## ALI REZAI, M.D.

MANI LOU ZUMIMENIMAN, EL UL. VS.

## THE CLEVELAND CLINIC FOUNDATION

`	101			THE CLEVELAND CLINIC FOUNDAT
		102	1	104
	Ι	IN THE COURT OF COMMON PLEAS	1	MR. LINTON: Let the record reflect
	2	CUYAHOGA COUNTY, OHIO	2	this is the continued deposition of Dr. Rezai,
120	3	MARY LOU ZIMMERMAN,	3	as well as the 30(B)(5) deposition concerning
	4	et al.,	4	The Cleveland Clinic web site. I'd like to
	5	Plaintiffs,	5	first see what
	6	JUDGE BURNSIDE -vs- <u>CASE NO</u> . 399411	6	MR. MALONE: I don't think that's true,
	7	VOLUNVIEII	7	the web site business. He didn't come here
	8	THE CLEVELAND CLINIC FOUNDATION,	8	until 2000. We've been through all this. He
	9	Defendant.	9	is Dr. Rezai, clearly, but I can't agree he's
	10	··· <u>·</u> ·	10	the most knowledgeable person as to any web
	11	Continued deposition of ALI REZAI, M.D., taken as	11	site.
	12	If upon cross-examination before Laura L. Ware, a	12	MR. LINTON: Who is, Jim?
	13	Notary Public within and for the State of Ohio, at	13	MR. MALONE: Idon't know.
	14	The Cleveland Clinic Foundation, 9500 Euclid Avenue,	14	MR. LINTON: Well, Jim, we requested
	15	Room M8-09, Cleveland, Ohio, at <b>3:37 p.m</b> . on Friday,	15	that deposition last October.
	16	September 14,2001, pursuant to notice and/or	16	MR. MALONE: Bob, I didn't come here
	17	stipulations of counsel, on behalf of the Plaintiffs	17	prepared to respond to that. He's the current
	18	in this cause.	18	head of psychosurgery. He's all the things he
	19		19	was when he began his deposition last time.
	20	*	2'0	MR. LINTON: We'll cover that, but it's
	21		2'1	been represented to us that Dr. Rezai also is
	22	WARE REPORTING SERVICE 21860 CROSSBEAM LANE ROCKY RIVER OH 44116 (216) 533-7606 FAX (440) 333-0745	22	the web site person.
	23	(216) 533-7606 FAX (440) 333-0745	2'3	MR. MALONE: Currently that's correct,
	24		24	but your patient allegedly and by the way,
	25		25	where is my discovery on that?
ψ_ <b>-</b>				
		103		105
	Ι	APPEARANCES	1	MR. LINTON: On the web site?
	2	Robert F. Linton, Jr., Esq.	2	MR. MALONE: Where are the materials
	3	Robert F. Linton, Jr., Esq. Stephen T. Keefe, Jr., Esq. Linton & Hirshman Hoyt Block Building - Suite 300	3	you claim your client was given or that Dr.
	4	700 West St. Clair Avenue	4	Donnelly gave them?
	5	Cleveland, Ohio 44113 (216) 771-5800,	5	MR. LINTON: Igot your letter. We'll
	6	-and -	6	respond to that separately.
	7	Mark W. Ruf, Esg.	7	MR. MALONE: Well, that's on old, old
	8	Hoyt Block Building - Suite 300	8	discovery request, too. I actually forgot it.
	9	Mark W. Ruf, Esq. Law Office of Mark W. Ruf Hoyt Block Building - Suite 300 700 West St. Clair Avenue Cleveland, Ohio 44113 (216) 687-1999,	9	I thought you responded.
	10	On behalf of the Plaintiffs;	10	MR. LINTON: We will get that. As to
	11	-	11	the web site, that was noticed for last
	12	James L. Malone, Esq. Reminger & Reminger 113 St. Clair Avenue	-12	October.
	13	113 St. Clair Avenue Cleveland, Ohio 44114 (216) 687-1311,	13	MR. MALONE: Is there a reason you
	14	On behalf of the Defendant.	14	haven't responded to my request, or is it
	15	Chochail of the Defondant.	<sup>-</sup> 15	something you haven't been able to get to?
	16		° <b>1</b> 6	MR. LINTON: Exactly, that's all it is.
	17	EXHIBIT INDEX	17	MR. MALONE: Fair enough.
	18	PAGE	18	MR. LINTON: The 30(B)(5) was sent out
	19	Plaintiffs' Exhibit 3 109	19	last October.
	20		20	MR. MALONE: Uh-huh.
	21		21	MR. LINTON: When can just so we're
the off	22		22	clear, for the record
1	23		23	MR. MALONE: The truth is, I don't
	24		24	know, nor does anyone know, who was responsible
	25		25	for that page on the web site that you pulled
			a.	

# WARE REPORTING SERVICE

## ALI REZAI, M.D.

1

2 3

A. Idon't know.

## THE CLEVELAND CLINIC FOUNDATION

108 Q. Do you know if this was provided to you by Reminger

& Reminger, the lawyers for The Cleveland Clinic?

<ul> <li>out. No one knows that. There are things</li> <li>that, in institutions of this size, no one</li> <li>knows when or how that was done. Ask him.</li> <li>He's here. But I mean, I can't tell you that</li> <li>he's the most knowledgeable person as to that</li> <li>web site in 1998.</li> <li>MR. LINTON: You're not producing him</li> <li>for that purpose?</li> <li>MR. MALONE: No.</li> <li>MR. LINTON: And you don't know who</li> <li>that person would be?</li> <li>MR. MALONE: I have no idea who that</li> <li>person would be.</li> <li>CONTINUEDCROSS-EXAMINATION OF ALI REZAI, M.D.</li> <li>BYMR. LINTON:</li> <li>Q. Dr. Rezai, I'd like to, first of all, cover what</li> <li>you've done since the last time we were here and</li> <li>took your deposition as it relates to this case.</li> <li>Can I do that?</li> <li>A Sure.</li> <li>Q. First of ail, have you had a chance to review your</li> <li>deposition, the actual transcript?</li> <li>A Yes.</li> <li>Q. Have you reviewed any other documents in connection</li> </ul>		106
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<ul> <li>20 Can Ido that?</li> <li>21 A. Sure.</li> <li>22 Q. First of ail, have you had a chance to review your</li> <li>23 deposition, the actual transcript?</li> <li>24 A. Yes.</li> </ul>	18	you've done since the last time we were here and
<ol> <li>A. Sure.</li> <li>Q. First of ail, have you had a chance to review your</li> <li>deposition, the actual transcript?</li> <li>A. Yes.</li> </ol>	19	took your deposition as it relates to this case.
<ul> <li>Q. First of ail, have you had a chance to review your</li> <li>deposition, the actual transcript?</li> <li>A. Yes.</li> </ul>	20	Can Ido that?
<ul><li>23 deposition, the actual transcript?</li><li>24 A. Yes.</li></ul>	21	A. Sure.
24 A. Yes.	22	Q. First of ail, have you had a chance to review your
	23	deposition, the actual transcript?
25 Q. Have you reviewed any other documents in connection	24	A. Yes.
	25	Q. Have you reviewed any other documents in connection

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#### with your deposition? 1 A. I reviewed a series of papers in this binder. 2 Q. And may I see those papers? 3 MR. MALONE: We will make copies for 4 you, and you can look at them, but you can't 5 keep the set that's here. Fair enough, 6 7 agreed? MR, LINTON: Sure. Let's mark this. 8 9 (Thereupon, Plaintiffs' Exhibit 3 was 10 mark'd for purposes of identification.) 11 12 13 Q. The materials that are marked Plaintiffs' Exhibit 14 Number 3, this is the binder materials. Did you assemble this or were these provided to you? 15 16 A. This was in my office. 17 Q. Your office put these together7 18 A. It was --- I don't know who put it together. 19 Q. Okay. Tell me how this file came to exist. 20 A. It was sitting in a box in my office along with the transcripts. 21 22 Q. And do you know who put this file together?

- 23 A. No.
- 24 Q. Did you request it be put together?
- 25 A. No.

-	
4	Q. You have no idea where it came from?
5	A. No.
6	Q. Was there a cover letter that went with it?
7	A. No.
8	Q. This just simply showed up one day in your office?
9	
0	(Pager interruption.)
1	
2	A. Sorry. Okay. Sorry.
3	Q. You went to your office one day and there was this
4	binder; is that correct?
5	A. Yes.

- 6 Q. The highlighting, is that your highlighting or was
- it highlighted when it came to you? 7
- 8 A. No, it was highlighted when it came to me.
- Q. And have you taken any steps to find out who 9
- 0 prepared this?
- 1 A. No.
- Q. Have you reviewed the materials? 2
- A. I've glanced through it, yes. :3
- Q. How much time did you spend glancing through this !4
- :5 binder?

