
19 Convention.

20 MS. CARPENTER: Your Honor, I believe in
21 his earlier testimony he's already interpreted the
22 Single Convention. He referred several times to

1 the fact that it required particular things. I
2 think it's fair for me to explore the basis of his
3 statements. If he knows. If he doesn't know--

4 JUDGE BITTNER: The witness has testified--and I
5 don't remember whether he said it on direct
6 or not. That's probably not worth the time for me
7 to look up. But he certainly did testify on cross
8 that his understanding that the government has to
9 provide marijuana is based on the Single
10 Convention. Now that understanding may or may not
11 be correct, and I'm not going to say that the
12 witness is or is not credible because his
13 understanding of the Single Convention is or is not
14 correct. But I think it would be useful, and I
15 know that we have discussed it in prehearing
16 conferences, to get to the question of what the
17 Single Convention says on this subject. So,
18 overruled, with the caveat I just gave.

19 I'm not going to make any determination on
20 Dr. El Sohly's expertise I other matters based on
21 what he knows about the Single Convention.

22 MR. BAYLY: Your Honor, may I have one

1 more comment?

2 JUDGE BITTNER: Yes.

3 MR. BAYLY: I would note too that I
4 believe we have objected to lay witnesses prior to
5 testifying as experts on the Single Convention, so
6 I'd like to get that objection on the record as
7 well.

8 JUDGE BITTNER: Right. I'm not taking him
9 as an expert on the Single Convention. I'm just
10 trying to pursue what he does and doesn't know
11 about it.

12 Go ahead, Ms. Carpenter.

13 And I now have forgotten what your answer
14 was, doctor. Would you repeat it, please?

15 MS. CARPENTER: If he remembers the
16 question.

17 JUDGE BITTNER: The question, if I
18 understood it correctly, was that--do you think
19 that there is someplace else in the Single
20 Convention that is the analog to Article 23 with
21 respect to marijuana, right?

22 MS. CARPENTER: I asked it a little

1 differently. Perhaps I should just start over.

2 I'll make it simpler.

3 JUDGE BITTNER: Okay.

4 BY MS. CARPENTER:

5 Q You are aware, are yo not, that the Single
6 Convention requires that marijuana be treated in
7 the same way as opium, that is, the cultivation of
8 marijuana be treated in the same way as cultivation
9 of opium?

10 A Yes. There is a reference with that to
11 Article 23, that's correct.

12 Q And so if you look at Article 23, which is
13 in the middle of page 26, that's Bates No. page 26
14 or Respondent's Exhibit 2, and if you look at No.
15 2, Article 23, 2, and then subsection (b), and the
16 sentence there is: "Only cultivators licensed by
17 the Agency shall be authorized to engage in such
18 cultivation." Now, there's an "s" on there, isn't
19 there, cultivators?

20 MR. BAYLY: Your Honor, I object. The
21 document speaks for itself.

22 JUDGE BITTNER: Sustained.

1 BY MS. CARPENTER:

2 Q Do you understand the word cultivators to
3 mean more than one?

4 JUDGE BITTNER: I think I'll take official
5 notice of that.

6 MS. CARPENTER: Okay, that's fine.

7 BY MS. CARPENTER:

8 Q If you look in paragraph D, and I'll just
9 read that--

10 JUDGE BITTNER: Article 23, 2(d)?

11 BY MS. CARPENTER:

12 Q Article 23, 2(b)--2(d), I'm sorry, "d" as
13 in dog. "All cultivators of the opium poppy"--of
14 in this case, cannabis--"shall be required to
15 deliver their total crops of opium"--or in this
16 case cannabis--"to the Agency. The Agency shall
17 purchase and take physical possession of such crops
18 as soon as possible, but not later than four months
19 after the end of the harvest."

20 Dr. El Sohly, do you deliver the crops
21 that you grown for NIDA to NIDA in any sort of
22 physical way?

1 A I consider that the material that I
2 produce for NIDA is actually delivered to NIDA, as
3 I am the contractor. I'm not an independent
4 contractor. If there is--

5 Q You're not an independent contractor?

6 A I'm not an independent grower I should
7 say. I'm not an independent grower, but just
8 growing to sell that marijuana.

9 Q Now, the marijuana that you grow for the
10 institute, do you deliver that marijuana to NIDA?

11 A I believe there is an exception to that
12 for this material. If it will be used for
13 developing a product out of that material, then it
14 could be done at the same place, so that the
15 intention is not to ship it somewhere, or to sell
16 it, or to do something with it, but rather to use
17 it for developing a product out of the plant
18 material.

19 Q And where do yo see that exception? Where
20 does that come from?

21 A I thought either to an amendment or to
22 something, but I did see that point.

1 Q In an amendment to this Convention?

2 A It may be another something in 1970 or
3 something like that, but I did see that point.

4 Q Okay.

5 A So there is an exception to that
6 particular point, that if you're going to have a
7 product out of that, you can do this at the place
8 that's cultivating.

9 Q So in that case, NIDA would not have
10 anything to do with that particular marijuana?

11 A That's correct, if it's used to, let's
12 say, make an extract or make a--you know, purify
13 for something, just make a product.

14 Q So to develop a product, you would not
15 have to go through NIDA.

16 A Yes. That's my understanding, and again,
17 I have to qualify my answer to you.

18 Q Not looking to you to be an expert, as I
19 said before.

20 And the agency that's referred to in
21 Article 23, do you understand that to be NIDA or
22 the DEA, or do you know?

1 A Whatever agency that is the government of
2 the country, whatever the country is, is supposed
3 to be in charge of this operation.

4 Q Yes. I'm asking do you know whether
5 that's DEA or NIDA?

6 A I think you have to have the proper
7 authorization from DEA to do that, and the
8 distribution is done by NIDA. So it's the
9 government. In my understanding, the agency means
10 the government.

11 Q So, for example, in 2(a) it says, "The
12 agency shall designate the areas in which and the
13 plots of land on which cultivation of the opium
14 poppy for the purpose of producing opium shall be
15 permitted." In your understanding, would that be
16 NIDA or would that be DEA?

17 A It says here, "one or more government
18 agencies."

19 Q Yes.

20 A Hereinafter referred to as the agency, so
21 they're not really saying that it's got to be one
22 agency.

1 Q Understand. But my question is with
2 regard to that first sentence, that is, 2(a). Is
3 there one agency that designates the areas in which
4 and the plots of land on which cultivation should
5 occur?

6 A Well, I'm clarifying the word "agency" as
7 in 2(a) by looking at item no. 1 that says "one or
8 more government agencies, hereinafter referred to
9 as agency."

10 Q I understand that, but listen to my
11 question, Dr. El Sohly. Do you understand--is it
12 the DEA who designates the area, or is it NIDA or
13 is it both, in your experience?

14 A It's NIDA.

15 Q It's NIDA.

16 MR. BAYLY: Your Honor, I want to object.
17 First, we're getting argumentative. Secondly,
18 we're really getting off course here in terms of
19 the cross and having the witness interpret this
20 treaty. I think as--

21 JUDGE BITTNER: Well, overruled. The
22 witness is giving his understanding. It's not--the

1 witness testified as to his understanding of why
2 the system is the way it is, and I think it's
3 appropriate to explore that on cross. Overruled.