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- 1 A. I would say about a half hour.
- Q. And when did you glance through it? 2
- 3 A I glanced through it, I would say, in the past
- 4 couple of weeks.
- 5 Q. Is that when you found it in your office?
- A. Yes. 6

7

0

- THE WITNESS: Let me get this page,
- 8 please.
- 9 - - - -
  - (Thereupon, a discussion was had off
- 1 the record.)
- - \_-2
- 3 Q. Did you recognize the information contained in this
- 4 binder?
- '5 A. What do you mean; can you rephrase that?
- Q. Had you seen any of these writings before? 6
- A. Some of them, yes, yes. 7
- 8 Q. The handwriting that's in here, is that your
- 9 handwriting or someone else's?
  - A. Some is mine. I have to look through to tell you
  - which one is mine or not.
- 2 Q. Sure.

!1

- A. That's mine.
- Q. The black ink? 14
- 15 A. Uh-huh.

## ALI REZAI, M.D.

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THE CLEVELAND CLINIC FOUNDATION

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### **VOLUMEII**

#### 110

- 1 Q. Why don't you go through here and tell us which of
- 2 these articles you were aware of before you reviewed
- 3
  - the binder. 4 A. This one I had not seen before.
  - Q. This, representing tab one? 5
  - A. Uh-huh. 6
  - Q. Correct? 7
  - A. Yes. Tab two I have seen before, three I have seen 8
  - before, four I have not seen, five I have not seen, 9
  - 10 six I have seen, seven I have seen, eight I have not
  - seen before, nine I have, ten I have, eleven I have 11
  - 12 not, twelve I have not, thirteen I have, fourteen I
  - recall vaguely seeing that before, and fifteen I 13
  - 14 have.
  - 15 Q. Who is a Candice, is it, Keiffer?
  - 16 A. Uh-huh.
  - 17 Q. Who is Candice Keiffer?
  - 18 A. Idon'tknow.
  - 19 Q. You don't know who she is?
  - 20 A. No. A lot of names, they're different colleagues,
  - 21 individuals.
  - 22 Q. Vicki Bokar, do you recognize her name?
  - 23 A No.
  - 24 Q. You don't recognize her as a paralegal in the legal
  - department at The Cleveland Clinic? 25
  - 1 A. No.
  - Q. Did anybody request that you review this binder? 2

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- A. This binder was along with this. 3
- Q. Did somebodytell you to review it? 4
- A. Iwas requested to review this. 5
- Q. This, being the transcript? 6
- A. The transcript, and that was with it. 7
- Q. And you assumed --8
- A. Nobody specifically requested that for me. 9
- Q. Did you review any of these before you prepared your 10
- paper in CNS Spectrums? 11
- 12 A. Imay have.
- 13 Q. Did you refer to any of these in your paper?
- 14 A. I may have.
- Q. Did you speak with Dr. Barnett at all about this 15
- case? 16
- 17 A. No.
- Q. Did you speak to him at all about any psychosurgery 18
- 19 issues since the time of your last deposition?
- 20 A. We've discussed the protocol that I'm putting
- 21 together, sure.
- 22 Q. And what was discussed about your protocol?
- 23 A. My deep brain stimulation protocol for psychiatric
- 24 patients.

(216) 533-7606

25 Q. And what input did Dr. Barnett have in the DBS

- protocol?
- 2 A. He's not part of the protocol.
- 3 Q. But you said you discussed it with him?
- A. Right. 4
- 5 Q. What input did he have?
- 6 A. No input. I just gave him the information, that we
- have this protocol we're running. 7
- Q. It was simply to inform him of what the protocol 8
- 9 was?
- 10 A. Informhim, yes.
- 11 Q. And is that a written protocol?
- 12 A. Yes, yes.
- 13 Q. And did you provide him with a copy of it?
- 14 A. No.
- 15 Q. You just let him know it was now available?
- 16 A. Yes.
- 17 Q. Is Dr. Barnett doing any DBS?
- 18 A. No.
- 19 Q. Are you the only one doing that here at The
- 20 Cleveland Clinic as it relates to psychiatric
- 21 conditions?
- 22 A. Yes.
- 23 Q. Is Dr. Barnett doing DBS for any other conditions?
- 24 A. He has done it in the past for Parkinson's.
- 25 Q. Is he presently doing it?

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## 1 A. No.

- 2 Q. Will you be the sole person here at the Clinic in
- 3 charge of DBS?
- 4 A. Me and the other two partners that just joined us.
- 5 Q. And who is that?
- 6 A. Dr. Jamie Henderson and Dr. Nicholas Boulas.
- Q. Do either of them have any experience in performing 7 8 psychosurgery?
- A. I don't know the details of that. I can't tell 9
- 10 you.
- 11 Q. When did this protocol take effect for the DBS?
- 12 A. This protocol still is being performed confidential
- 13 through the FDA, so I cannot disclose the details of 14 that yet.
- 15 Q. So it has not yet been adopted as formal protocol or 16 it is protocol?
- 17 A. It is protocol.
- 18 Q. Pursuant to the FDA study?

22 A. Yes, correct, correct.

19 A. Yes.

21

23

24

25

WARE REPORTING SERVICE

20 Q. Is this the same study you referenced before involving the Clinic, Bingham & Brown?

Q. And as lunderstand it, just in a generic sense,

you're comparing the success rates for radio

Page 110 to Page 113

frequency, for gamma knife and DBS?

VOLUME 11

## ALI REZAI, M.D.

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### THE CLEVELAND CLINIC FOUNDATION

1 A. No, we're not doing a comparison. This is just deep

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- 2 brain stimulation.
- 3~ Q. Is there any study being done at The Cleveland
- 4 Clinic, to your knowledge, as it relates to
- 5 psychosurgery, either radio frequency or gamma
- 6 knife?
- 7 A. Not that I know of.
- 8 Q. So the study you referred to before, the joint study
- 9 with Bingham, Brown and the Clinic, is involving
- 10 only DBS, correct?
- 11 A. Correct, yes.
- 12 Q. Is DBS now your treatment of choice for patients
- 13 with psychiatric conditions who you believe need
- 14 surgery?
- 15 A. It is one of the options that we offer patients.
- 16 Q. In addition to gamma knife, capsulotomy?
- 17 A Possible gamma knife, capsulotomy.
- 18 Q. Or radio frequency cingulotomy?
- 19 A. Radio frequency cingulotomy or capsulotomy.
- 20 Q. Now, when we last talked, you said you had
- 21 personally seen about five patients for psychiatric
- 22 conditions who were considering surgery?
- 23 MR. MALONE: That was just at the
- 24 Clinic. He's seen more than that, and he's
- 25 participated in more surgeries than that.

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- 1 MR. LINTON: I understand. Here at the
- 2 Clinic.
- 3 Q. My question is, have you seen any additional
- 4 patients for that purpose since the time of your
- 5 deposition last April?
- 6 A. Yes.
- 7 Q. And how many more patients?
- 8 A. Idon't recall the exact number.
- 9 Q. Give me your best estimate.
- 10 A. Less than ten.
- 11 Q. Less than ten total or less than ten additional?
- 12 A Probably less than ten total at this time.
- 13 Q. Now, have you actually performed any surgery,
- 14 psychosurgery, since coming here to the Clinic?
- 15 A. No.
- 16 Q. Have you -- we talked about the five patients
- 17 before. I don't want to go back there. Let's --
- 18 MR. MALONE: Was that question have you
- 19 performed any additional psychosurgery?
- 20 MR. LINTON: Yes.
- 21 MR. MALONE Additional, okay, I
- 22 understand. Excuse me.

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- 23 Q. The additional five patients  $\mathbf{or}$  so that you estimate
- 24 you've seen since the time of your deposition, have
- 25 you recommended surgery for any of those five

- patients?
- 2 A. Yes.
- 3 Q. And how many of the five?
- 4 A. I don't recall the exact number of all these
- 5 patients.
- 6 Q. More than one of them?
- 7 A. Yes.

9

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- 8 Q. What procedures did you recommend?
  - THE WITNESS: Do I have to answer that

116

- 0 in terms of the confidentiality of the
- 1 patients?
  - MR. MALONE: No, you can't name the
  - patient. He's talking in the abstract.
- 4 Q. Only in the abstract.
- 5 A. Well, we've discussed the options and put that forth
- 6 to the patients and let them choose.
- 7 Q. And what options have you put forth to the patients?
- a A. Gamma knife, radio frequency or deep brain
- .9 stimulation.
  - Q. And capsulotomy or cingulotomy for the gamma knife?
- 1 A. Capsulotomy for the gamma knife.
- 2 Q. Radio frequency capsulotomy or cingulotomy or both?A. Both.
- Q. Both, by that meaning either a cingulotomy or a cingulotomy radio frequency?
- 1 A. Yes.
- 2 Q. You, yourself, do not perform a combined procedure,

117

- 3 cingulotomy and capsulotomy, at the same time on a
- 4 patient for OCD, correct?
- 5 A. Not in one setting.
- 6 Q. Have you ever performed that procedure for a
- 7 patient?
- 8 A. The combined procedure?
- 19 Q. Yes.
- A. No.
- 2 Q. That's not something that you've recommended for any patient either, correct?
- **3** A. It's not the option that I provide.
  - Q. Okay. So --
- 5 A. Or offer.
- 6 Q. You have not recommended that to a patient,
- 8 correct?
- A. Not in my practice.

to exactly?