4 MS. CARPENTER: Thank Your Honor.

5 BY MS. CARPENTER:

6 Q Dr. El Sohly, let me ask you this. Is it
7 your understanding that the Single Convention
8 limits countries to have only one grower of
9 marijuana in a country? That is, a bulk
10 manufacturer, not--

11 A No. I would say it limits the
12 distribution of marijuana to the government, but
13 not the number of growers. So according to this,
14 if you want to have three, or four, or five
15 different growers, they all have to hand their
16 materials to the agency, if you will, quote and
17 unquote.

18 Q So there could be three, or four, or five
19 different growers, who then are required somehow to
20 transfer possession or--

21 A If the government wants to do that.

22 Q Okay. With regard to the marijuana that

1 you intend to grow for Mallinckrodt, do you intend
2 to--which will then be turned into an extract,
3 which will then be turned into THC, which will then
4 be used in human clinical trials or humans
5 directly, I guess. Are you required to turn over
6 in any way those crops to NIDA or to DEA for any
7 period of time?

8 A You know, again, I'm not distributing
9 marijuana. I'm growing--it's the purpose of what
10 you are growing the material for. If you're
11 growing it for distribution as the request for
12 UMiss registration for the distribution, then it's
13 a different activity than what I am doing. What we
14 are doing is we're growing this material to prepare
15 the extract, and it's the extract that's being
16 distributed, not the marijuana.

17 Q And this distinction between growing and
18 distribution, where do you get that from? Is that
19 in the Single Convention, do you think?

20 A I think the exception that I saw in the
21 other document is the one that says, except, unless
22 this would be used for--

1 Q Developing the product.

2 A --doing a product or something out of this
3 material. That exception is there.

4 Q Okay. So clearly in your view, growing
5 the marijuana to make the extract for Mallinckrodt
6 would not violate the Single Convention?

7 A That's correct.

8 Q Even though the crops that you grow are
9 never delivered to NIDA or DEA?

10 A That's my understanding, that's correct.

11 MS. CARPENTER: Your Honor, could I
12 suggest we take about a 10- or 15-minute break, and
13 then I think I'll be just about done.

14 JUDGE BITTNER: Okay. Ten minutes.

15 [Whereupon, at 11:16 a.m., there was a
16 brief recess.]

17 JUDGE BITTNER: On the record.

18 BY MS. CARPENTER:

19 Q Dr. El Sohly, if an organization like
20 MAPS, for example, a nonprofit or a pharmaceutical
21 organization, wanted to try to develop smoked
22 marijuana into an FDA-approved medicine, could it

1 use the marijuana that you grow to do the
2 preclinical and clinical testing if NIDA agreed?

3 A I would say yes.

4 Q Now, assume that that testing is complete
5 and the FDA does approve smoked marijuana as
6 medicine, at that point, that organization who wa
7 sponsoring the research, their only option to
8 obtain materials to fill the FDA approved
9 prescriptions would be you because your master drug
10 file would underlie that FDA approved product,
11 isn't that true?

12 A I would say not necessarily because my
13 understanding is if they approves marijuana as
14 marijuana, as a smoked delivery system, as a smoked
15 product, it becomes a Schedule II drug, not a
16 Schedule I drug, and as a Schedule II drug, it's
17 not bound by the same regulations that binds the
18 Schedule I.

19 Q Understand. But if the testing, the
20 preclinical and clinical testing that supported
21 that FDA approved medicine used your product, would
22 it not be necessary to continue using your product

1 to provide the prescription medicine?

2 A Again, I would say not necessarily. They
3 would have to produce material, because
4 manufacturers of approved FDA products change
5 suppliers all the time. It's not--that doesn't
6 have to be bound by that. They have to have a
7 product that meets the qualifications of the
8 material that was used for the testing.

9 Q And so you think the FDA would approve
10 marijuana grown in a different place with a
11 different drug master file for use in
12 prescriptions, when the testing was done with a
13 product that was--with a different product?

14 A If it changes supply--and I'm not, again,
15 I'm not an expert on FDA regulations again, but I
16 would say that there have to be qualification of
17 the raw material that's being used for the final
18 product, that would be approved by the FDA.

19 Q But in this case the smoked marijuana
20 would be the final approval, wouldn't it--would be
21 the final product, wouldn't it?

22 A Yes, but the--

1 Q The raw material, rather.

2 A But that material, the qualifications with
3 that material, there would have to be a new drug
4 master file for the new material.

5 Q So somebody else would have to start
6 growing marijuana and have to create a new drug
7 master file, and that would have to be approved by
8 the FDA. And only then would that organization
9 that had put the time and money into developing the
10 product, be able to have a different source to go
11 to. Is that your understanding?

12 A I would say that they would have to do
13 that, because they can't just grow material and put
14 it on the market. You have to go through that
15 qualification of the product that you would be
16 putting on the market.

17 Q Now, yesterday you testified about the
18 contract that you have with NIDA, and you referred
19 to that as a cost reimbursement contract, is that
20 correct?

21 A Yes.

22 Q So what did you mean by that? What kind

1 of costs are reimbursed under that contract?

2 A The cost of production, the cost of the
3 operation.

4 Q Okay. So it would be salaries for
5 employees?

6 A Yeah.

7 Q And all the material?

8 A Yes. It's all outlined in the contract.

9 Q So overhead, et cetera?

10 A Yes.

11 Q So there's no money out of University of
12 Mississippi's pocket in order to grow this
13 marijuana for NIDA; it's all covered by the
14 contract; isn't that right?

15 A That's correct. There might be some that
16 are not reimbursed.

17 Q Not reimbursable?

18 A Not reimbursable. The things that the
19 university would do just to maintain, you know, the
20 research and activities that are going on. That
21 doesn't necessarily have to go back and charge NIDA
22 for it.

1 Q Okay. That would be because the institute
2 has research interests in the same subject, is that
3 right?

4 A Possibly.

5 Q Now is your salary or part of it paid by
6 the NIDA contract?

7 A Not all of it.

8 Q Part of it?

9 A A portion of it, yes.

10 Q Is part of it paid by the institute as
11 well?

12 A Yes.

13 Q Now, you discussed yesterday the samples
14 that you tested, and indicated that the university
15 tests more samples than are required in the
16 contract. Do you recall that testimony?

17 A Yes.

18 Q And as those samples come in, they're
19 tested by employees that are paid under the NIDA
20 contract, is that right?

21 A Yes.

22 Q Are those employees also paid for other

1 work or are those employees dedicated to the NIDA
2 contract?

3 A They are dedicated to the NIDA contract.

4 Q And are they billed out by the hour? That
5 is, if they work five hours on a day, does five
6 hours get billed to NIDA, or is it more of a
7 straight salary will pay--

8 A It's a straight salary that doesn't--we
9 don't break it down.

10 Q Okay. So it--

11 A Percentage time.

12 Q Percentage time.

13 A Yeah.

14 Q Okay. So if they do more work, that is,
15 they evaluate more samples, are there more costs
16 that are reimbursed by NIDA? Do you understand my
17 question?