- 9 Q. Correct?
  - A. Yes.

!4

25

WARE REPORTING SERVICE

- 21 Q. And why do you not recommend that as an option?
- 2 A. Let me get this straight, you're talking about the combined simultaneous staged -- what are referring

Q. Exactly what you said, the combined simultaneous

Page 114 to Page 117

## ALI REZAI, M.D.

### 118

- 1 procedure, combined capsulotomy and cingulotomy,
- 2 single setting.

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- 3 A. I don't think, in my opinion, that's an option for
- 4 the patients, in my practice.
- 5 Q. And I appreciate that. And why is that?
- 6 A. Because I think it's too many lesions in one setting7 for the patient.
- 8 Q. And what do you see as being the down side of that
- 9 or disadvantage?
- 10 A. Potential side effects.
- 11 Q. And what potential side effects?
- 12 A. There are a wide variety of side effects with
- 13 lesioning with either procedure alone. Either
- cingulotomy or capsulotomy can give you the sameside effects.
- 16 Q. Would it be fair you would have double the side
- 17 effects if you combine the procedure?
- 18 A. I can't say that.
- 19 Q. But you certainly increase the side effects, in your
- 20 opinion, if you combine the procedures?
- 21 A. That's a potential risk.
- 22 Q. And what side effects would you be concerned about
- 23 causing or increasing the likelihood of them
- 24 occurring if you combined the two procedures in one
- 25 setting?

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- 1 A. Potential side effects, which, again, can happen
- 2 with each procedure alone, are frontal lobe
- 3 dysfunction, changes in mood, changes in patterns of
- 4 bladder control, changes in personality, seizures,
- 5 what's in the literature, a wide variety of things.
- 6 Q. And you don't know of any documented studies that
- 7 you find reliable that have said that there is an
- 8 advantage to combining those two in one setting,
- 9 correct?
- 10 A. I have seen studies saying they're combined, that
- 11 has been done.
- 12 Q. But my question is, in terms of the articles or
- 13 studies that you find reliable, you don't know of
- 14 any that advocate that?
- 15 A. In my practice, I do not do the combined,
- 16 simultaneous combined procedures.
- 17 Q. We went through, in your last deposition, you didn't
- 18 cite to those when you went through the literature
- 19 search?
- 20 A. Idid not cite those in the paper.
- 21 Q. And your goal in preparing that paper was to provide
- 22 the best available literature that was out there, in
- 23 your opinion, to people considering these
- 24 procedures?
- 25 A. That's our way of practicing surgery for psychiatric

- 120 1 conditions, my way and my colleagues' way. 2 Q. And you could not find, at the time you prepared 3 your paper, any reliable articles or studies that 4 combined those procedures in a single setting, 5 correct? A. I did not include any in my paper at that time. 6 7 Q. Because you didn't feel that any were accurate and 8 reliable? 9 A. I think accurate and reliable -- in my search, I did 0 not believe that that was the thing to do for my 1 patients, so that's why I did not include it. 2 Q. Andwhynot? 3 A Because I think that it may carry increased risk, in 4 myopinion. Q. And do you see any increased benefit? 5 A. There may be increased benefits because you're 6 7 disrupting the circuits, sure, so some advocates may 8 say doing it simultaneously may have increased 9 benefits to the patient. 0 Q. But you don't know of any documented studies that have shown to you that there is, indeed, benefit? 1 2 A. There are studies in this that I have seen. Where 3 did it go, the binder? Q. The binder? 4 5 A. The binder shows these procedures, cingulotomy and 121 1 capsulotomy. 2 Q. But in terms of the literature you had reviewed for 3 purposes of your scientific journals, you did not 4 run across any such articles? 5 A. Yeah, to the best of my recollection, I did not 6 include those articles. I may have seen them, but I 7 did not include them as part of the paper. 8 Q. And can you show me the articles in binder number 9 three, that mysteriously showed up in your office, 0 that show what you believe to be an increased 1 benefit in combining the procedures? 2 A. I can't say to the increased benefit, but it does 3 show that there's combined procedures. For example, 4 article three says, for cingulotomy and capsulotomy,
- both are done in patients with schizo-affective
  disorder. That's --
- 7 Q. That's not the same as OCD, is it?
- 8 A. There are some components that may be in OCD, but9 it's not the same as OCD.
- 20 Q. And does that show that they were combined
- !1 procedures simultaneously?
- A It does not say here. It says two surgicalprocedures.
- '4 Q. Does that suggest to you they were -- you don't know
  - then if they were simultaneous or if they were

5

## ALI REZAI, M.D.

## THE CLEVELAND CLINIC FOUNDATION

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consecutive? 1

**VOLUMEII** 

A. Ican't tell. It doesn't say here.

- 3 Q. So we can't look at that and say that that
- 4 article -- strike that.
- And that article does not show any increased 5
- 6 benefit in combining the two procedures, either
- together or separately, correct? 7
- 8 A. To me, this article, all it says is that cingulotomy
- and capsulotomy were done in patients. That's all I 9
- 10 can say, basically. I cannot say any other
- judgments based on what's written here. 11
- 12 Q. So you cannot use that as a basis for saying that
- the two procedures combined would benefit the 13
- patient any more than if they were done separately, 14
- 15 based on that article?
- 16 A. Based on this article, all that it tells me is that
- 17 lesions were done in these two areas for this one
- patient, and I'm not going to make any judgments as 18
- 19 far as the benefits or side effects of these two
- 20 together.
- 21 Q. Nor does that report any benefit, any increased
- 22 benefit, by doing those two procedures as opposed to
- doing one or the other? 23
- 24 A. It does not say here. It reports these two lesions,
- 25 but it does not discuss it further based on what's

here 1

2 Q. Are there any articles in this binder which provide

123

- scientific support for the theory that combining 3
- 4 these two procedures simultaneously is an increased
- benefit to the patient in terms of the likelihood of 5
- 6 success?
- 7 A. I did not go with a fine-tooth comb through this
- entire article, this binder, so I don't know. I'd 8
- have to review the whole thing in detail to give you 9
- an answer. 10
- 11 Q. Can you cite to any one, based on your review so 12 far?
- 13 A. As to what, as to --
- 14 Q. That show a benefit to the patient in terms of
- 15 increased success rate by combining them in a single
- setting. Pardon me, is this your handwriting as 16 17 well?
- 18 A. No, that's not my handwriting.
- 19 Q. And just for the record, I'm referring to tab seven,
- page --20
- 21 A. 3665.
- 22 Q. As well as 3666.

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- 23 A. Here is one specific area, it says combination
- procedures, and actually this literature and others 24
- 25 there is a combined procedure of subcaudate

### 124

- tractotomy, which involves a cingulotomy and a 1
- 2 modified capsulotomy, not a standard capsulotomy, so
- 3 that is performed simultaneously, which is not
- 4 exactly--
- 5 Q. That was not the same thing that --
- 6 A. It's avariance.
- Q. But that was not what was done to Mary Lou Zimmerman 7
- 8 in this case?
- A. I do not know the details of what was done to her. 9
- 0 I have not seen the x-rays or the lesions or the
- 11 details.
- 2 Q. Why don't you take a look at, if you would, at the
- 13 operative report.
- 4 A. Okay. This refers to anterior capsulotomy and
- 5 cingulotomy.
- 6 Q. That is not the same procedure as referenced on page
- 17 3668. is it?
- 8 A. No. It says here I was referring to limbic
- 9 leukotomy is a separate thing here. Limbic
- leukotomy is a combined procedure. 20
- Q. And I appreciate that. Maybe my question isn't 21
- 22 clear.
- 23 A. Okay.
- 24 Q. I'm asking now just if you know of any support in
- 25 this binder for combining a capsulotomy and a

### 125

- 1 cingulotomy in a singular procedure like what was
- 2 done to Mary Lou Zimmerman?
- 3 A. It says here the procedures, cingulotomy, subcaudate
- 4 tractotomy and anterior capsulotomy have been
- 5 combined to provide possible better results. So
- 6 this indicates a combination indicating better
- 7 results.

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WARE REPORTING SERVICE

- 8 Q. Of course, that's three different procedures, not
- 9 just the two?

unproved.

A. Sure.

foundation here.

- 10 A. Right. Well, I don't know which one they're
- 11 referring to. We have to talk to the authors. Have
- 12 been combined to provide possibly better results.
- 13 Limbic leukotomy is a combination of cingulotomy and
- 4 subcaudate tractotomy. That's what I was telling
- 15 you about. Improvements in patients' symptoms have
- 16 been determined for OCD and schizophrenia. 84
- 17 percent for OCD, schizophrenia 63 percent.
- 18 Cingulotomy has also been described in combination
- 19 with anterior capsulotomy, so that's the indication
- 20 of both being performed here, although improved efficacy over other procedures alone remains

Q. So that would not support -- let me just lay a

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## THE CLEVELAND CLINIC FOUNDATION

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- 1 Q. Your thinking or your theory is that if you combine
- 2 these it may be of some benefit to the patient,
- 3 correct?

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- 4 A. It potentially could because you're disrupting more
- 5 of the abnormal circuits in the brain causing OCD.
- 6~ Q. But you couldn't say with any sort of medical or
- 7 scientific certainty or even probability that that
- 8 would be of an increased benefit to the patient,
- 9 correct?
- 10 A. In my practice I don't think that it would offer any
- 11 benefits simultaneously.
- 12 Q. And, in fact, you think it would create more risk to
- 13 the patient without any proven or reasonable
- 14 probability of improved benefit?
- 15 A. That's a potential risk, but either or alone can
- 16 have more of a risk than combined, so the risk is
- 17 very relative. I mean, you can just do a single
- 18 side capsule lesion and get major devastating
- 19 consequences, or you can do both, make seven or
- 20 eight lesions, and have no problems.
- 21 Q. Lunderstand, but if you thought in your mind
- 22 combining them had better results with no more
- 23 risks, you'd be doing them, wouldn't you?
- 24 A. Most likely I would be doing them.
- 25 Q. And you don't do them because there's no proven

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- 1 benefit, and in your mind it's more risky?
- 2 A. In my practice, I don't like doing both
- 3 simultaneously.
- 4 Q. Again, because you don't see the benefit and you
- 5 think there's the possibility of more risk?
- 6 A. In my opinion, there may be increased risk of doing
- 7 both simultaneously.
- 8 Q. We can agree that that article says that the success
- 9 rates have not yet been proven, of combining the
- 10 procedures, correct?
- 11 A. Well, it's confusing because it says have been
- 12 combined to provide possibly better results on one
- 13 part, and another part says remains unproved, so it
- 14 says both things here.
- 15 Q. So which do you believe?
- 16 A. I don't know. I mean, this is the author's --
- 17 they're referencing various articles here, so they
- 18 need to be looked at in more detail.
- 19 Q. You couldn't say this article is necessarily
- 20 reliable medically?

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- 21 A. Oh, I cannot say that. It comes from a very
- 22 reputable textbook, Youmans, which I wrote articles
- 23 in, too, Youmans textbook.
- 24 Q. So you do think the textbook is reliable?
- 25 A. This is a very famous textbook, yes.

- 128
- 1 Q. But you've not reviewed the underlying article 2 itself to determine if, in fact, it's reliable?
- 3 MR, MALONE: You're calling it an
- 4 article. Ithink this is a chapter.
- 5 A. This is a chapter.
  - MR. MALONE: It's a chapter from a
- 7 text.

6

12

- 8 Q. Isn't it referencing articles?
- 9 A. Referencing articles.
- 10 MR. MALONE: But what he's reading from
- 11 is an article.
  - MR. LINTON: Thank you for the
- 13 clarification.
- 14 A. In a textbook, yeah.
- 15 Q. What I'm saying is would you look at the footnotes
- 16 being referenced --
- 17 A. Uh-huh.
- 18 Q -- and tell me whether you can say if those are
- 19 medically reliable?
- 20 A. Oh, I don't know if I can say that. They're
- 21 published in journals that are --Acta Neurochir,
- 22 another textbook, another textbook, another
- 23 textbook, 38, Surgical Technique, a postgraduate
- 24 medical journal. So textbooks and journals, they've
- 25 been published, based on the one they're referencing

### 129

- 1 in this particular paragraph, combination
- 2 procedures. Let me look through some more.
- 3 Q. Excuse me.
- 4 A. Sure.
- 5 Q. You're not prepared to say that the annotated
- 6 textbooks and articles are, in fact, reliable, areyou, without reviewing those?
- 7 you, without reviewing those?
  8 A. Ineed to review those, and these are published by
- 9 peer reviewed journals, so I assume that other
- 10 colleagues have reviewed them rigorously and decide
- 11 to publish or not. So I can't say at this point, as
- 12 to your question, I can't give you an answer to
- 13 that, but they have been reviewed by other
- 14 colleagues. Can I go through?
- 15 Q. Sure.

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WARE REPORTING SERVICE

- 16 A. I have to go fast through all this. I wish I was a
- 17 speed reader.

various.

- 18 Q. Take as much time as you need, Doctor.
- MR. MALONE: You can take as much timeas you need.

A. It may be in other areas. I really have not gone

through this in detail. I've just combed it very

quickly, so, again, as I'm going through this, the

limbic leukotomy, the combined procedure, there's

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## THE CLEVELAND CLINIC FOUNDATION

### 130

1	Q.	Limbic	leul	kotor	ny, jus	t so we're clear, is not wh	nat
~						•	

- was done to Mrs. Zimmerman? 2
- 3 A. Not from the operative note. I was talking about 4 combination procedures, which is a similar area.
- 5 Q. But in terms of her procedure, combining a
- 6 capsulotomy and a cingulotomy simultaneously, that's
- what we're talking about here. 7
- 8 A. Okay. In this paper they performed both. It
- doesn't say if they did it simultaneously. 9
- 10 Q. This paper you're referencing is tab fourteen?
- A Uh-huh. 11
- 12 MR. MALONE I think this is a text.
- 13 A. This is an Acta Neuro -- it's a peer reviewed paper,
- 14 Fodstad.
- It's not here, so that's the areas. 15
- 16 Q. So there's nothing you've been able to point to so
- 17 far that shows any scientific basis for showing that
- 18 there would be an increased benefit for combining
- 19 the procedures, correct?
- 20 A. Except in that one paragraph that says may.
- 21 Q. It said it may be of benefit, but it also said it's
- 22 unproven, correct?
- 23 A. Right, so they're saying two --
- 24 Q. Conflicting statements?
- 25 A. Which paragraph was that; do you remember what

### 131

- number it was? 1
- 2 Q. It was Youmans textbook.
- 3 MR, RUF: Seven.
- A. Seven. Under combination procedures, yeah, it says 4
- have been combined to provide possibly better 5
- 6 results.
- 7 Q. It also talked about combining three procedures?
- A. Right. It doesn't say which one in combination, 8
- it's not clear, and then it says although improved 9
- 10 efficacy of cingulotomy and capsulotomy over other
- 11 procedures alone remains unproved, but they've done 12 it.
- 13 Q. Forget about that they've done it. There's nothing
- 14 in here that says it is of proven benefit?
- 15 A. In a very cursory review of this, I have not gone
- 16 through this in detail, so just looking at it very
- 17 quickly I don't see anything except that one
- statement here, possible better results. That says 18 19 it's better.
- 20 Q. Have you ever taken the position at any professional
- 21 seminar, speech, lecture, grand rounds that you've
- 22 given that those two should be a combined procedure
- 23 done at the same time?
- 24 A. That's not what I say, no.
- 25 Q. Have you, in fact, said the opposite?

- 132
- A. My reference is do staged procedures. 1
- 2 Q. Okay. And staged meaning?
- 3 A Meaning do one and then do the other.
- 4 Q. But you, yourself, have not even done staged
- 5 cingulotomy and capsulotomy, correct, you
- 6 personally?
- 7 A. Correct. Idon't recall doing that. I'm not a
- 8 hundred percent sure, but I don't recall. It's been
- 9 manyyears.
- 10 Q. You don't train your residents to do a combined
- simultaneous procedure, do you? 11
- 12 A Not in my practice, no.
- Q. And you have not written in any professional journal 13
- 14 or paper or article that those two procedures should
- 15 be combined simultaneously in the same setting?
- 16 A. To the best of my knowledge, no.
- 17 Q. If, in fact, a neurosurgeon was going to perform a
- 18 procedure where there would be a combination
- 19 cingulotomy and capsulotomy where there was unproven
- 20 benefit and possibly increased risk, would that
- 21 require, in your opinion, additional informed
- 22 consent?