18 A No.

19 Q Okay. Now, you also referred to the bid
20 process for the NIDA contract, and you indicated
21 that the bids were secret. So you don't actually
22 know if anyone else submitted a bid for the NIDA

1 contract, do you?

2 A No, I don't.

3 Q It could be that you were the only, that
4 the University of Mississippi was the only entity
5 that ever submitted a bid?

6 A It's possible, but I don't know that.

7 Q Okay. Now, the contract--and we can turn
8 to it if you'd like, and I'm happy to do that; just
9 see if you remember it without going through that--refers to
10 the inventory bring distributed on a FIFO
11 plan, that is, first in, first out. Do you recall
12 that?

13 A I'm sorry. Say that again.

14 Q Does the NIDA contract require you to use
15 inventory--excuse me--on a first in, first out
16 basis, that is, you use the oldest inventory first
17 and work your way up?

18 A Not a requirement.

19 Q I'll ask that the witness be shown
20 Respondent's Exhibit 13, which was entered
21 yesterday. I think it was--I'm sorry.
22 Government's Exhibit 13. I beg your pardon. For

1 the record, that's the contract that was most
2 recently signed.

3 MR. BAYLY: For the record, we've been
4 referring to it as the current contract.

5 JUDGE BITTNER: Okay.

6 BY MS. CARPENTER:

7 Q If you would turn to page 7 of
8 Government's Exhibit 13, Dr. El Sohly, and look at
9 paragraph 5. And just below, there's a series of
10 A, B, C and D. Just below the contract says, "All
11 stock items shall be maintained on a first in,
12 first out (FIFO) inventory system unless otherwise
13 designated by the project officer."

14 A I think this refers to the cigarettes.

15 Q Just to the cigarettes?

16 A Yes, ma'am.

17 Q Does it refer to all the stock items that
18 are listed above? That would be both cigarettes
19 and bulk.

20 A It's--this applies to item no. 5, which is
21 the stock of the cigarettes that are in place.

22 Q And number (d) and 5, 5(d) says 1,000

1 kilograms crude bulk, does it not?

2 A But that material--at this point, if we
3 send that material to RTI, this would be at RTI.

4 Q So all this material would be at RTI?

5 A Yeah, but we haven't--RTI doesn't have
6 bulk material now. All the bulk material we have
7 in place.

8 Q So whether it's RTI or whether you're
9 distributing the bulk material, the contract
10 requires that the inventory that's been there
11 longest go out first unless the project officer
12 designates otherwise; isn't that true?

13 A Well, actually, the way that the materials
14 go out anyway, it goes by authorization of the
15 project officer. So that requirement, even though
16 it's written first in, first out and so on, unless
17 designated by the project officer, everything is
18 designated by the project officer, so that's really
19 not a point of disagreement.

20 Q So the project officer goes in and chooses
21 a particular barrel to go out the door?

22 A Well, when we--well, there are no barrels

1 that go out the door anywhere, except going to RTI
2 to make cigarettes, and the decision which barrels
3 to use, we can't just have the material that we--we
4 still have material in stock from 1994 or '95 or
5 '96 or '99. To make cigarettes, we pick the
6 barrels that have the right THC content to make the
7 appropriate batch of THC, or we pick the--if
8 somebody ordered bulk material, depends on what
9 they ordered, which bulk material they order, what
10 they want to do with the bulk material. We pick
11 the barrel that contains the appropriate material
12 to send to the individual regardless if it was
13 first in or not.

14 So, you know, getting materials out is a
15 matter of meeting the request of the investigator,
16 rather than, well, we can't give you this material
17 here because that material was made before that, so
18 you have to this, no.

19 Q What if there were two barrels. One was
20 made in 1996, one was made in 2002, and it was the
21 same content. Would this contract require you to
22 send out the 1996 one unless--or would you send out

1 the 1996 barrel?

2 A There is some discretion there between the
3 project officer and the project director, which is
4 myself, that if I have two barrels of the same
5 composition and I have to make a batch of
6 cigarettes, I will use the newer batch rather than
7 the older batch.

8 Q Okay. Even though--

9 A Well, I will get the consent of the
10 project officer, so I have not violated the, you
11 know, spirit of the contract.

12 JUDGE BITTNER: Why? Why would you use
13 the newer stuff?

14 THE WITNESS: Because, Your Honor, the
15 fresher the material is, the better the material
16 is. You have material that is 1994 material that
17 has been in storage till 2004 is 10-years-old. So
18 we talk--or I talked yesterday about the fact that
19 the THC content goes down by time. So if I need
20 material that is, let's say, 2 percent, and I have
21 material from the '94 inventory that has a THC
22 content of 2 percent, this material probably in '94

1 was 3 percent, and now by 2004 is 2 percent. It's
2 going to have some--if I can say that--CBN, that
3 other cannabinoid in there. It would have a higher
4 level of CBN--

5 JUDGE BITTNER: Because some of the THC
6 has degraded.

7 THE WITNESS: That's correct. Than the
8 fresh material. So I would like to provide as
9 fresh material as possible, to the benefit of the
10 investigator, to the benefit of the contract, to
11 the benefit of the research. So the first in, if
12 we have materials of the same composition that is
13 2003 versus 2004, yes, I think it would make a lot
14 of sense to have the 2003 out first, gives the 2004
15 another year of storage where it could be used and
16 have basically the same thing as the other
17 material.

18 BY MS. CARPENTER:

19 Q But I think you testified earlier that you
20 have not grown a crop for NIDA since 2001-2001.

21 A I'm just using as an example.

22 Q I know. I just want to be clear that you

1 don't actually have 2003 or 2004 materials.

2 A No, just as an example.

3 Q That's fine. I just want to be clear.
4 How old is the oldest stock of marijuana that you
5 have in inventory, if you know?

6 A I don't really know exactly, but we have
7 some material from a long time before, but it's
8 not--it's kept because of historic reasons, not
9 because it's going to be used in cigarettes. But
10 if I may look at current inventory of the material
11 that will be ready to make cigarettes, if need be,
12 I can tell you the--

13 Q Does the inventory say when they were
14 grown?

15 A Yes.

16 Q Okay. I thought you had looked at it
17 earlier and--

18 A No. The inventory that I looked at before
19 was the cigarette inventory.

20 Q I see.

21 A I'm talking about bulk material inventory.

22 Q Yes, if you would, that would be helpful.

1 A All this material that I have is '97.

2 Q 1997?

3 A Yes.

4 Q And what would you use that material for?

5 A Well, it's there. If need be, let's say,
6 all of a sudden we get a request to make half a
7 million cigarettes or something, it's better to
8 have material that is old, than not having material
9 ready to make those cigarettes. So it's in
10 inventory. It doesn't hurt to stay there. But if
11 I have to make, this material happen to have a THC
12 content of 2.88 percent THC. Now, I might have
13 some material from a newer. For example, I have
14 here from 2001 that has 2.96. That's pretty close
15 to the same value, and if I need, you know, 2.5 or
16 2.4 percent cigarettes, I'll probably use the 2001
17 material.