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- 23 A Ithink that's up to the neurosurgeon. I mean, this
- 24 is how I practice, and others do it differently,
- 25 other colleagues around the country, and actually in

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- Europe there may be colleagues who do it simultaneously, and in their opinion it may be the right thing to do to help these end stage patients. So it's really a judgment call of each individual person. For me, personally, I don't do that, but when you have a patient that's so severe end stage suicidal, nothing more to do, some colleagues want to do the best they can, and they may be wanting to do simultaneous lesions to try to 10 offer the best hope for the patient.
- 11 Q. But you also cause irreversible permanent brain
- 12 damage when you do the lesions, correct?
- 13 A. Yes.
- 14 Q. There's no turning back the clock once you've done
- 15 damage to the brain?
- 16 A. No.
- 17 Q. So doesn't it make more sense to, at the very least,
- 18 do them in staged procedures so that you can see the
- 19 benefit of doing one to see if a second is, in fact,
- 20 necessary?
- 21 A. In my mind, that's how Ithink about it, but I'm
- 22 saying that whenever you have a patient that's so
- 23 severely incapacitated, some colleagues may say,
- 24 okay, 111 do them both at the same time to give you
- 25 the maximum chance. And at that point, I think that

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## ALI REZAI, M.D.

2

3

## THE CLEVELAND CLINIC FOUNDATION

	134
1	has to be explained to the patient, the potential
2	risks and benefits of the surgery.
3	Q. Tell me, a patient presents to you with
4	long-standing OCD and says, Doctor, I want you to
5	tell me what my options are here at The Cleveland
6	Clinic, what do you tell them are their options?
7	MR. MALONE: This is 20017
8	A. 2001?
9	Q. Correct.
10	A. Yeah, today I would tell the patient options are
11	gamma knife, capsulotomy or radio frequency
12	cingulotomy, radio frequency capsulotomy or deep
13	brain stimulation.
14	Q. And what would you say are the advantages and
15	disadvantages of the different procedures?
16	A. Oh, that's a very complex question. I think the
17	advantages of the deep brain stimulation is that it
18	is fully reversible in 2001 and is adjustable over
19	time. You can adjust the pacemaker to maximize the
20	benefit for the patient, so you're not destroying
21	brain, you're modulating brain. So I think that's
22	the most advantageous.
23	Regarding lesioning, in my opinion lesioning
24	provides a one shot deal, so you just make a
25	destruction of the abnormal circuits. You know

135

Ι	exactly where you are with radio frequency lesions.
2	With gamma knife, you may have what we call
3	runaway lesions or after burn lesions where it may,
4	down the line, it's unpredictable, but you may have
5	a lesion just exploding and causing catastrophe in a
6	patient. So that has to be explained to each
7	patient. It's rare but can happen. So I would tell
8	the patient about lesions, you see the results, it's
9	a one shot deal, and it's irreversible.
10	Gamma knife is progressive versus radio
11	frequency, and it may go into a runaway state so
12	it's unpredictable, blossoming. And I say to them
13	if there is a side effect it may be permanent
14	because you're burning the areas, whereas with a
15	stimulator you're not destroying the areas, so you
16	can have the chance of being fully reversible.
17	Q. Now, are you presently doing DBS, in fact, with a
18	patient?
19	A. We have a protocol at the Clinic for deep brain
20	stimulation for OCD.
21	Q. If a patient came in and wanted the DBS, you could
22	perform that?
23	A. Per our protocol with the FDA, yes.
24	Q. Now, back in 1998the other procedures were
OF	available: ware they not?

25 available; were they not?

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- 1 A. Yes.
  - MR. MALONE: At The Cleveland Clinic?
  - He wasn't there.
- 4 A. I don't know about The Cleveland Clinic. That's a
- 5 good question.
- 6~ Q. Certainly the neurosurgical community there was the
- 7 gamma knife, capsulotomy and the radio frequency
- 8 cingulotomy and capsulotomy?
- 9 A. In 1998 where  $I \, \text{was}$  practicing, other areas, those
- can be available all together, gamma knife and radiofrequency.
- 2 Q. And I assume the success rate in 1998, based on what
- 3 you told us at your last deposition, was basically
- 4 the same as it is now in 2001 for those procedures?
- 5 A. Again, this is a very tricky area as far as success
- 6 rate is concerned. The literature, it takes on many
- 7 different outcome scores, many different definitions
- 8 of what success is. Percent improvement can be a
- 9 small or large degree, so it's really very difficult
- 0 to comb through literature and come up with some
- 1 sense of exact percent of success.
- 2~ Q. Maybe my question is not clear. Let me see if I can
- 3 clarify. I'm not talking about trying to state a
- 4 success rate right now, I'm just talking about in
- 5 terms of the overall success of the procedure it's

## 137

- 1 pretty much the same today, 2001, as it was in
- 2 19987
- 3 A. I would say, yes, that it has not changed
- 4 significantly.
- 5 Q. And the outcomes have not changed significantly
- 5 either, as far as you know?
- 7 A. There's no studies that I know that have shown
- 8 radically different outcomes.
- 9 Q. So you would expect the same success today as you
- 0 would have expected in 1998 in those other
- 1 procedures, those being gamma knife, capsulotomy or
- 2 radio frequency cingulotomy and capsulotomy?
- 3 A. Most likely, correct.
- 4 Q. Now, the DBS patient comes to you, you have a
- 5 written protocol, you have a written consent form
- 6 that they have to sign, correct?
- 7 A. Yes.
- ${\bf 8} \quad {\bf Q}. \ \ {\bf D} o \ you \ also \ have \ a \ written \ consent \ form \ a \ patient$
- 9 has to sign if they do another type of psychosurgery
- 0 here at the Clinic in 2001?
- 1 A. Everybody at the Clinic for any procedure has to
- 2 sign a consent form, so it's a standard consent
- 3 form.
  - MR. MALONE: Don't say something you
  - don't know.

5

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MARY LOU ZIMMERMAN, et al. vs.

## VOLUME 11

- 138 1 THE WITNESS: Okay. 2 MR. MALONE I mean, you can talk about your area, but don't tell them about hearts 3 because you don't know. There are no informed 4 consents. Be careful what you say, because you 5 just said something that's just simply not 6 7 true. 8 THE WITNESS: Fair enough. Q. You're just talking about neurosurgery? 9 A. From my surgeries, we have to have consent for every 10 11 procedure I do. It's a consent form. 12 Q. It's a written consent form? 13 A. Yes. 14 Q. And that's been the case since you've been here at 15 the Clinic? 16 A. Yes. Q. And that would include for anybody getting a 17 cingulotomy or a capsulotomy or a combined 18 capsulotomy/cingulotomy? 19 20 A. For any kind of procedures I've been involved with 21 it's required, consent. 22 Q. Now, why have none of the 10 or so patients that you've seen not had the surgery done? 23 24 A. Because we have not started the protocol. Q. So even if somebody wanted the DBS today, they could 25
- 1 not yet have it done?
- 2 A. Once the protocol is underway, yes, they can. We're

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- dealing with the FDA, and there's a lot of different 3
- groups that we're working with for this protocol. 4
- Q. What do you tell a patient today who wants it in 5
- terms of when they can reasonably expect to have the 6 7 surgery?
- 8 A. We say these are your options, if you wish to go
- ahead with the deep brain stimulation you have to 9
- 10 wait until the protocol is fully ready to go from
- the FDA and other parties and then we can proceed. 11
- 12 Q. Aside from the materials in the binder that showed
- up on your desk, have you reviewed any other 13
- literature or records in connection with this case 14
- or your deposition to prepare for your deposition? 15
- 16 A. No.
- 17 Q. I assume that as part of your normal practice, you
- make it a habit of staying current with the 18
- literature in your field? 19
- 20 A. Uh-huh, yes.
- Q. And in particular, since one of your specialties is 21
- psychosurgery, staying current with the 22
- psychosurgery literature? 23
- 24 A. Yes.
- Q. How do you do that; how do you stay current? 25

	THE CLEVELAND CLINIC FOUNDATION
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1	A. I read papers and journals, I also review papers
2	submitted I'm the editor, so I review papers for
3	journals submitted regarding surgery for psychiatric
4	disorders.
5	Q. Have you reviewedstrike that.
6	In your efforts to stay on top of the
7	psychosurgery literature, have you seen anything
8	since the time of your last deposition as it relates
9	to psychosurgery and success rates?
0	A. Yes.
1	Q. What specifically have you seen?
2	A I don't recall the exact details and numbers, but
3	I've seen several articles that have been submitted
4	for publication.
5	Q. Have any actually been published?
6	A. Yes, there have been articles that have been
7	published on surgery of psychiatric problems.
8	Q. In what journals?
9	A. Idon't recall.
!0	Q. You are editor of Neurosurgery Clinics of North
!1	America, and specifically is it an article entitled
!2	Neurosurgery for Psychiatric Disorders?
!3	A It's a book I'm editing for psychiatric disorders.
!4	Q. That's to be published in 2002?
!5	A. 2002, 2003. These things take a long time.
	4.44

- Q. Have you actually started to type a manuscript?
- 1 2 A I have many authors working on papers, yeah, yes.
- Q. Are you going to publish a separate chapter in that 3
- book? 4
- A. Something that I am writing? 5
- Q. Yes. 6
- 7 A. Yes.
- Q. And what is your topic? 8
- A. It's a topic about the evolution of psychiatric 9
- neurosurgery and requirements for centers conducting 0
- surgery for psychiatric disorders. 1
- 2 Q. What sort of requirements?
- 3 A. It's basically the requirements that our group is
- putting together, has put together --4
- 5 Q. And --
- A. --as state of the art from 2001 on, at this point 6
- 7 what we recommend.
- Q. And have you started to write that yet? 8
- 29 A. It's in the outline stages and so on, so it's no definitive form, no. It's manycolleagues, so it's
- !1 notjust me.
- 2 Q. Who are the other contributing authors?
  - A. The authors are from other universities, Brown
- 25 University.
  - Q. Dr. Rasmussen?

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1	A. Yes.	
	O 2Who else?	

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- 3 A. Dr. Greenberg, Rasmussen, a few other colleagues.
- 4 Q. What other colleagues?
- 5 A. Dr. Newton. Idon't recall the names. There's a
- 6 lot of people. They may have brought other
- 7 colleagues, because this is not done yet, so each
- a group is providing their input, and then we're
- 9 putting it all together.
- 10 Q. When are you to submit your manuscript to theeditor?
- 12 A. As soon as Iget a chance. I am the editor.
- 13 Q. I'm sorry. Do you have to submit it to --who do
- 14 you submit it to, the publisher?
- 15 A. I review it with other editors, the two other
- 16 editors for this, and we submit it to the publisher,
- 17 right.
- 18 <sup>a</sup>Q. So what are the requirements now, 2001, for research
- 19 centers performing psychosurgery?
- 20 A. It's a complex issue that's being --that's
- 21 evolving. Does it have anything to do with this
- 22 case or what was done in 1998?
- 23 Q. It may or may not.
- 24 A. I mean, basically we have to have a patient who's
- 25 intractable for several years, must have had several

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- I medications and has not responded io medications,
- 2 must have been deemed completely end stage
- 3 refractory by a psychiatrist, must be very severely
- 4 affected despite optimization of medication therapy
- 5 or behavioral therapy, psychotherapy, and we're
- 6 recommending a board to see each patient.
- 7 Q. The multi-disciplinary board we talked about?
- a A. To see patients and decide whether there's any other
- 9 avenues and options and so on, and also the patient
- 10 has to understand risks and benefits clearly and
- 11 options, have ethicists involved. That's basically
- 12 in a nutshell. It's much more complex than that.
- 13 111 send you an article when it comes out.
- 14 Q. Okay. When do you expect it to be published?
- 15 A. We're writing an editorial to the Neurosurgery
- 16 journal regarding this, so probably by early next
- 17 year, a variation of that, because it's a book.
- 18 Q. Has that been submitted to the Neurosurgery journal?
- 19 A. It's sitting on my desk.
- 20 Q. Which journal is that?
- 21 A. Neurosurgery. It's called Neurosurgery.
- 22 Q. The requirements you just walked through, are those
- 23 right now in anywritten form?
- 24 A. Some shape and form, not finalized.
- 25 Q. Just in a draft form?

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- 144
- 1 A. Draft form, right.
- 2 Q. What must be done to make sure the patients
- 3 understand the risks and benefits of the procedure?
- 4 A. Ithink you just explain basically what the surgery
- 5 is about, what they're about to undergo, what
- 5 potential complications can happen, and what are the
- 7 benefits of the procedure.
- B Q. And then there are also --
- 9 A. Risks, benefits, alternatives.
- 0 Q. And there also then has to be the multi-disciplinary
- 1 review board we talked about?
- 2 A. The review board's role is different. Consent is
- 3 with the patient and surgeon, predominantly. The
- 4 board's role is different in terms of patients'
- 5 candidacy and *so* on.
- 6 Q. But the surgery cannot go forward until the patient
- 7 consents and both the board approves, correct, under
- 8 your proposed -- under your current requirement?
- 9 A. Under the current requirement, 2001, yes.
- 0 Q. On the current panel that's in place at The
- 1 Cleveland Clinic, are they employees that sit on the
- 2 board or people from outside the Clinic?
- 3 A. The current panel --

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1

- 4 MR. MALONE: Let me show an objection.
  - THE WITNESS: Sorry.

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- MR. MALONE: I'm going to object.
- 2 We're getting way far field now. Go ahead.
- 3 A. It's mainly people from the Clinic. They may have
- 4 other appointments, other institutions, but they're
- 5 at The Cleveland Clinic.
- 6 Q. Who are the lawyers that are on the panel?
- 7 A. I don't recall the names.
- 8 Q. How about the bioethicists?
- 9 THE WITNESS: Do I have to give names
- 0 of these people for confidentiality relations?
- 1 MR. MALONE: Ithink this is
- 2 confidentiality. This is far field. This is
- 3 what's going on now. It had nothing to do with4 '98.
- 5 A. It's basically confidential and we have not made it
- 6 public yet, so I'd like to disclose it once we get
- 7 going with the protocol. The board is being
- 8 assembled and all that at this time. Maybe in a few

Q. When will we know once it's in the public record?

A. Once we start with the protocol, once we get going

A. They'll be within Cleveland Clinic records and so

Page 142 to Page 145

- 9 months it will be all public record, but at this
- 0 time I would like to --

with the protocol.

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WARE REPORTING SERVICE

Q. Okay.

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1	on.
2	MR. LINTON: Ithink that, and Jim, we
3	can talk about this, I think that this is
4	relevant. Ithink we're entitled to it. I'm
5	more than happy to enter into a confidentiality
6	agreement to make sure this is not disclosed
7	outside of the purpose of this lawsuit.
8	MR. MALONE: Well, it's certainly not
9	relevant. Whether I guess the standard is
10	whether it leads to something that's
11	discoverable that might be relevant or
12	admissible. Quite frankly, I am taxed even in
13	my imagination, but you're always ahead of me
14	on creativity and imagination, and perhaps you
15	can manufacture some reason for it.
16	MR. LINTON: It will not be
17	manufactured, but there is a good reason, I
18	assure you.
19	MR. MALONE Tell me what it is right
20	now and perhaps I can respond now.
21	MR. LINTON: I guess the overall
22	question is
23	MR. MALONE: He's not going to tell you
24	because he considers it confidential. Whether
25	or not I don't know anything about that. I
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	147
1	don't know what it is, but you're talking about
2	how we do things and how we are planning to do
3	things in the future as we sit here on
4	September 14th, 2001, and the case at hand, I
5	believe, involves surgery that was done in
6	1998.
7	MR. LINTON: All right.
8	MR. MALONE: Roughlythree years ago.
9	Q. Just so I'm clear, Doctor, you're not willing to
10	answer these questions; is that correct?
11	A. Because our protocol is still confidential and
12	involves our group, we're not disclosing it, yes.
13	Q. Is that's right?
14	MR. MALONE: He just asked if you're
15	willing or not willing.
16	A. I prefer not to at this point because it's not
17	public yet.
18	Q. Unless we get a Court order or work it out with
19	counsel, you're $\operatorname{not}$ prepared at this point?
20	A. No.
21	Q. It would be a waste of time
22	MR, MALONE: He may not tell me
23	either.
24	Q. Just so I'm clear, it's going to be a waste of time
25	to get into the details of that because you're not

willing to reveal that information at this point,	
correct?	
A. As far as details of the board, who they are a	and so
on, no, I'm $\operatorname{not}$ going to disclose who they are	<b>)</b> .
Q. Protocol, documents, et cetera?	
A Absolutoly yes for sure 111 be aladte aive	:+

A. Absolutely, yes, for sure. I'll be glad to give it

- to you at a later point, some point. 7 8
  - MR. MALONE: You just answer his
- 9 questions. Geez.
  - THE WITNESS: Okay, fine.
- 1 Q. Have you taken any steps to continue your efforts to
- 2 try to put together a worldwide web in terms of a
- 3 database on neurosurgical procedures like you had in
- 4 New York where you can track patients?
- 5 A. Explain that again.
- Q. Okay. Is there any system in place currently, aside 6
- 7 from the FDA project, to track patients who have
- psychosurgery here at The Cleveland Clinic? 8 9
  - MR. MALONE What FDA project are you referring to?
  - MR. LINTON: The one that he doesn't
- 22 want to talk about.
  - MR. MALONE: That's not even in place
- <u>19</u> yet.
  - A. Right.

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1	MR. MALONE: That's not even started.
2	Q. Right. But Lassume strike that.
3	I'm talking about other patients who have
4	undergone psychosurgery at The Cleveland Clinic.
5	A. I haven't done any. I don't know any that have had
6	psychosurgery at the Cleveland Clinic. Since I've
7	been here, I have not seen anybody that has or know
8	of anyone that has done any.
9	Q. Now, you don't know of any scientific evidence,
10	Doctor, that there is a 70 percent success rate of
11	positive results in patients that have undergone
12	cingulotomy for OCD?
13	A. Actually, there are in this binder.
14	Q. This is the binder that mysteriously showed up in
15	your office?
16	A. In the binder that was along with the, what's it
17	called, the transcript.
18	MR. MALONE: The deposition
19	transcript.
20	A. The deposition transcript.
21	Q. It came from the legal department, Vicki Bokar?
22	MR. MALONE: He said he doesn't know.
23	A. These were together on $\operatorname{my}\operatorname{desk}\operatorname{along}\operatorname{with}\operatorname{many}\operatorname{of}$
24	the papers.
25	Q. Tab 8 it says Vicki Bokar, office of general
I .	