18 Q Okay.

19 A Since I have ample supply. If there is a
20 problem with the supply, then that's another issue.

21 MS. CARPENTER: Your Honor, I'd request
22 that we have a chance to see the document that Dr.

1 El Sohly used to refresh his recollection.

2 JUDGE BITTNER: Any objection, Mr. Bayly?

3 MR. BAYLY: I'm sorry. What was that?

4 JUDGE BITTNER: Ms. Carpenter would like
5 to see the document.

6 MR. BAYLY: Oh, yes. No, no, no, most
7 certainly.

8 JUDGE BITTNER: Thank you.

9 [Pause.]

10 BY MS. CARPENTER:

11 Q So, just to be clear, when you--and do you
12 get the year that the crop was grown from the
13 designation CEF--and then there's a two-digit
14 number?

15 A The last two digits are the year, yes.

16 Q So 00 would be 2000?

17 A Right.

18 Q Okay. And again, this is just for the
19 bulk marijuana that you have; is that correct?

20 A That's correct.

21 Q And do you have this information for the
22 cigarettes, or that's what you didn't have?

1 A No. I have the information on the
2 batches, but I don't have the date they were
3 manufactured.

4 Q Okay. Your Honor, I'd request that a copy
5 of this be made part of the record.

6 JUDGE BITTNER: You want to offer it as
7 your own exhibit?

8 MS. CARPENTER: Yes.

9 JUDGE BITTNER: Any objection?

10 MR. BAYLY: I haven't seen it.

11 JUDGE BITTNER: Would you like to look at
12 it?

13 [Pause.]

14 JUDGE BITTNER: This would be 53.

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

16 [Respondent's Exhibit No. 53
17 marked for identification.]

18 MR. BAYLY: Your Honor, before I stipulate
19 to allowing this into evidence, I think I would
20 request respondent to articulate a basis for
21 getting this in.

22 JUDGE BITTNER: Could I see it?

1 MR. BAYLY: Yes.

2 MS. CARPENTER: And I think the reason,
3 Your Honor, simply would be that he used it to
4 refresh his recollection and I think it's relevant
5 for that reason.

6 JUDGE BITTNER: Actually, I think it's
7 more past recollection recorded, isn't it?

8 MS. CARPENTER: And for that reason as
9 well, Your Honor. We would like to have it
10 submitted.

11 JUDGE BITTNER: Without highlighting.

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

13 JUDGE BITTNER: Mr. Bayly, any objections?

14 MR. BAYLY: No.

15 JUDGE BITTNER: So Respondent's 53 is
16 received, and Ms. Carpenter, would you get copies
17 made? I don't think they need to be in color.

18 MS. CARPENTER: Thank you.

19 [Respondent's Exhibit No. 53
20 received in evidence.]

21 MR. BAYLY: I don't think any of us have
22 copies.

1 MS. CARPENTER: I'll just take it and get
2 copies and bring them back.

3 BY MS. CARPENTER:

4 Q Dr. El Sohly, what is the highest
5 percentage THC marijuana in bulk or cigarettes that
6 you know of that NIDA or you has ever shipped to
7 medical marijuana researchers?

8 A I would say that batch that was made at 8
9 percent is the--cigarettes, but we have not had
10 requests to ship bulk material to investigators in
11 the clinical program.

12 Q Okay. You testified yesterday about
13 vegetative propagation.

14 A Yes.

15 Q If you vegetatively propagate a marijuana
16 plant, and you grow it under the same conditions,
17 all the vegetative propagations under the same
18 conditions, would it be fair to say you would have
19 a number of plants that were genetically identical,
20 that is, all the plants that were grown under those
21 conditions and that had been vegetatively
22 propagated--

1 A Yes.

2 Q --would be genetically identical?

3 A Yes.

4 Q Now, there was some testimony yesterday
5 that you were informed that after you had provided
6 8 percent THC cigarettes, that you had heard
7 information that subjects couldn't tolerate 7 or 8
8 percent THC marijuana; is that correct?

9 A Yes.

10 Q Now, you also testified, I believe, that
11 the average potency of marijuana that's available
12 illicitly is about--was about 7 percent in 2004.
13 Isn't that correct?

14 A That's correct.

15 Q Now, isn't it true that research protocols
16 could be designed that would use a higher potency
17 product, but smaller amounts of that product at the
18 time of titration? Do you understand that
19 question?

20 JUDGE BITTNER: I don't.

21 THE WITNESS: Not really.

22 BY MS. CARPENTER:

1 Q When a research protocol uses a marijuana
2 cigarette, is it necessary that the entire
3 cigarette be smoked?

4 A Yes, because if you want to compare a 7 or
5 8 percent cigarette, the effect of that with the
6 effect of a 4 percent cigarette, with the effect of
7 2 percent cigarette, the individual has to consume
8 the whole cigarette for all four, five different
9 doses. That's a dose. So they have to. If they
10 cannot tolerate it, then that does is out.

11 Q Okay. And isn't it true that a research
12 protocol could be designed that would have a--that
13 could be a smaller cigarette at that potency or
14 would be fewer puffs if it's a smoked marijuana
15 cigarette at that potency?

16 A No, it cannot be because then it's not a
17 blind study, it's an open study.

18 Q Well, there still could be placebos if you
19 had half cigarettes. Couldn't they give you half a
20 placebo in half a marijuana cigarette?

21 A Yeah. If you can have a half, and you can
22 have a half of all the different cigarettes, that's

1 okay. You can do that.

2 Q So you can just half--a smaller amount of
3 the 8 percent marijuana, for example--

4 A But then you're not comparing those doses.
5 You'll be similar to comparing if you take half a
6 cigarette of 8 percent and half of 4 and half of 2,
7 and half of placebo, that would be like having a
8 placebo 1, 2 and 4. So why--I think we have to
9 really make a distinction between the desire to use
10 a half-potency material versus the effect of high
11 dose of THC. And let alone the fact that maybe a
12 higher percentage, one can use a smaller amount,
13 and therefore, less smoke and less side effects,
14 and all of those things. But for doing the initial
15 study, for doing the study to evaluate the dose, it
16 doesn't matter whether using half a cigarette of 8
17 percent or one cigarette of 4 percent, you're
18 getting the dose which is equivalent to about 40
19 milligrams or 80 milligrams or 20 milligrams of THC
20 in that cigarette.

21 Q Okay. Are you aware, Dr. El Sohly, that
22 in Canada the government distributes marijuana

1 cigarettes with 12.5 percent THC?

2 A Absolutely, I'm aware of that, yes.

3 Q Are you aware that in the Netherlands, the
4 government distributes marijuana cigarettes with 13
5 to 18 percent THC content?

6 A They don't, they don't give cigarettes,
7 they don't. They give a package of marijuana that
8 has this high potency marijuana, and people roll
9 their own cigarettes.

10 Q Okay.

11 A You cannot do a clinical trial with
12 rolling your own cigarettes.

13 Q Okay. And are you aware that at least in
14 the Netherlands, the marijuana that--the medical
15 marijuana that the government distributes also has
16 .8 percent CBD?