## ALI REZAI, M.D.

## MARY LOU ZIMMERMAN, et al. vs.

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1	counsel.	1
2	A. Okay.	2
3	MR. MALONE Is that your question, or	3
4	are you showing you can read upside down?	4
5	MR. LINTON: I'm showing that for the	5
6	record.	6
7	MR. MALONE: What's the significance to	7
8	that; is there some significance to it?	8
9	thought if you put it on the record it had to	9
10	be significant. I guess it's not.	0
1	A. Can you repeat your question earlier again as far as	1
2	percentage of	2
L3	MR. MALONE: 70 percent success for	3
4	cingulotomywas the question.	4
5	A. So again, the literature always has many different	5
16	success rates reported, so just going through this	6
L7	binder and many other papers, you see ranges	7
8	anywhere from 20 percent to 90 percent for various	8
19	procedures, and that's based on each person, the way	9
20	they look at outcomes, what score they use, how many	0
21	month follow-ups, so it's very diverse and variable.	1
22	MR. MALONE: Okay. That's well and	2
23	good, Dr. Rezai, but, please, listen to this	3
24	man's question. He asked you a very specific	4
25	question. Is there anything in this binder or	5

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- that you know of that demonstrates a 70 percent 1
- 2 success rate for cingulotomy for
- obsessive-compulsive disorder patients? I 3
- 4 think that's the question. Is that the
- question or not? 5
- MR. LINTON: Correct. 6
- A. Okay. I did see a high I have to look through 7
- this whole binder again. As I was going through it, 8
- there are reports of, for example, 62 percent 9
- improvement with cingulotomies here reported. 10
- 11 Q. What report is that from?
- 12 A. From a 1987 report, from a retrospective study of
- 190 patients who went through cingulotomy. 13
- Q. And that would be more reliable than your 2000 CNS 14
- Spectrum article? 15
- 16 A. This may be this is looking at different papers
- of different individuals. 17
- 18 Q. So that would be more --
- 19 A. I did not include that in my paper because the
- 20 significant level would be different from these and
- others. I used my own significant levels based on 21
- my experience. 22
- 23 Q. So you're not suggesting that that article is more
- 24 reliable than your article?
- 25 A. This article is published in a peer reviewed

- 152 journal. Q Are you saying that that's --A. I don't compare it to my article in that regard. Colleagues have reviewed, for example, the 70 percent reporting in this paper. Q. That was the one Mr. Malone just pointed to? A. The one I put a cross, a box on. Q. I'm sorry, is this your writing? That's my writing. It's my writing. Q. And where does that 70 percent number come from? A. From the paper published 2000, July, 2000, Modern Neurosurgeryfor Psychiatric Disorders. Q. And who published that? A. Neurosurgery, 70 percent improvement. Q. Do you know the basis for that number? A. No. It says significant improvement, so again significant can be five percent improvement, it can be 99 percent improvement. That's why I'm going through this. You find 20 percent, 30 percent, 50 percent, 60 percent. Q. Doctor, when you see a patient, you try to give them the most accurate rates that you know of based on
- your thorough review of the literature and your
- clinical experience, correct?
- A. Uh-huh.
- 153
- Q. Isn't that right? 1
- 2 A. Correct.
- Q. And it would be misleading if you suggested to a 3
- patient that the success rate was 70 percent or 80 4
- percent or 90 percent, wouldn't it? 5
- A. From my own practice. 6
- 7 Q. Absolutely.
- 8 A. I say based on what I know and what I think and what
- 9 I believe in.
- 0 Q. Exactly.
- A. But any physician can say anything. Like for 1
- 2 example, a doctor can look at this paper X here and
- 3 quote these numbers.
- Q. But that wouldn't be accurate to selectively quote 4
- 5 one study to a patient that was at the high end when
- 6 there was overwhelming literature that it was much 7 lower, correct?
- A. Right. For my practice I use different numbers. 8
- 9 Q. Right. You use what you think are the most accurate
- numbers out there, correct? 0
- 1 A. Based on my experience, yes.
- Q. And it would be misleading in your practice and in 2
- 3 your experience and in your judgment to quote a high
- 4 number of 70 and 90 percent, correct?
- 5 A. In my practice, I do not quote a 70 to 90 percent.

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I Q. Right. You don't even quote just 70 percent or 70

- 2 to 75 percent, correct?
- 3 A. In my practice, no.

4 Q. That would be inaccurate and misleading, based on

- your experience and your thorough review of the 5
- literature? 6

7 A. Based on my experience, my practice, I don't quote

- those high numbers. 8
- 9 Q. Because that would be inaccurate and misleading,
- wouldn't it, based on your experience? 10
- 11 A. Based on my experience. But others can look at the
- literature and peer reviewed journals and --12
- 13 Q. Just your experience, Dr. Rezai. That would be
- based on your experience, right? 14
- 15 A. Right.
- 16 Q. Because there is overwhelming literature out there
- that conflicts with the one article **ar** two articles 17
- you showed me that suggests a 70 percent improvement 18
- 19 rate, correct?
- 20 A. There are more than one or two articles, but they
- 21 are conflicting. And this was my whole point
- earlier, is that there's -- they say significant 22
- 23 improvement. That can be a five percent improvement
- 24 in your symptoms or 90 percent. Significant is
- arbitrary depending on each person. 25

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- Q. And shouldn't the patient know there's a range out 1
- 2 there that's wide and varied?
- 3 A. A patient should know that; however, the problem is
- 4 that the literature is -- it's, again, full of
- nonstandardized outcomes, and it's very difficult to 5
- 6 sift through and look at different outcomes and
- percentages. But myself, I have very 7
- conservative --- I, myself, am very conservative when 8
- 9 Italk to my patients.
- Q. And why do you want to be conservative when you talk 10
- 11 to your patients?
- 12 A. Because Itend to go on the low end.
- Q. And why do you want to go on the low end and be 13
- 14 conservative with your patients?
- 15 A. Because I believe they have to understand basically
- the minimum is what I want them to understand, the 16
- 17 minimum improvement. That's personally what I like
- to communicate to the patients, so I am very 18
- 19 conservative.
- 20 Q. Because, again, it would be misleading and
- inaccurate for a patient to walk into a surgery 21
- 22 thinking there was a 70 to 75 percent success rate
- and not being told about the other literature out 23
- 24 there suggesting it's far, far lower?
- 25 MR. MALONE: Well, I'm going to show an

1	objection. The application we review all		
2	medical literature with patients before they		
3	undergo a procedure is simply inappropriate		
4	here. Idon't know that any doctor anywhere		
5	has ever given the whole body of medical		
6	literature to a patient contemplating a		
7	surgery. Having said that, he may answer, as		
8	he sees fit.		
9			
io	(Pager interruption.)		
11			
12	Q. Do you need to take that page?		
13	A. Go ahead. I'll answer the question.		
14	MR. LINTON: Read back the question,		
15	please.		
16			
16 17	(Thereupon, the requested portion of		
	(Thereupon, the requested portion of the record was read by the Notary.)		
17			
17 18			
17 18 19	the record was read by the Notary.)		

- A. In my practice I do not quote those high numbers, 23
- 24 but others may well do it.