17 A Yeah, but compare that to how much?

18 Q I'm sorry, CBD.

19 A That's correct. Compare that with how
20 much THC?

21 Q With 18 percent THC?

22 A Yeah. So it's--relatively speaking, it's

1 a very small dose of CBD relative to THC. Same
2 thing like we have.

3 Q Are you aware, Dr. El Sohly, of what the
4 price is for the 12.5-percent THC medical marijuana
5 that's available in Canada? Do you know?

6 A No, I'm not, but I'm aware of the price in
7 the Netherlands, which is a heck of a lot more than
8 what we have here.

9 Q Would you be surprised if in Canada the
10 price was \$5 per gram?

11 A I wouldn't be surprised if it's 5 or 50.

12 Q Okay.

13 A They are not providing cigarettes, either.

14 Q And what's the price per gram of, say, for
15 example, the 7-percent marijuana, 7-percent THC
16 marijuana that's available through NIDA?

17 A The price is not based on the percent.

18 Q Okay.

19 A The price is just based on the cigarette,
20 whether it's active or placebo.

21 Q Okay. And what would the price--

22 A And I think the--

1 Q --per gram of--

2 A --placebo is a little bit more expensive,
3 actually, than the active--

4 Q Actually, the placebo is just the
5 marijuana cigarettes.

6 A I don't really know the exact figure right
7 now, but it's roughly around \$7 or \$8.

8 Q Per gram?

9 A Something like that.

10 Q Okay. So for that--I'm sorry, is that per
11 cigarette or per gram?

12 A Well, the cigarette--excuse me.

13 Q Per cigarette?

14 A A cigarette is about a gram.

15 Q About a gram, okay. So \$7 or \$8 for 7-percent
16 THC. Is that accurate?

17 A Or 10 or 15 or zero.

18 Q Okay

19 A No, not zero, but one.

20 Q Okay.

21 A Because the 0 is more expensive.

22 Q Okay.

1 JUDGE BITTNER: I'm sorry. How much was
2 it, around \$7 you thought?

3 THE WITNESS: It's about \$8, Your Honor,
4 roughly.

5 [Pause.]

6 MS. CARPENTER: I'm sorry, Your Honor.

7 BY MS. CARPENTER:

8 Q Dr. El Sohly, you testified yesterday--you
9 commented on some comments from some of the
10 researchers that were included in some interview
11 forms. Do you recall those?

12 A Yeah.

13 Q Okay. Now, you were not present at those
14 interviews, were you?

15 A No, I was not.

16 Q Okay, and so you don't have any
17 information about what the people who wrote down
18 those forms meant when they wrote things down, do
19 you?

20 A I'm interpreting what was written down.

21 Q Okay. But you don't have any separate
22 information. Your basis--

1 A No, I don't.

2 Q Your basis of knowledge is simply what's
3 written down in the--

4 A That's correct.

5 Q Okay. And so when you were suggesting
6 yesterday that perhaps some of the issues of
7 harshness came from placebos, that's not from any
8 independent knowledge you have, is it?

9 A Well, I think one of the investigators
10 indicated that those--that there was no follow-up
11 to know whether the people that reported harshness
12 of the cigarettes were given placebos at that time
13 or active.

14 Q Right. One investigator indicated that.
15 That's correct.

16 A Right. So that's--

17 Q But you don't have--my question is, sir:
18 Do you have any independent knowledge--

19 A No, I don't.

20 Q --of whether those issues were caused by
21 marijuana or by placebos?

22 A Well, the placebo is marijuana also.

1 Q Okay. By the active cigarettes or the
2 placebos?

3 A That's correct.

4 Q Okay. And so any information--the
5 information that would be in those documents would
6 be the most accurate source for that information,
7 wouldn't it?

8 A That's correct.

9 Q Okay.

10 A But the harshness, regardless of whether
11 it's actually--in my opinion, whether the harshness
12 is coming from placebo or coming from active really
13 doesn't--it doesn't surprise me. It doesn't--it
14 doesn't make a difference because you are not
15 saying--or the investigators are not saying that
16 all the subjects have complained about harshness.
17 One subject here, one subject there. I think you
18 had like 50 subjects, and only three or four
19 complained of the harshness. That's a very small
20 percentage. You are going to get that regardless
21 of what you administer. So to take that as being a
22 criticism of the material I think is just pushing

1 too far.

2 Q Okay.

3 A Or pushing more than--more than being
4 reasonable.

5 Q But you would agree with me that the
6 researchers who conducted that investigation and
7 who spoke to the patients would have a better
8 understanding of whether it was a problem for their
9 research than you would, wouldn't you?

10 A I am not interfering in any way or
11 interpreting their feelings.

12 Q Would you agree with that comment?

13 A I'm interpreting the actual data.

14 Q Okay. Would you agree with me, sir, that
15 the researchers who conducted that investigation
16 would have a better understanding of whatever the
17 problems were with their research than you do?

18 A I would say yes. I mean, that's
19 reasonable.

20 Q Now, let me ask you this: Yesterday you
21 testified about the different increments of
22 percentages of THC that were available through

1 NIDA, and I think I wrote--I may have written this
2 down wrong, but did you have 0, 1, 1.5, 2 percent,
3 2.5? Did they go up in half-a-percentage
4 increments, or how did they go?

5 A No, I'm just using that as a--not
6 necessarily to be the actual figures, but I'm
7 saying we have materials, you know, throughout the
8 spectrum.

9 Q Okay.

10 A And you can blend materials to create any
11 percentage that you want, but obviously if your
12 highest percent is 10 percent, you can't create
13 something more than 10 percent.

14 Q Okay.

15 A So taking the highest you have and the
16 lowest you have, you can blend between those to
17 have anything in between. That's my point.

18 Q Okay. And you also indicated that there
19 was a 20-percent, plus or minus, variability in the
20 percentage of THC content--

21 A I said--

22 Q --that that was acceptable under your

1 standards?

2 A I'm sorry. Say that again?

3 Q I believe you testified yesterday that
4 there was a plus or minus 20-percent variability in
5 THC content that was acceptable under your
6 standards.

7 A I'm saying that--

8 JUDGE BITTNER: Between what was--between
9 what's stated and what another test would show?

10 MS. CARPENTER: Right.

11 BY MS. CARPENTER:

12 Q Between what is stated to be the THC
13 content and what it might actually be.

14 A I'm saying--

15 Q Or what another test would show.

16 A I'm saying that not in my standards or any
17 particular person's standards. I'm saying in the
18 analytical area there is a variability, analytical
19 variability that's allowable that will extend to 20
20 percent, plus or minus 20 percent.

21 Q And who allows that? Is that the FDA?

22 A The scientific community. Not the FDA.

1 Q Okay. And so--

2 A But--

3 Q Go ahead.

4 A But we are trying to--when we analyze the
5 material, at the time when we analyze it, whatever
6 the value comes out is what's actually reported.
7 So the 8-percent cigarettes--the initial design was
8 to have 8-percent cigarettes. Those cigarettes
9 were made. They were analyzed at that time, and
10 they were 8 percent. The raw material was 8
11 percent; the cigarettes were 8 percent. At the
12 time when they were started to be shipped and so on
13 and re-analyzed, they were 7-point-something
14 percent. To me that's not--it was labeled as such,
15 as, you know, this is the analytical--the analysis
16 sheet, the certificate of analysis that goes out
17 with the cigarettes said that it was 7-point-something
18 percent. It didn't say 8 percent in the
19 paper, in the analytical values certificate. It
20 said 7-point-something percent, and that's why the
21 investigators said, well, we thought we were
22 getting 8 percent, but that's what the analysis

1 said.

2 Now, that analysis--

3 Q If they had ordered--if they had ordered 8
4 percent, why did they get 7.4 percent?

5 A Well, you don't order 8 percent. You
6 order material around 8 percent, and you make the
7 cigarettes, whatever the cigarettes come out to be,
8 that's what they are.

9 Q Okay. Now, when you say it's an allowable
10 variability, is that because of the particular
11 equipment that you use?

12 A No. No, this is--whether I'm doing it or
13 you're doing it or somebody else is doing it, that
14 variability in the analytical process is there. We
15 have quality control material that we put into the
16 process, and that quality control material is
17 allowed plus or minus 20 percent to say that the
18 batch is acceptable.

19 Q Okay, and--

20 A I believe all our analyses are from day to
21 day to day to day is--for that quality control
22 material is within 10 percent, so we're a lot more

1 tighter than the scientific community allows.

2 Q And who came up with the quality control--with
3 that quality control number of 20 percent?

4 That's my question.

5 A That's a common knowledge in the
6 analytical area.

7 Q For any product or just for marijuana or
8 cannabis?

9 A No, for any materials. You look at the
10 federal guidelines for drug-free workplace. The
11 allowed analytical variation when you participate
12 in proficiency testing at the National Labs
13 certification program or the College of American
14 Pathologists program, it allows, you know, plus or
15 minus 20 percent as an allowable error in your
16 reporting of results. So--and I'm saying this is
17 allowed, this is acceptable. But we're trying to,
18 you know, make that more tight than that.

19 Q Okay.

20 A But it doesn't matter--my point is it
21 doesn't matter what the actual value comes out to
22 be. We are telling you this actual value that's

1 coming out 7.2 percent or 7.4--I don't remember
2 what the decimal point was--is within plus or minus
3 10 percent of that value, which overlaps with the 8
4 percent. So that's--you know, you're making a
5 cigarette that is about 8 percent, a cigarette
6 that's about 4 percent. This is not a tablet or a
7 capsule or a single entity chemical substance.
8 This is material that you're going to smoke that a
9 good amount of that material goes out on the side
10 stream anyway. The amount of material that's
11 actually getting into the system is probably
12 somewhere between 15 to 20 percent. When you say
13 between 15 and 20 percent, that's a 33-percent
14 error for the 15, 20 percent--25 percent error for
15 the 20.

16 So we were talking about we're trying to
17 make marijuana to be such a decisive material,
18 which it is not. It's absolutely not.

19 Q Okay. So just to be clear, a 4-percent--a
20 cigarette that, if somebody asked for a 4-percent
21 cigarette from NIDA's inventory, they could get a
22 cigarette with as little as 3.2 percent or with as

1 high as 4.8 percent. Is that correct?

2 A Well, what--

3 Q But then the 20 percent--

4 A Would you like for me to pull that and
5 just use some real examples of the inventory of the
6 cigarettes?

7 Q No. I'd just like an answer to that
8 question.

9 A Okay. We look and see what's available
10 that closest to the value that the investigator
11 wants. It could be 3.88, it could be 3.76. If we
12 only have 3.2, we say, listen, we only have 3.2,
13 can you use that? But we're not going to make a
14 special batch for someone just to have this extra
15 few percents to get the exact right figure. I
16 don't think it makes sense.

17 Q Okay. So somebody needs--

18 A Knowing the imperfection of the smoking
19 process.

20 Q So if somebody, a researcher, needs an 8-percent
21 cigarette for their research and they're
22 comparing it to 2 and 4 and 6, which are not very

1 different, they just have to take whatever you give
2 them; is that right?

3 A Around--

4 Q Within the plus or minus 20 percent.

5 A Around that number, yes. If the supply is
6 available, the NIDA supply of cigarettes is
7 available, and if what's available in the supply
8 does not fit with the investigator's needs with a
9 reasonable anticipation of what they actually want,
10 then we could make another batch. They could ask
11 NIDA, well, we really need this, they have to have
12 a good justification as to why we need to make a
13 new batch.

14 Q Okay. And that's what you did for the 8-percent
15 cigarettes; is that right?

16 A That's correct.

17 Q You made a special batch for the 8-percent
18 cigarettes?

19 A That's correct.

20 Q Okay. And then when the researchers
21 received them, they were 7.4; is that right?

22 A Yeah, and the subject couldn't tolerate

1 it, so it doesn't matter if they were 7.4 or 8.

2 They couldn't tolerate it.

3 Q But they were 7.4; isn't that right?

4 A Yes.

5 Q Okay. Now, turning your attention to--I
6 think you looked at some pictures yesterday of some
7 marijuana that said it was from an unrolled
8 cigarette. Do you recall those pictures?

9 A Yes.

10 Q Okay. And do you recall that was in an
11 article by Dr. Ethan Russo?

12 A That's correct.

13 Q Okay. And you indicated--I think you said
14 there's no way this was the material in the
15 cigarettes?

16 A I'm saying that the size of those
17 materials, it's very hard for me to believe that
18 this material is actually coming from the
19 cigarettes. It might be coming from the raw
20 material.

21 Q Okay.

22 A The raw plant material.

1 Q Okay.

2 A Just based on the size of this material.

3 MS. CARPENTER: One moment, Your Honor.

4 [Pause.]

5 MS. CARPENTER: Well, let me just do it
6 this way:

7 BY MS. CARPENTER:

8 Q So if the article said that that picture
9 was the picture of an unwrapped cigarette, would
10 you disagree with that article?

11 A I'm not disagreeing with the article. I'm
12 saying that it's hard for me to believe that those
13 are materials from--actually coming from a
14 cigarette. It could be the raw material.

15 Q If somebody said that they were, are you
16 saying that they're--

17 A Well, I'm saying--

18 Q --not telling the truth?

19 A You know, if they said they were, they
20 were, but I don't believe that such big materials
21 would be in a cigarette. I'm just saying it would
22 tear that cigarette.

1 Q Okay. But do you believe then that that
2 picture was manufactured somehow, that it wasn't
3 what it said it was in the article?

4 A No. I'm saying it could be the raw
5 material.

6 Q But if the article said it was an
7 unwrapped cigarette, do you believe that the
8 article was lying?

9 A I'm not saying the article's lying.

10 MR. BAYLY: Your Honor, I'm going to
11 object here. We're kind of speculating, "if the
12 article says." I mean, is there something in
13 there--

14 THE WITNESS: It could be a typo in the
15 article. It could be a typo in the figure.

16 MR. BAYLY: Could we get the exhibit
17 number

18 MS. CARPENTER: That's what I'm trying to--I had
19 it as Respondent's 19, but I'm not sure if
20 that's correct or not.