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25 Q. Because you don't believe the literature supports

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- it, based on your best information and your experience and your judgment? A. Based on my experience and my judgment, I think those numbers are not reflective of what I think it should be. Q. Or what it's reported to be, if you look at the entire body of literature? A. Other literature reports it up to 80, 90 percent. Q. But if you look at the entire body of literature? A Right, there's a big range. There's a range from 20 percent to 90 percent. 12 Q. Right. And the patient is entitled to know there's arange? A. And it also depends on what study the physician
- 15 knows of and what study the physician is quoting,
- 16 sure. I mean, I agree with you because you're
- 17 saying, you know, it's impossible to know all the
- 18 literature. There's just so many papers out there,
- 19 thousands and thousands of journals and papers
- 20 coming out, so there may be a paper that came out
- 21 that I don't know about.
- 22 Q. Okay.
- 23 A. But based on my experience, yes, this is my
- 24 experience.
- Ъ Q. Now, aside from what you pointed to in the white

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	V	DLUME II	
		158	160
	1	binder	1 unproven benefit and there's nothing in the
	2	A. Yes.	2 literature that establishes with any degree of
	3	Q,what other medical literature or scientific	3 probability that it has a better result, and, in
	4	studies are you aware of that would suggest that	4 fact, it has a possibility of worse side effects
	5	there's a 70 to 75 percent success rate for	5 than doing either one by themselves, don't you have
	6	cingulotomy?	6 to tell that patient that as part
	7	A So	7 MR. MALONE: This is a hypothetical
	8	Q. I'm talking about aside	8 question, of course?
	9	A aside from this?	9 Q as part of the informed consent process?
	10	Q. Aside from this.	10 A. Ithink, first of all, the improved benefits, that's
	11	A. Other than the papers here, I do not know of	11 up to question based on that one paragraph, at
	12	literature, to the best of my knowledge.	12 least, and it needs to be looked at in more detail.
	13	Q. Do you need to answer that page?	13 I tell the patient based on my experience, my
	14		14 practice, I do not prefer to do two lesions
	15	(Thereupon, a recess was had.)	15 simultaneously in one setting.
	16		16 Q. When you say two lesions, do you mean bilateral
	17	Q. Doctor, when you used the term success rate, we're	17 or
	18	talking about what you perceive or the likelihood of	18 A. I mean bilateral on two different sites, capsulotomy
	19	positive results in a patient from your proposed	19 and cingulotomy.
	20	surgery?	20 Q. So it would really be four lesions?
	21	A Uh-huh.	21 A. Right, yes, four lesions, yes. Different location
	22	Q. Correct?	22 is what I meant.
	23	MR. MALONE: You've got to say yes.	23 Q. But assuming that there's no scientific literature
	24	A. Yes. Sorry. Yes. I'm getting the lingo here.	24 or studies out there that show with any degree of
	25	MR. MALONE: Well, there are a lot of	25 probability that combining these two, in fact, has
-			
		159	161
	1	things going on. I understand if you don't.	1 an increased benefit and there <b>is</b> a possible risk,
	2	Q. And just so I'm clear, you, yourself, have not	2 increased risk, when you combine them, don't you
	3	performed a cingulotomy or a capsulotomy since	3 have to explain that to a patient?
	4	you've come to The Cleveland Clinic, correct?	4 MR. MALONE: Objection.
	5	A. Correct.	5 Q. In your judgment?
	6	Q. And to your knowledge, nobody else at the Clinic has	6 MR. MALONE: Objection.
	7	since you came here?	7 Q. You can answer, Doctor.
	8	A. I don't know the answer to that.	8 A. In myjudgment, again, I prefer 🛶 I tell the
	9	Q. But do you have knowledge of any other	9 patient not to do simultaneous surgeries in one
	10	A. Not that	10 setting. That's what I tell them because I am not
	11	Q doctor	11 comfortable in my practice to do two bilateral
	12	A. Not that I know of, not that I know of.	12 lesions.
	13	Q. So you don't know of any other doctor here at the	13 Q. And that's because of the risk or that's because
	14	Clinic who has performed a cingulotomy or a	14 there's a lack of proven benefit or both?
	15	capsulotomy or any type of psychosurgery since you	15 A. I think more so, in my opinion, it would be because
	16	came here, correct?	16 of the potential risk.
	17		17 Q. There's nothing that you have seen so far to
	18	Q. Now, help me with the concept of informed consent.	18 establish a proven benefit?
	19	Obviously, you haveyou're trying to help the	19 A. There may be a potential proven benefit and there is

- 20 patient. You also have research interests, but
- 21 ultimately it's the patient who has control over
- 22 their own body, correct?
- 23 A. Absolutely.
- 24 Q. And if there is a procedure out there, like a
- 25 combined capsulotomy and cingulotomy, that has
- 22 Q. We're talking about simultaneous.23 A. Other than that, I don't know of others, in my
- judgment. To my best recollection, I haven't seen

proven benefit of a staged bilateral, so if you do

25 others.

it separately --

20

21

VOLUME 11

1	Q. Doctor, help me out, if you can. When a patient has
2	a cingulotomy/capsulotomy combined, that requires

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- 3 there to be four bur holes that are drilled into the
- 4 skull, they're bilateral?
- 5 A. Bilateral, four. You can do it through the same bur
- 6 hole. You don't have to have different bur holes.
- 7 You don't have to. You can do it through four or
- a two bur holes, depending on the surgeon's preference
- 9 or technique.
- 10 Q. Let's say you decide you're going to go with four
- 11 bur holes. You have to actually, obviously, go
- 12 through skin, go through skull to get to the brain,
- 13 correct?
- 14 A. Correct.
- 15 Q. And you insert an electrode that kind of looks like
- 16 a knitting needle, for lack of better words --
- 17 A. Yes.
- 18 Q. --that actually heats or cooks, according to Dr.
- 19 Barnett, the brain cells?
- 20 A. Correct.
- 21 MR. MALONE: I don't think it has a
- 22 hook on it like a knitting needle.
- 23 MR. LINTON: You're talking about
- 24 crochet, and I'm talking about knitting.
- 25 MR. MALONE: I misunderstood. I can't

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1	imagine a hook on the thing. I don't do
2	either, do you? Do you crochet a lot?
3	MR. LINTON: I'm a knitter, not a
4	crocheter, Jim.
5	MR. MALONE: I'm trying to pick up
6	needlepoint, but I haven't had any luck with
7	it.
а	Q. That the patient develops, Doctor, a deep brain
9	abscess. First of all, have you ever heard that
10	occurring from any form of psychosurgery?
11	A. To the best of my knowledge, I haven't seen that.
12	Q. Okay. Let's assume further that it happens, a deep
13	brain abscess, and then it tests positive for two
14	organisms, one is a staph aureus, the other is
15	something called klebsiella oxytoca.
16	A. Uh-huh.
17	Q. Have you ever heard of that organism, the klebsiella
18	oxytoca?
19	A. Klebsiella, yes; oxytoca strain, no.
20	Q. Do you know where klebsiella typically comes from,
21	where in the body?
22	A. Klebsiella can be either the urine, enteric, can be
23	in the oral cavity.
24	Q. Okay.

25 A It's a gram negative.

### 164

1 Q. Right. 2 A. Many areas. Same as staph. 3 Q. Right. Now, assuming that occurs, how does that sort of infection happen; what are the possible 4 5 causes or sources of a contamination? 6 MR. MALONE: I'm going to show an 7 objection. I don't think he needs to go into а this, Bob. This is a guy who wasn't here in 9 1998, never laid eyes or hands or Mrs. 0 Zimmerman, and for you to attempt to turn him 1 into an expert witness feeding him 2 hypotheticals in a chart he has never looked a 3 at, it's simply out of bounds and 4 inappropriate. He's answered your questions so 5 far, but we're not going to answer a 6 hypothetical based on her care. 7 Q. Doctor, you're not answering that question? 8 MR. MALONE: I've instructed him not 9 to. !0 Q. Okay. And you're not answering any -- you do know, !1 based on your neurosurgical practice and your 2 training and education and your experience, you would certainly have opinions on what the potential 2 sources of an infection like that would be in this type of surgery, correct?

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MR. MALONE: You don't need to answer
that. Objection. He's not
MR. LINTON: Excuse me, Jim. Am I
wasting my time getting into this line of
questioning?
MR. MALONE: Yes.
MR. LINTON: We'll go back to the
Court, if necessary.
MR. MALONE: Okay, good.
MR. LINTON: If I can have just a
minute.
(Thereupon, a discussion was had off
the record.)
MR. LINTON: That's all the questions I
have at this time. Thanks.
MR. MALONE: Okay.
ALI REZAI, M.D.

!1 !2

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1			
2	CERTIFICATE		
3	The State of Ohio) SS:		
4	County of Cuyahdga.)		
5			
6	I Laura L Ware a Notary Public within and for thk State of Ohio, do hereby certify that the within named witness ALI REZAL M.D., was by me		
7	within named witness ALI REZAI M.D., was by me first duly sworn to testify the truth, the whole truth, and nothing but the truth in the cause		
а	aforesaid: that the testimony then given was reduced		
9	by me to stenotypy in the presence of said witness, subsequently transcribed into typewriting under my		
10	direction, and that the fo <b>regoing is a</b> true and correct transcript of the testimony so-given as		
11	aforesaid.		
12	I do further certify that this deposition was taken at the time and place as specified in the		
13	foregoing caption, and that I am not a relative counsel or attorney of either party, that I am dot, ngr is the court reporting firm with which L am		
14 15	affiliated, under a contract as defined in Civil Rule <b>28(D)</b> , or otherwise interested in the outcome		
15 16	of this action.		
17	INWITNESS WHEREOF, I have hereunto set my hand and affixed my seal of office at Cleveland,		
18	Ohio, this 29th day of September, 2001.		
19			
20	Laura L. Ware, Ware Reporting Service		
21	21860 Crossbeam Lane, Bocky River, Ohio 44116 My commission expires May 17, 2003.		
22			
23			
24			
25			

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