21 MR. BAYLY: Yes, it is 19. The pictures
22 are on page 50.

1 JUDGE BITTNER: Thank you.

2 MS. CARPENTER: Thank you, Mr. Bayly.

3 BY MS. CARPENTER:

4 Q Have you found page 50 there, Dr. El
5 Sohly?

6 A Yes.

7 Q Okay. And I think--correct me if I'm
8 wrong--the picture you were referring to is Figure
9 6?

10 A Yes.

11 Q Okay. And what's the caption there?
12 Doesn't it say "Close-up of debris from three NIDA
13 cannabis cigarettes"?

14 A Yes.

15 Q Okay. And so if someone--are you
16 suggesting that that is not debris from three NIDA
17 cannabis cigarettes?

18 A I'm suggesting that this material, the
19 size of this material, the way it looks, looking at
20 the seeds and looking at those particles, that it's
21 very hard for me to believe that those materials
22 were actually in a cigarette in that paper.

1 Now, I know what the caption says for the
2 picture. That could be a typo in terms of the
3 title of the--it may be equivalent to three NIDA
4 cigarettes, not three actual--three cigarettes that
5 were unrolled and done like equivalent to three.
6 So that's debris from, you know, so many grams of
7 material that's equivalent to three cigarettes.
8 But it's just--if it is, that's the way it is,
9 that's the way it is. But I'm just saying unless
10 the picture is taken in such a way to enlarge the
11 stem particles more than the seeds, those seeds are
12 about one and a half or two times the actual size
13 of seeds. If that's the case, then those particles
14 are just too big to make it into a cigarette.

15 Q So you're not saying that--

16 A That's my assessment. You know--

17 Q So you're not suggesting it was
18 manufactured in any way?

19 A No, no.

20 Q Okay. Just that there may have been some
21 error.

22 A That's correct.

1 Q Okay.

2 [Pause.]

3 MS. CARPENTER: Your Honor, if I could
4 take two minutes--

5 JUDGE BITTNER: Okay.

6 MS. CARPENTER: --to speak right here, and
7 then we'll be--

8 JUDGE BITTNER: Okay. Off the record.

9 [Recess.]

10 MS. CARPENTER: Your Honor, just one more
11 question, and then we're done.

12 JUDGE BITTNER: On the record.

13 BY MS. CARPENTER:

14 Q Going back for just a minute to the
15 medical marijuana that the Government of the
16 Netherlands and the Government of Canada make
17 available to patients in those countries, are you
18 aware--do you know what the price is for medical
19 marijuana in the Netherlands? I know you indicated
20 it was expensive. Do you know--

21 A It was--it was--I just came back. It was
22 very expensive. By my calculations at the time

1 when I heard the price, it was very expensive.

2 Q Do you recall how much?

3 A It's like maybe 10 euros a gram.

4 Q Ten euros a gram?

5 A Something like that. I think it was like
6 5 grams for 50 euros or something like that. I
7 remember it was very expensive.

8 Q Okay.

9 A I made the calculation at the time that it
10 was more expensive than what we have as cigarettes.
11 This material is provided as, you know, just buds
12 in a packet.

13 Q All right. But it is true, isn't it, that
14 that material is much higher in THC content than
15 the material available through NIDA; isn't that
16 right?

17 A That's correct, but it's also raw
18 material. It's not processed materials. It's not
19 made into cigarettes. It doesn't have all the
20 expense that goes into making the cigarettes.

21 Q Okay. But the material is higher in THC--

22 A And it's not standardized to the point

1 where you actually have cigarettes that are
2 standardized that you can use in a clinical, you
3 know, set-up.

4 Q I understand.

5 A To use in a clinical set-up, you've got to
6 have everything looking exactly the same way to be
7 able to do a blind, controlled study.

8 Q Okay. And for that, the patients who pay
9 that price in the Netherlands, they get
10 considerably higher percentage THC per dollar spent
11 of gram, wouldn't they? Even though the price may
12 be higher, there's a higher THC content, so
13 essentially they're getting more THC for less
14 amount of marijuana; isn't that correct?

15 A Yes, but what I don't know is when you do
16 the analysis, you actually manicure the samples,
17 take and do the analysis. How much of that bud
18 that they have of that weight is actually marijuana
19 that will be rolled into the cigarette and how much
20 is debris that is going to be thrown out that
21 doesn't get rolled into the cigarettes, I don't
22 know.

1 Q But regardless of that, the THC--

2 A No, no, it's not--

3 Q --percentage is higher, isn't it?

4 A No. The THC--

5 Q It's not?

6 A No, it's--well, I'm not saying it's not
7 relative to what--I'm saying that the THC, when you
8 analyze for the THC content, you take that bud, you
9 manicure it, you take the manicured material and
10 analyze it, and that's what the 16 percent--or
11 whatever the percentage is, is coming out from the
12 usable material.

13 Q And are you suggesting that what the Dutch
14 Government distributes to its patients is not that
15 manicured product?

16 A No, it's not manicured. It's just the bud
17 as it is. It has the stalk and everything in it.
18 It's just buds. I went through the whole process.
19 I saw the facility. I saw how they make it, how
20 they package it and everything.

21 Q Okay.

22 A They take those buds as they are. They

1 put them in a--by the way, they have an excellent
2 operation. And they took those buds, put them into
3 the little plastic bags, and that's what goes off
4 to the pharmacies.

5 MS. CARPENTER: Okay.

6 [Pause.]

7 MS. CARPENTER: Okay. I think I have no
8 further questions, Your Honor.

9 JUDGE BITTNER: Okay. Redirect?

10 MR. BAYLY: Maybe we should take the lunch
11 break now.

12 JUDGE BITTNER: My concern about taking a
13 lunch break was I had no idea how long redirect
14 would take, and it's 12:30.

15 MR. BAYLY: All right. Judge Bittner, we
16 would request a 10-minute break, and the 10-minute
17 break I think will be cost-effective, because at
18 this point I don't have a lot of redirect, and when
19 we discuss our strategy, we may even whittle that
20 down.

21 JUDGE BITTNER: Okay. I'm not the one
22 getting on a plane, for once.

1 MR. BAYLY: I understand.

2 JUDGE BITTNER: Okay. Ten minutes. Off
3 the record.

4 [Recess.]

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

6 MR. BAYLY: Thank you, Judge Bittner.

7 REDIRECT EXAMINATION

8 BY MR. BAYLY:

9 Q Dr. El Sohly, is the University of
10 Mississippi under its manufacturing and registration with
11 NIDA able to provide researchers with any
12 potency of marijuana in terms of its THC content,
13 whether it's allowed to do so or not?

14 A In terms of the capability, the capability
15 is there to produce marijuana with any potency that
16 could be required by the investigators, yes.
17 Whether the investigator can get this material or
18 not, that's really another issue. But in terms of
19 the capability that we have, yes, we have the
20 capability of producing any potency that could be
21 required by an investigator.

22 Q Dr. El Sohly, do you make any distinction

1 between the marijuana herbal plant material and the
2 THC delta-9 extract?

3 A Yes, the extract actually is a product out
4 of the cannabis plant. It is basically--it's
5 cannabinoids. It has all the cannabinoids in the
6 extract. It's not the--it's not the plant
7 material. And THC, as THC, the singular chemical
8 entity THC, is yet another preparation that's not
9 extract and not plant material.

10 MR. BAYLY: Your Honor, I'd like the
11 witness to be shown Government Exhibit--well,
12 actually, I have it. It's not admitted yet. It's
13 78.

14 JUDGE BITTNER: Okay.

15 MR. BAYLY: For purposes of the record,
16 Government Exhibit 78 marked for identification is
17 entitled "Memorandum of Agreement." May I present
18 the witness with this exhibit?

19 JUDGE BITTNER: Yes.

20 MR. BAYLY: And I want to make sure
21 everybody's got it.

22 [Pause.]

1 JUDGE BITTNER: Do you have it, Ms.
2 Carpenter?

3 MS. CARPENTER: I do, Your Honor.

4 JUDGE BITTNER: Okay.

5 BY MR. BAYLY:

6 Q First of all, Dr. El Sohly, Government
7 Exhibit 78, can you identify that for the record?

8 A This is a Memorandum of Agreement between
9 the Drug Enforcement Administration and the
10 National Center for Natural Products Research.

11 Q All right. And that memorandum of
12 agreement, can you turn to the last page with the
13 signatories, Dr. El Sohly?

14 A Yes.

15 Q And who are the signatories?

16 A The signatories are Dr. Ronald Borne, who
17 was the Interim Vice Chancellor for Research at
18 that time; Dr. Alice Clark, who was the Director of
19 the National Center for Natural Products Research
20 at that time. And then it was signed--for the DEA,
21 it was signed by Mr. George Kazenavette III, and by
22 Mr. John King III.

1 Q And the date of this memorandum of
2 agreement?

3 A The university signature was on September
4 20th of '99 and the DEA signature was in October of
5 '99.

6 Q Okay. And before today, were you aware of
7 this memorandum of agreement?

8 A Yes, sir, I was.

9 Q And the memorandum of agreement, Dr. El
10 Sohly, concerns what subject generally?

11 A It actually concerns the conditions under
12 which DEA would allow the registration and the
13 manufacture of the extract.

14 Q Okay. All right. And I'd like you to
15 turn, please, to page 2. And you see under
16 paragraph 4 there--

17 A Yes.

18 Q And what subject does paragraph 4 discuss?

19 A Paragraph 4 discusses distribution of
20 marijuana prohibited by treaty.

21 Q And what treaty is that?

22 A Single Convention.

1 Q Okay. And is that the same treaty you
2 were referring to during cross-examination?

3 A Yes, sir.

4 MR. BAYLY: All right. Your Honor, I'd
5 like to move this into evidence particularly and
6 just for the purpose of the treaty issue, which is
7 mentioned, I believe, in Section 4 of this
8 memorandum of agreement. I think that covers pages
9 2 and 3.

10 MS. CARPENTER: I think if the exhibit
11 comes in, it should all come in or not.

12 JUDGE BITTNER: Yes, I'd rather it were in
13 overall. There may be other relevant portions to
14 it, but since I haven't read it, I wouldn't know.

15 MR. BAYLY: Oh, yes, I don't--I'm
16 admitting it overall because I think you need--I
17 don't think you can chop it up, but my purpose of
18 admitting it is just for that one excerpt.

19 JUDGE BITTNER: Any objection?

20 MS. CARPENTER: Just there's some
21 handwriting on the last page--I'm sorry, page 5.
22 Could we just identify whose that is?

1 [Pause.]

2 JUDGE BITTNER: Dr. El Sohly, do you know
3 whose--

4 THE WITNESS: Oh, an explanation from me?

5 JUDGE BITTNER: Well, do you know whose
6 handwriting it is?

7 THE WITNESS: No, I don't, Your Honor.

8 JUDGE BITTNER: Mr. Bayly, do you?

9 THE WITNESS: It's not mine, for sure.

10 JUDGE BITTNER: Okay. That's useful. Mr.
11 Bayly, do you know whose handwriting it is?

12 MR. BAYLY: I don't.

13 JUDGE BITTNER: Are you offering this
14 without the handwriting?

15 MR. BAYLY: I think--yes.

16 JUDGE BITTNER: Okay.

17 MS. CARPENTER: That's fine.

18 MR. BAYLY: We'll take a big bottle of
19 Wite-Out or--

20 JUDGE BITTNER: No. I'll just--Government's 78 is
21 received with the exception of
22 the handwritten notation on page 5.

1 [Government Exhibit No. 78
2 received in evidence.]

3 MR. BAYLY: Thank you. That's all I have.

4 JUDGE BITTNER: Okay. Recross?

5 MS. CARPENTER: Yes, just very quickly.

6 RECROSS-EXAMINATION

7 BY MS. CARPENTER:

8 Q I just want to understand, Dr. El Sohly,
9 the relationship between the entity here, which is
10 the National--excuse me, I'll get the name right--National
11 Center for Natural Products Research, is
12 that center connected with what we've been
13 referring to as "the institute" at the University
14 of--

15 A That's correct, yes.

16 Q --Mississippi? Okay. And how are they
17 connected?

18 A It's the same.

19 Q It's the same.

20 A The structure of the School of Pharmacy at
21 the University of Mississippi, you have the School
22 of Pharmacy and you have different departments, the

1 academic departments, and then you have the
2 Research Institute of Pharmaceutical Sciences. And
3 under the Research Institute of Pharmaceutical
4 Sciences comes the National Center for Natural
5 Products Research as a part of the institute, which
6 is the research branch of the School of Pharmacy.
7 So when I saw any reference to the institute or the
8 university or NCNPR or National Center for Natural
9 Products Research, it's that organization.

10 Q Okay. So that's all the same. So when we
11 were referring earlier to any licenses for the
12 institute, that would also include the National--

13 A That's correct.

14 Q --Center?

15 A Yes, ma'am.

16 MS. CARPENTER: Okay. That's fine.

17 I think that's all, Your Honor.

18 JUDGE BITTNER: Okay. Any re-redirect?

19 MR. BAYLY: No, Judge Bittner.

20 JUDGE BITTNER: Dr. El Sohly, is there a 3
21 o'clock flight?

22 [Laughter.]

1 THE WITNESS: I wish.

2 JUDGE BITTNER: Okay. Thank you, Doctor.

3 THE WITNESS: But I think I'll have a
4 leisurely lunch, Your Honor.

5 JUDGE BITTNER: You certainly may.

6 THE WITNESS: Thank you.

7 JUDGE BITTNER: Thank you. You may step
8 down.

9 [Witness excused.]

10 JUDGE BITTNER: I'm trying to think where
11 we are. Let's go off the record.

12 [Discussion off the record.]

13 JUDGE BITTNER: We will now quit for the
14 day and resume at 9 o'clock tomorrow morning.

15 Off the record.

16 [Whereupon, at 12:48 p.m., the hearing was
17 adjourned, to reconvene at 9:00 a.m., Wednesday,
18 December 14, 2005.]